CMS Manual System

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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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SUBJECT: Revisions to Chapter 5, "Quality Improvement."

I. SUMMARY OF CHANGES: This chapter captures changes which resulted once the Medicare Prescription Drug, Improvement and Modernization Act of 2003 was enacted. It details the requirements of the Quality Improvement Program that the Medicare Advantage Organizations (MA organization) must meet and the applicable timelines. Each MA organization must conduct quality improvement projects that include the entire organization, and focus on both clinical and non-clinical areas. Additionally, the levels of accreditation for health organizations are outlined as well as the monitoring role of CMS. References to Medicare + Choice (M + C) is changed to Medicare Advantage (MA), and Quality Assessment and Performance Improvement (QAPI) is changed to Quality Improvement (QI).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 20, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

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Medicare Managed Care Manual

Chapter 5 - Quality Improvement

(Rev. 78, 01-20-06)

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10 – Introduction

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Title 42 CFR Part 422, Subpart D, "Quality Improvement," establishes the quality improvement *(QI requirements)* that *Medicare Advantage Organizations (MA 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:

1. Section 20 - Quality Improvement Program

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

3. Section 30 – *Medicare Advantage* Deeming Program

4. Section 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.

20 - *Quality Improvement Program (QIP)*

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Starting in 2005 CMS will begin to use "Performance Assessment" data for broader purposes. Since 2003 CMS has reviewed Performance Assessment data (HEDIS, CAHPS, HOS, Disenrollment and financial metrics in order to provide benefit to high performing managed care plans by way of exempted segments of the on-site monitoring audit. Starting in 2006, CMS will revilew this data in order to provide targeted revieew and intervention for those health plans demonstrating low Performance **Assessment scores. Specific criteria will be developed in the near future.**

All MA organizations must give priority to quality improvement 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 MA organizations toward a common goal of ensuring high-quality and cost-effective care.

Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the following requirements *for the services it furnishes to its MA enrollees*. The quality insurance program *must:*

- Have a chronic care improvement program that meets the requirements *described below.*

- Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction *and that meet the requirements described below.*

- *Encourage its providers to participate in* CMS and HHS quality improvement initiatives.

Requirements for MA Coordinated Care Plans

Except for regional MA plans, MA *coordinated care plans as well as local preferred provider organization* (PPO) plans that are offered by organizations that are licensed or organized under State laws as HMOs, *must have a* quality improvement program *that* meets the following requirements:

1. Follow written policies and procedures that reflect current standards of medical practice in processing requests for initial or continued authorization of services.

2. Have in effect mechanisms to detect both under utilization and over utilization of services.

3. Measure performance *under the plan* using the measurement tools required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by *CMS*.

4. Make available to CMS information on quality and outcomes measures that will enable *current and potential beneficiaries to compare health coverage options and.make informed decisions with respect to the available choices for Medicare coverage.*

20.1 Chronic Care Improvement Program (CCIP)

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

CCIP Requirements

Each MA organization (other than MA private-fee-for-service plans) must have a chronic care improvement program and must establish criteria for participation in the program. The CCIP must have a method for identifying enrollees with multiple or sufficiently

severe chronic conditions who meet the criteria for participation in the program and a mechanism for monitoring enrollees' participation in the program.

Plans have flexibility to choose the design of their program, however, in addition to meeting the requirements specified above, the CCIP selected must be relevant to the plan's MA population.

The MA organizations are required to submit annual reports on their CCIP program to CMS. For 2006, information to be reported includes: the chronic illnesses of those enrollees served by the program, the types of services offered including the scope of services, and a description of the types of measures that the plan uses to assess program performance, including significant outcomes (clinical, satisfaction and costs. Plans will not be reporting actual performance data, but only the types of performance measures collected.

CCIP Design Considerations

The Disease Management Association of America publishes informational material on disease management.

Disease management, as defined by the Disease Management Association of America, is a "system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant."

We suggest that you review the materials published by this Association.

Quality Improvement Projects

Each MA organization *(other than MA private-fee-for-service plans) must conduct quality improvement projects that include the entire organization, focus on clinical and non-clinical areas, and meet the following requirements*:

1. Measurement of performance;

2. System interventions, including the establishment or alteration of practice guidelines;

3. Improving performance; and

4. Systematic and periodic follow-up on the effect of the interventions.

For each project, the organization must assess performance under the plan using quality indicators that are:

1. Objective, clearly and unambiguously defined;

2. Based on current clinical knowledge or health services research; and

3. Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

The organization's assessment of performance on the selected indicators must be based on systematic ongoing collection and analysis of *valid* and reliable data.

Interventions must achieve demonstrable improvement.

The organization must report the status and results of each project to CMS as requested.

Program review - For each plan, other than a private fee for service plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its QIP.

Remedial action - For each plan the organization must correct all problems that come to its attention through internal surveillance, complaints or other mechanisms.

20.2 - Administration of the *Quality Improvement Program*

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The organization's Quality Improvement *Program (QIP)* is administered through clear and appropriate administrative arrangements.

There must be evidence that the MA organization has an on-going quality improvement program. Most organizations will have a *QIP* 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 *quality improvement* activity and that effective organizational structures are in place to ensure communication and coordination. The organization's *QIP* 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 *QIP's* effectiveness and make any necessary changes. The evaluation should assess both progress in implementing the *quality improvement* strategy and the extent to which the strategy is in fact promoting the development of an effective *QIP*. 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 *QIP*. 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 *QIP*, or it may designate a committee to perform this function. There must be evidence that the policy making body approves changes in the *QIP* description and approves the annual work plan. It must receive and review periodic reports on *QIP* activities.

There must be a single official responsible for the overall functioning of the QIP. 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 *quality improvement* effort. If the responsible official is not the chief medical officer, the organization must show, through the *QIP* description or other documentation, that the chief medical officer has substantial involvement in *QIP* 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 *QIP* and the other functional areas of the organization, e.g., health services management and member services.

The MA organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan provided by the organization, which includes the *QIP* (42 CFR 422.202(b). This rule applies to subcontracted physician groups as well (422.202(c)). Key activities that physicians should be involved in may include: selecting and prioritizing QIP projects, developing indicators, analyzing study results, identifying and proposing solutions to problems, and aiding in communication of *QIP* activities and results to other providers.

The organization should establish some mechanism for obtaining enrollee input into the priorities for its *QIP*. Possibilities could include enrollee representation on a quality assurance committee or subcommittees or routine inclusion of *QIP* 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.

Please note that private fee-for-service plans are exempted from these requirements.

20.2.1 - MA Organizations Using Physician Incentive Plans

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The MA organization that adopts a physician incentive plan that places *a* physician *or physician group* at substantial financial risk (as defined at 42 CFR 422.208(d)) for the care of Medicare or Medicaid enrollees, must include in its QIP continuous monitoring of the potential effects of the incentive plan on access or quality of care. 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 *QIP* projects.

20.*3* - Health Information System

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The organization *must* maintain a health information system that collects, integrates, analyzes, and reports data necessary to implement its *QIP*. 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 *QIP* 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 *QIP* 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 *QIP* should assess, in addition to information generated within the organization, information supplied by purchasers, such as data on complaints.

The organization *must* ensure 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 *QIP* 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 *must* review 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 Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 require that the Secretary of the Health and Human Services adopt a set of national electronic data interchange (EDI) standards for the health care industry. The Department was to adopt standards for: (1) transactions and code sets, (2) identifiers for health plans, providers, employers, and individuals for use in the transactions, (3) security of health information, and (4) privacy of health information.

The MA organizations, Medicare cost plans, and HCPPs are designated as health plans and must comply with the HIPAA requirements. All health plans must have the capability to exchange covered transactions electronically and meet the other HIPAA requirements as a covered entity.

To date, the implemented HIPAA provisions include the transactions and code sets, privacy, and security requirements. Additional HIPAA requirements are under development and MA organizations must comply with these as they are implemented. CMS will continue to provide specific instructions for transactions and code sets, privacy, security, and other HIPAA requirements as necessary.

The organization must make all collected information available to CMS.

20.*4* - Quality Improvement (QI) Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

20.4.1 - Basic Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Each MA organization (other than MA private-fee-for-service plans) must conduct *quality* 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 internal surveillance* discovers a systemic problem pertaining to an aspect of care delivery as a result of performing *oversight activities*, the organization is expected to address the problem promptly.

Quality Improvement Projects Begun Prior to January 1, 2006.

The MA organizations are not required to either continue or report on Quality Assurance Performance Improvement (QAPI) projects begun prior to January 1, 2006, including the 2005 project. CMS will not accept submissions of projects begun prior to 2006.

20.4.2 - Project Initiation Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Each newly contracting *MA* organization is expected to *initiate a QI* 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*, 2006,* and organization B signs a contract August 1*, 2006*. For both organizations, the second contract year will be *2007*. Initiation of a *QI* project is not required in year *2006,* the first year of the contract.

This extended time frame allows new *MA* organizations to enroll beneficiaries and accumulate data prior to the initiation of a QI project. This time frame is also similar to HEDIS requirements.

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

20.4.3 - Types of QI Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

20.*4.*3.1 – *Optional* National QI Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Although national CMS or DHHS projects are not a plan requirement, MA organization participation in proposed national projects is encouraged. Proposed national QI projects *will* address 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 MA organization. To the degree possible, these proposed national QI projects will be created and defined with input from beneficiaries, industry representatives, and members of the provider community. *CMS has not announced any optional national QI projects for 2006.*

20.*4.*3.2 - *MA* Organization Selected *QIP* Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Each MA organization (other than MA private-fee-for-service and MSA plans) is required to undertake one new QI project annually that can be expected to have a favorable effect on health outcomes and/or and enrollee satisfaction. In meeting this

requirement, plans have the ability to target their QI efforts to the needs of their Medicare enrolled population. Thus, the plans can include all their enrollees in the project, as long as they include Medicare enrollees and can provide separate data on them.

20.*4.*3.4 - Local Marketplace Initiative *QI* Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

MA organizations may voluntarily collaborate in local marketplace initiatives, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. A local marketplace collaborative project should:

- *Be* a community-wide initiative in which most or all *MA* organizations participate, and be initiated, facilitated, *endorsed* or required by a private purchaser group, QIO, State Medicaid Agency or other State government agency. *An M+A* organization may serve in the role of facilitator, initiator or requestor;

- *Address a topic* relevant to the Medicare population; *and*

- Include Medicare enrollees in the population sample for the project. Each MA organization *participating in a local market initiative* must report *their* organization*'s* 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.

In conducting a local market initiative, MA organizations must follow QI project process requirements of baseline measurement, intervention*(s),* and re-measurement..

20.*4.*3.*5* - Multi-Year *QI* Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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

1. 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;

2. Improvement of outcomes can come only after process improvements that are not closely enough related to outcomes to meet the requirement

3. Improvement will require multiple system interventions that cannot be implemented over a short period.

All other project types listed previously (national*, organization selected, or* local market place initiative) are not considered multi-year projects, in this context, even though they are conducted over several years.

The MA organization should *notify CMS of* its intention to do a multi-year project in advance of the proposed implementation date. *CMS notification may be accomplished via an e-mail to michelle.turano@cms.hhs.gov or shaheen.halim@cms.hhs.gov.*

20.*5* - Attributes of Quality Improvement (QI) Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

These attributes are applicable to all QI projects. CMS also applies these attributes in the development of *optional* CMS national projects. An individual QI project involves:

1. Identification of an aspect of clinical care or non-clinical services to be studied;

2. Specification of quality indicators to measure performance in the selected area;

3. Collection of baseline data;

4. Identification and implementation of appropriate system interventions to improve performance;

5. Repeated data collection to assess the immediate and continuing effect of the interventions and determine the need for further action;

6. Significant improvement sustained over time.

Because the key QI 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 B for specific guidance in the development of a QI project.*

20.*6* - Significant Improvement

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The *MA* organization's interventions in its *QI* 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 *QI* project initiated in a given year will achieve improvement in that same year. The CMS assumes a 3-year cycle for most MA 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 MA 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 *MA* 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 MA 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.*6*.1- Benchmarks

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

For MA organization selected projects and local marketplace initiatives, 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 *MA* organization must be able to document the basis on which its

benchmark was determined. *CMS may establish benchmarks for the optional national QI projects.*

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.

20.6.2 - Performance Targets

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 MA organization may create an internal performance target based on a clear rationale. The target should be something that an MA organization strives for, but may not necessarily reach. Failure of a MA organization to attain the stated performance target for a required QI project will not result in a negative score in the final evaluation report as long as there is evidence of continued improvement.

20.7 - Evaluation of *QI* Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The evaluation methodology used for review of QI projects will be similar to the methods used to review QAPI projects. MAOs can expect to submit baseline, intervention and remeasurement data for all projects. Specific guidance regarding the process forevaluation of QI projects will be provided as it is finalized.

20.7.1 - Accrediting Organizations That Are Approved for MA Organization Deeming Authority

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Accrediting organizations that are approved for MA organization deeming authority will review *QI* projects for those *MA* organizations that have selected deemed status via accreditation. Accrediting organizations are required to assess the *MA* organization's *QI* projects and report the results of the evaluation to CMS. The *MA* organizations are encouraged to contact the relevant accrediting organization for further instructions.

20.7.2 - CMS Regional Office Representatives

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The CMS Regional Office staff will continue to be available to MA organization staff when questions arise regarding QI projects. The MA organizations may share project information with RO Representatives to inform them about the projects and interventions that are being developed and discuss CMS QI requirements.

The CMS RO staff will continue to monitor the other aspects of the *QI* 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 *QI* project submissions in preparation for a site visit.

20.7.3 - Review of QI *Projects*

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

This section will be provided as it is finalized.

20.7.4 - Project Completion Report

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The Project Completion Report will provide the *MA* organization with an effective reporting tool for *QI* projects. The reporting unit will be the H-number (CMS contract identification number) level or less. The *MA* 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. 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 *QI* project.

The *MA* organizations which have consolidated contract H numbers over the course of the project will report on the current H-number as recognized by CMS. The *MA* 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.

The Project Completion Report is a Word-format template. The report will be submitted by the MAO in advance of their routine monitoring visit.

An *MA* organization may report any information regarding the project that it feels will describe and support understanding of the project by the reviewer. The *MA* 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 *MA* organization chooses to report more than one, it will be evaluated only on the indicator(s) for which it achieves significant improvement.

20.7.5 - Reporting of QI Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

CMS will review QI projects as part of an MAOs routine monitoring visit. In advance of such a visit, the MAO will be asked to compile reports for all QI projects that have yet to be reviewed in final. For example, if an MAO is having a 2008 routine monitoring visit, they should prepare reports for their 2006, 2007 and 2008 QI projects. Each project will be in a different phase of its cycle, and the reports should reflect that. CMS will provide specific guidance regarding: 1) to whom the QI reports should be submitted, and 2) what format should be used for compiling the QI reports. The MAOs will be provided with a template for the Project Completion Report (as mentioned above) to use for their QI reports.

Time Frames for All QI Projects
Based on Data Period

Project	Baseline Data Year	Intervention Year	Demonstrable Improvement Period 1	Demonstrable Improvement Period 2
2006 Project	2005	2006	2007	2008
	2006	2007	2008	2009
2007 Project	2006	2007	2008	2009
	2007	2008	2009	2010
2008 Project	2007	2008	2009	2010
	2008	2009	2010	2011

20.7.6 - Project Review Report

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

A Project Review Report will be sent to the CMS RO and will be contained in the final report of the MAO's monitoring visit. 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 *MA* organization did not satisfy all of the requirements

All aspects of the *QA* projects are important, however, some areas such as demonstrable and sustained improvement were determined to be the most significant.

20.7.7 - Communication Process

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Specific guidance will be forthcoming regarding the communication process for both deemed and non-deemed MAO's.

20.8 - Other Tools

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

In addition to the Project Completion Report and Project Review Report, other tools will be developed to assist MA organizations in the implementation of the QI projects.

20.9 - Corrective Action Plans

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

In the event that an MA organization does not meet the set requirements in the standards and guidelines determined by CMS, a Corrective Action Plan (CAP) will be required. The CAP is meant to bring the MA organization into compliance with the QI requirements. *Any CAP from a QI project will be incorporated into the findings of the routine monitoring visit*.

Possible Examples of CAP Elements

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

2. Methodology is appropriate and study is sound, but did not achieve significant and demonstrable improvement - The MA 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.

3. Interventions do not support indicators - The MA organization may be required to implement new interventions or collaborate with *the* QIO on future projects.

4. Conducts a project, but has poor planning, methodology, indicators, interventions, etc. - The MA organization may be instructed to collaborate with *the* QIO in future projects.

5. Failure to conduct a QI project - The MA 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 QI project and the MA organization's performance in conducting its QI projects.

25 - Summary of *MA Regional and MA Local Plans That are* Preferred Provider Organization (PPO) Quality Improvement Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The following provides a summary of quality improvement requirements relating to *MA regional plans and MA local plans that are PPO plans*. These requirements closely follow the provisions of 42 CFR 422.152(e). The requirements for these organizations have been extracted from the overall MA provisions and are listed separately so that PPO/PFFS plans may quickly identify applicable requirements.

MA Regional Plan Definition

An MA regional plan is a coordinated care plan structured as a PPO that serves one or more entire regions. An MA regional plan must have a network of contracting providers who have agreed to a specific reimbursement for the plan's covered services whether provided in or out of the network.

***Local* PPO *Plan* Definition:**

A local PPO plan is an MA plan that—

1. Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

2. Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

3. *Is* offered by an organization that is not licensed or organized under State law as a health maintenance organization.

Regional plans and Local PPO plans must have an ongoing quality improvement program per 42 CFR 422.152(a). The program must include the following elements:

1. *Have a chronic care improvement program meeting the requirements at 42 CFR 422.152(c);*

2. *Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction and that follows the QI project process requirements of baseline measurement, intervention(s), and re-measurement; and*

3. *Encourage the MA plan's providers to participate in CMS and HHS quality improvement initiatives.*

Additional requirements of the QI program stipulate that *the MA plan must*:

1. Measure performance under the plan using standard measures required by CMS *and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.*

   CMS has adopted the National Committee for Quality Assurance's (NCQA) Health Plan Employer Data and Information Set (HEDIS)™ as an acceptable standardized performance reporting system. A preliminary discussion of the HEDIS reporting requirements for regional and local PPOs can be found at http://www.cms.hhs.gov/healthplans/performance/. This site contains a list of measures that NCQA planned to study in a pilot test with PPOs. A draft report from NCQA with the results of the pilot test is currently under review in CMS. We anticipate issuing final details on the reporting requirements later in the Fall of 2005.

2. Evaluate the continuity and coordination of care furnished to enrollees.

3. If the organization uses written protocols for utilization review, the organization *must* base those *protocols* on current standards of medical practice, and have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

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

5. 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 *MA regional plan/local PPO plan* should routinely review reported data for accuracy, completeness, logic, and consistency; 42 CFR 422.152(f)(1).

6. Makes all collected information available to CMS for review purposes; 42 CFR 422.152(f)(1)(iii)

7. Evaluates the impact and effectiveness of the QAPI program at least annually. This would include an evaluation of the effectiveness of the *MA regional plan's or local PPO* 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; 42 CFR 422.152(f)(2).

8. 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 QI 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).

9. 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 422.504(i)

   a. 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.

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

   c. 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.

26 – Private-Fee-For Service Plans

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

An M&C Private Fee-for-Service Plan (PFFS) 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 serevice 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))

The quality requirements for PFFs are as follows:

1. *Maintain health information systems;*
2. *Ensure information from providers is reliable and complete;*
3. *Make all collected information available to dms to conduce quality reviews; and*
4. *Take corrective action for all problems that come to their attention.*

30 - Summary of Special Needs Plans Quality Improvement Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Special Needs Plans (SNPs) Definitions

Special needs individual *means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.*

Specialized MA Plans for Special Needs Individuals *means a MA coordinated care plan that exclusively enrolls or enrolls a disproportionate percentage of special needs individuals and that, beginning January 1, 2006, provides Part D benefits under Part 423 to all enrollees; and which has been designated by CMS as meeting the requirements of a MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.*

SNP QI Requirements

All SNPs will have to meet the chronic care improvement program and QI project requirements that have been described previously.

As we have done so with Medicare Advantage plans for many years, generally, we will require Special Need Plans (SNPs) to use CAHPS/HEDIS/HOS for performance measurement and reporting.

At this time the one exception to use of the traditional measures are the institutionalized SNPs. In the final rules we indicated we would consider applying other measures such as the Minimum Data Set (MDS) which is currently used for the institutionalized under the fee for service program. We believe those measures are more applicable than CAHPS/HEDIS/HOS data. For instance, it is difficult for nursing home patients to fill out

surveys. For other measures, they are of lower priority compared to concerns about measures such as pain and pressure ulcers.

Note that some of the SNPs, particularly the chronic care ones, may have enrollment which is too small for a relevant sample size for data collection. As in the past., we would not expect to require performance measurement until the plans attains an appropriate number of enrollees. We plan to work further with plans serving persons with chronic diseases to develop additional or alternative measures, but will apply the traditional measures at this time. We anticipate that alternative measures may be more appropriate, but until we have made that determination, we plan to use the traditional measures in the meantime.

35 - *Medicare Advantage* Deeming Program

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

This section discusses the *Medicare Advantage* 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), the Balance Budget Refinement Act of 1999 (BBRA*), and the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.* The BBA directed HCFA, now CMS, to establish and oversee a program that allows private, national accreditation organizations to "deem" that a Medicare Advantagee organization (MA 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. *The MMA further expanded the deemable areas to include the Medicare prescription drug program requirements*.

35.2 - Deeming Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Congress gave CMS the authority to deem Medicare requirements in the following 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);

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

7. Access to covered drugs (§1860D-4(b) of the Social Security Act);

8. Drug utilization management, quality assurance measures and systems, medication therapy management, and a program to control fraud, waste and abuse (§1860D-4(c) of the Social Security Act); and

9. Confidentiality and accuracy of enrollee prescription drug records (§1860D-4(i) of the Social Security Act).

It should be noted that items 7-9 are not being implemented at this time in the deeming program. However, we expect to revise items 1-6 soon per changes due to MMA and the final MA rules. as published in the January 28, 2005 ***Federal Register****.*

35.3 - General Rule

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

An *MA* organization may be deemed to be in compliance with certain Medicare requirements, if the *MA* organization has been accredited and periodically reaccredited by a private, national accrediting organization that has been approved by CMS. To deem a *MA* 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 *MA* 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 *MA* organization is accredited by the accreditation organization.

An *MA* 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 *MA* 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 *MA* organization's deemed status effective date would be March 1.

35.4 - Obligations of Deemed *MA* Organizations

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

As noted above, to be granted deemed status an *MA* organization must be fully accredited and periodically re-accredited by a CMS-approved accrediting organization. In addition, a *MA* 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

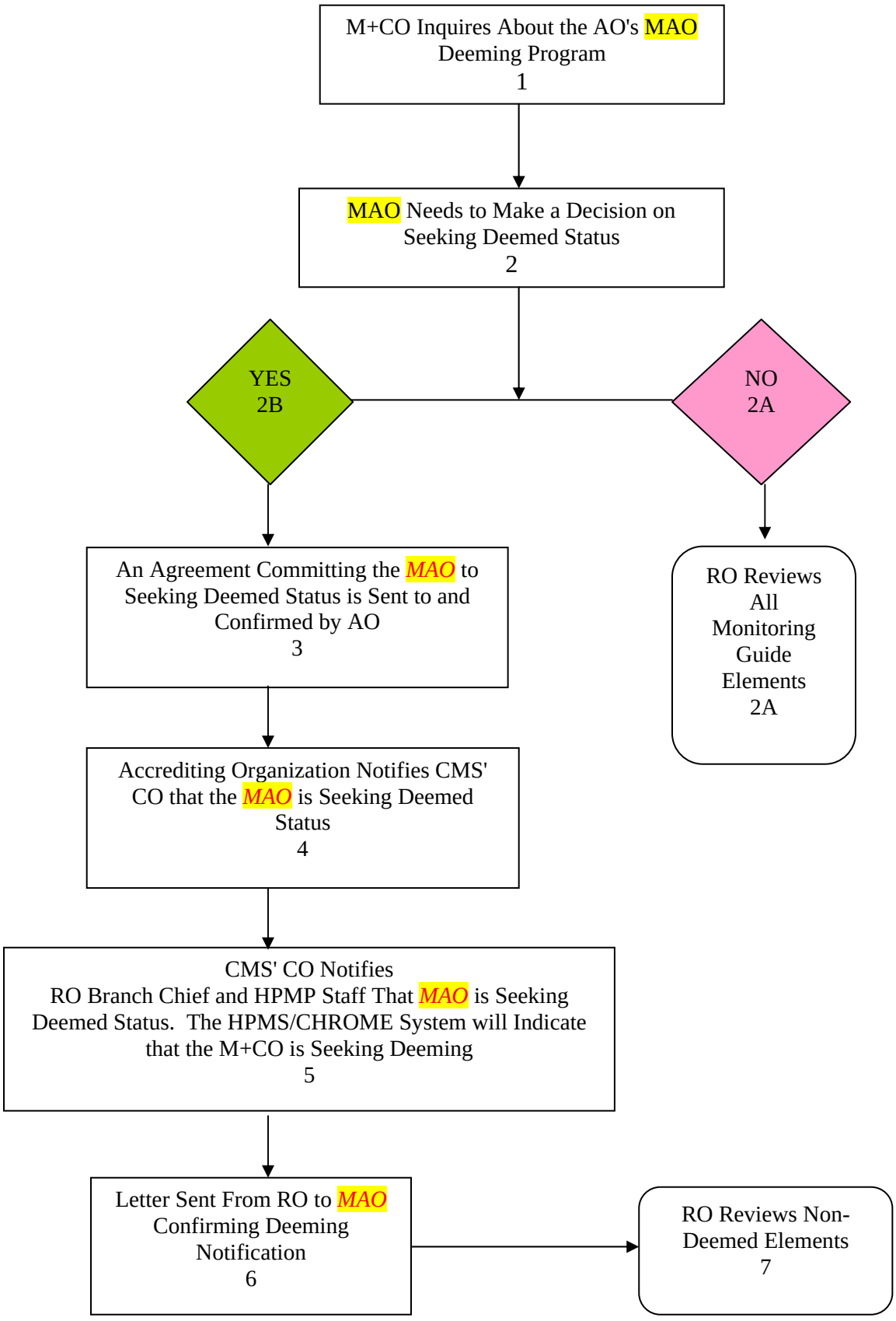
2. Retrospective (or look behind) surveys.

An *MA* 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).

The *MA* organizations *that* seek deemed status via accreditation by a CMS-approved accrediting organization can include the cost of accreditation as an administrative cost for use in the construction of their bid submission.. Administrative costs that bear a significant relationship to the *MA* plan seeking deemed status are allowed to be included.

However, the cost for the accreditation should be allocated between the *MA* organizations' Medicare and non-Medicare line of business using an appropriate cost allocation method, consistent with the bid instructions.

The following chart demonstrates the process that an *MA* organization must follow to initiate deemed status.


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

1. The *MA* organization Inquires About the Accreditation Organization's (AO's) *MA* Deeming Program:

    a. The Medicare Advantage organization (MAorganization) contacts the AO to inquire about the AO's *MA* deeming program. This is the opportunity for the *MA* organization to learn more about AO's deeming program.

    b. The AO sends informational materials pertaining to its MA deeming program to the *MA* 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.

    c. The *MA*organization reviews the information and contacts the AO with any questions or additional information that it may require.

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

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

    a. The Decision is No: The RO Reviews All Monitoring Guide Elements. The *MA* 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*.

    b. The Decision is Yes: If the *MA* organization decides to seek deemed status, the MA 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 *MA* organization to seeking deemed status.

3. An Agreement Committing the *MA* Organization Seeking Deemed Status is Sent To and Confirmed by the AO:

    a. If the *MA* 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 *MA* deeming authority, an agreement that relates specifically for *MA organization deemed status is signed. The AO will only review for the supplemental* MA

standards that were added to the AO's accreditation program in order for the AO to be granted *MA* deeming authority.

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

c. The *MA* organization sends the agreement to the AO with all the applicable processing fees.

d. At this point it is determined that the MA organization is seeking deemed status via accreditation.

e. The RO continues to work with MA 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 9 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 MA 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 MA organization is seeking deemed status. The AO will provide the date of the deemed status accreditation onsite visit, the MA 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.*

   a. Once the AO notifies CMS that it has a signed agreement that the MA 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.

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

c. HPMS staff will initiate the indicator in HPMS/CHROME system, which will alert RO staff that the MA organization is seeking deemed status via accreditation.

d.. 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 MA 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 *MA* Organization Confirming Deeming Notification:

After receiving notification from the central office that the *MA* organization is seeking deemed status, the RO will then send the *MA* organization a letter that notifies the *MA* organization that the AO has informed CMS that it (the *MA* organization) is seeking deemed status. This letter will also be a vehicle to confirm that the *MA* 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 MA 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. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

An MA organization that is accredited by a CMS-approved accrediting organization is still subject to CMS surveys. As noted above in § 35.2, an approved accrediting organization may only deem an *MA* organization for one or more of nine areas:

1. Quality assessment and improvement;

2. Confidentiality and accuracy of enrollee records;

3. Anti-discrimination;

4. Access to services;

5. Information on advance directives; and

6. Provider participation rules.

7. Access to covered drugs (§1860D-4(b) of the Social Security Act).

8. Drug utilization management, quality assurance measures and systems, medication therapy management, and a program to control fraud, waste and abuse (§1860D-4(c) of the Social Security Act).

9. Confidentiality and accuracy of enrollee prescription drug records (§1860D-4(i) of the Social Security Act).

It should be noted that items 7-9 are not being implemented at this time in the deeming program. However, we expect to revise items 1-6 soon per changes due to MMA and the final MA rules. as published in the January 28, 2005 ***Federal Register****.*

Thus, CMS's regional and central offices will still need to conduct surveys to assess compliance with those requirements that are not deemable, such as grievances and appeals, beneficiary disclosure, marketing, enrollment, and organization determinations. In addition, if the accrediting organization only has deeming authority in one of the nine deemable areas, such as access to services, then CMS will conduct a survey to assess the other *eight* areas, as well as non-deemable requirements. The CMS will also retain the authority to investigate "serious" complaints about an *MA* organization.

35.4.2 - Removal of an MA Organization's Deemed Status

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

The CMS will remove part or all of an *MA* organization's deemed status if:

1. We determine, based on our own survey, that the *MA* 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 *MA* organization; or

3. The *MA* organization fails to meet the obligations of a deemed *MA* 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 *MA* organization's deemed status will also be withdrawn. The *MA* organizations will be notified of the withdrawal of deemed status via a public notice. The accrediting organization must notify all their accredited *MA* organizations within 10 days. Upon removal of an *MA* organization's deemed status, CMS immediately assumes responsibility for ensuring that the organization meets *MA* standards.

35.5 - CMS's Role

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06 10, 08-14-02)

The CMS has been directed to establish and oversee the MA 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 MA organization requirements within a deeming subset (area).

If, during the course of monitoring for non-deemable requirements, CMS' RO staff identifies that an MA 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. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 equivalency reviews 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 onsite observations 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 MA 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 MAO 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:

    a. 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;

b. 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

c. 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 *MA* organization deeming program, CMS will conduct the accreditation organization survey during the application and reapplication process.

35.5.2 - Enforcement Authority

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 *MA* 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.

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35.6.1 - Application Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

A private, national accrediting organization may seek deeming authority for any or all of the *nine* 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 MA 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 *MA* 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 *MA* organization they are seeking authority to deem, including:

    .a. Frequency of surveys performed, whether the surveys are announced or unannounced, and how far in advance surveys are announced;

    b. Copies of survey forms and guidelines and instructions to surveyors;

    c. A description of the organization's survey review and accreditation status decision making process;

    d. The procedures used to notify accredited MA organizations of deficiencies and the procedures to monitor the correction of those deficiencies;

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

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

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

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

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

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

e. The policies and practices with respect to participation in surveys or in the accreditation decision process pertaining to 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 the organization's 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 MA deeming authority.

10. A list of all the MA organizations that the organization has currently accredited, by state and type, and the category of accreditation and expiration date of 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 3 months indicating organization type, date, state, and whether each managed care organization is an MA 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 3 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.

35.6.4 - Reporting Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 *MA* organizations;

    d. Information about any *MA* organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the MA 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 *MA* 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 *MA* 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 *MA* 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 MA organizations accreditation survey.

7. Accrediting organizations must report its assessment of accredited MA organization QI 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 Advantage* 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 *MAs*.

40.1 - Background

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 Advantage (MA)* 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 *MA* 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 MA 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.

Please note that Private Fee-For-Service Plans are excluded from these 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. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06 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; for PACE, Mass Health SCO, M-SHO & WPP, members enrolled one month 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, *including Program of All Inclusive Care for the Elderly (PACE) plans,* 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. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

A - Effects of the Medicare Modernization Act of 2003

The **Medicare Modernization Act of 2003** replaced the Medicare+Choice program with the Medicare Advantage program. The reporting requirements contained in this section of Chapter 5 apply to organizations that hold an MA contract, a §1876 cost contract, or a demonstration contract, in accordance with applicable law, regulations, and contract requirements. The HEDIS submission requirements also apply to deemed *MA* organizations. Please see section C below for exceptions to this requirement, such as organizations that have terminated their MA 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:

        1. The contract was in effect on 1/1 of the measurement (previous) year or earlier;

        2. The contract had initial enrollment on 1/1 of the measurement year or earlier;

        3. Contract had an enrollment of 1,000 or more on 7/1 of the measurement year;

        4. The contract was not terminated on or before 1/1 of the reporting (current) year.

    The HEDIS technical specifications are updated annually. For example, MAOs preparing HEDIS 2005 data submissions must follow instructions in HEDIS 2005, Volume 2 and relevant updates. 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 1-888-278-7885 to obtain a copy. The 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 MAOs must report are listed in Exhibit I, and the Medicare relevant measures that continuing cost contractors must report are listed in Exhibit IA. The PFFS requirements apply through 2005, but will be reduced as of January 2006. 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.

a. Health Outcomes Survey (HOS) - All MCOs, including the Program of All Inclusive Care for the Elderly (PACE) plans, 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.

b. Medicare Advantage CAHPS Survey - All Organizations that had a Medicare contract in effect on or before July 1, of the previous year, must comply with the MA CAHPS survey of current enrollees and disenrollees.

c. 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 MAOs 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 MAOs to report HEDIS measures; MAO 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 MAOs 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 MAO 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 MAO must report all the CMS-required Medicare HEDIS measures, even if the MAO 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 - MAOs 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 MAO 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 - *MAOs* With Special Circumstances

1. *MAOs* with Multiple Contract Types - A MAO cannot combine small contracts of different types, e.g., risk and cost, into a larger reporting unit.

2. *MAOs* Carrying Cost or former HCPP Members - HEDIS performance measures will be calculated using only the Medicare enrollment in the *MA* 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 MA 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. *MAOs* with New Members "Aging-in" from their Commercial Product Line - These MAOs 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 MAO's commercial

product line to the *MAOs* 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. *MAOs* with Changes in Service Areas - *MAOs* 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 *MAO's* visitor plan and the home plan are considered continuously enrolled in the plan.

7. New Contractors and Contractors Below the Minimum Enrollment Threshold - *MAOs* 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, MAOs 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 *MAOs* - 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. *MAOs* 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 *MAOs* 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 *MAO.* 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. MS will provide in the near future an update to this chapter of the manual which will delineate the PPO HEDIS requirements.

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. Note that Private Fee for Service Plans sare exempt from these demonstration projects.

Demonstration	HEDIS	HEDIS Audit	MA CAHPS	Disenrollee Reasons Survey	HOS
Social HMOs	YES	YES	YES	YES	YES
Minnesota Senior Health Options	NO	NO	NO	NO	YES
Massachusetts Health Senior Care Options	NO	NO	NO	NO	YES
Wisconsin Partnership Program	NO	NO	NO	NO	YES
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 MA 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 *MAOs* to use the data, including HOS data, for internal quality improvement. The data should help MAOs 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 *MAOs.* 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 *MAOs* can also view their own PAS

information online via secured access to the Health Plan Management System. For organizations that are subject to frailty adjusted payment, the data will also be used to determine an organization-level frailty adjuster.

40.3 - HEDIS Submission Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06))

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. *MAOs* must submit summary measures, after completing the NCQA HEDIS Compliance Audit required by Medicare, by the end of June of each reporting year. *MAOs*, including MA 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 - *MAOs* 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). The *MA* 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. The *MAOs* 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. The *MAOs* 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. The *MAOs* 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 *MAOs* regarding the

tool and the submission process. The *MAOs* 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 - *MAOs* 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. *MAOs* 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 *MAOs* 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. *MAOs* 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 *MAO* 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 *MAO* 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 MAO of the Final Audit Report from the NCQA-licensed audit firm, the *MAO* 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 *MAO'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 *MAO* and CMS deem proprietary will not be released, unless otherwise required by applicable law.

40.4 - The Medicare Health Outcomes Survey (HOS) Requirements

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 *MAOs* 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 *MA* organizations and continuing cost contracts that held §1876 risk and cost contracts, all Program of All-Inclusive Care for the Elderly (PACE) plans, 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. In addition all Massachusetts Health Senior Care Options, Minnesota Senior Health Options, and Wisconsin Partnership Program plans regardless of contract effective date must comply with this survey requirement.

To expedite the survey process, *MAOs* may be asked to provide telephone numbers or verify telephone numbers for the respondents unable to be identified using other means. *MAOs,* 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 *MAO* 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.

MAOs 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 MAO.

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 *MAO's* Medicare enrollees, was developed and extensively tested to ensure that *MAOs* 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 Improvement (QI)* 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 *MAO* 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. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 Advantage 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+A 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 *MAOs* 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 *MAOs* for the CAHPS sample embedded within a larger list of beneficiaries enrolled in the *MAO.* 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 MA 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 *MAOs* 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.

Exhibit II - Submitting Patient-Level Data

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

Required Measures

MAOs must provide the patient identifier, or HIC number, for all beneficiaries included in the summary data. *MAOs* 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 *MAOs* use this number for accretions and deletions. In addition to the patient identifier, *MAOs* 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 MA *MAO* 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

Controlling High Blood Pressure

Beta Blocker Treatment After A Heart Attack

Persistence of Beta-Blocker Treatment After a Heart Attack

Cholesterol Management After Acute Cardiovascular Events

Comprehensive Diabetes Care

Follow-up After Hospitalization for Mental Illness

Anti-depressant Medication Management

Glaucoma Screening in Older Adults

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

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 *MAO* 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 *MAOs* with exact file specifications and explicit instructions by the spring of the reporting year, which is sufficient time to allow *MAOs* 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. *MAOs* are advised to frequently review the NCQA Web site for updates on the data submission process.

Appendix A - *MA Quality Glossary*

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

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 *MA* Deeming

The duration of CMS' recognition of the validity of an accrediting organization's determination that a Medicare Advantage organization (MAO) 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.

Chronic Care Improvement Program (CCIP)

A set of interventions designed to improve the health of individuals who live with multiple or sufficiently severe chronic conditions, and include patient identification and monitoring. Other programmatic elements may include the use of evidence-based practice guidelines, collaborative practice models involving physicians as well as support-services providers, and patient self-management techniques.

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 *MA* organization to deliver the benefit package approved by CMS. Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), *regional or local* preferred provider organizations (PPOs), as well as other types of network plans (except network MSA *and private-fee-for-service* 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 MA organization (MAO) 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 MA Organization (MAO) 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 Advantage 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® 2005 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 *MA* contract.

Measures of Performance

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

MA 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 MA contract requirements. See 42 CFR 422.2.

MA Local Plan

An MA plan that is not a regional plan.

MA Plan

Health benefits coverage offered under a policy or contract offered by a Medicare Advantage 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 MA plan. See 42 CFR 422.2. An MA plan may be a coordinated care plan (with or without point of service options), a combination of an MA medical savings account (MSA) plan and a contribution into an MA MSA established in accordance with 42 CFR 422.262 (this section number may be incorrect) , or an MA private fee-for-service plan. See 42 CFR 422.4(a)(3).

MA Regional Plan

A coordinated care plan structured as a preferred provider organization that serves one or more entire regions. The plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services whether provided in or out of the network.

MCO

Managed care 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 MA 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 MA 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)(v).

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.

Special Needs Plan (SNP)

Any type of coordinated care plan that has been designated by CMS as meeting the requirements of a MA SNP and either exclusively enrolls or enrolls a disproportionate percentage of special needs individuals. See 42 CFR 422.4 (a)(1)(iv).

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 Advantage organizations (MA 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 B - Attributes of Projects

(Rev. 78, Issued: 01-20-06; Effective/Implementation Date: 01-20-06)

This section, "Attributes of Projects," applies to all *QI* 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 *MA* organization to fulfill the *QI* 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 *QI* 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 QI 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 QI 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

QI projects are required to address and achieve significant and sustained improvement in varying focus areas over time. Although it is not possible for any MA 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:

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

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

c. Care of acute conditions;

d. Care of chronic conditions;

e. High-volume services;

f. High-risk services; and

g. 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:

a. Availability, Accessibility and Cultural Competency of Services

b. Appeals, Grievances and Other Complaints

QI 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.

MA 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 MA 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 QI 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.

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 MA 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 QI 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 QI 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 QI 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 MA organization's performance on the selected indicators is based on systematic, ongoing collection and analysis of valid and reliable data. Documentation of completed QI 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 QI 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 *QI* 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:

a. 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:

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

    2. 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

    3. 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.

b. 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.

c. An MA 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 QI project, Medicare must be reported separately. If the QI 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.