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SUBJECT: Chapter 5, “Quality Improvement Program”

I. SUMMARY OF CHANGES: This manual update includes new and sections that provide detailed, up-to-date information, the relevant Code of Federal Regulations citations for all requirements, and an updated glossary of terms.

NEW / REVISED MATERIAL = EFFECTIVE DATE: August 5, 2011

IMPLEMENTATION DATE: August 5, 2011

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
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III. FUNDING: No additional funding is currently provided by CMS; contractor activities are to be carried out within their own FY 2010 and/or future operating budgets determined by the organizations.

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***Unless otherwise specified, the effective date is the date of service.**

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Chapter 5 – Quality Improvement Program

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10 - Introduction

10.1 Overview of Quality Improvement (QI) Program Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

This chapter operationalizes the statutory and regulatory requirements for Medicare Advantage organizations (MAOs) to implement and maintain a quality improvement (QI) program as required under 42 CFR §422.152. The chapter also clarifies the types of data to be collected and reported, the administration of QI programs, types of chronic care improvement programs (CCIPs) and quality improvement projects (QIPs), evaluation of CCIPs and QIPs, and the unique requirements for specific plan types, including special needs plans (SNPs), regional and local preferred provider organizations (PPOs), and private-fee-for-service (PFFS) plans.

All MAOs are required to have a QI program. MAOs must initiate QIPs that measure and demonstrate improvement in health outcomes and beneficiary satisfaction and a CCIP for at least one chronic condition. The QI program must include a health information system to collect, analyze, and report quality performance data as described in 42 CFR §422.516(a) and §423.514 for Parts C and D, respectively.

As provided under section 1852(e) (3) of the Social Security Act (the Act), MAOs must collect and report “data that permits the measurement of health outcomes and other indices of quality.” Accordingly, MAOs must collect and report data from the Healthcare Effectiveness Data and Information Set (HEDIS®), the Health Outcomes Survey (HOS) and the Consumer Assessment of Healthcare Providers and Systems (CAHPS®). MAOs must collect and report data elements that measure plan performance in terms of utilization of services, serious reportable adverse events, grievances, and plan oversight of sales and marketing agents and brokers, among other requirements. Part D sponsors must collect and report Medication Therapy Management Program (MTMP) and grievances measures, among others.

MAOs must ensure that (1) their reported data are accurate and complete, (2) they maintain health information for CMS review as requested, (3) they conduct an annual review of their overall QI program, and (4) they take action to correct problems revealed through complaints and QI program performance evaluation findings. This chapter provides guidance on the following topics:

- General information on the QI program;
- QI program requirements for MAOs using physician incentive plans (PIPs);
- QI program requirements for regional and local PPOs;
- QI program requirements for PFFS plans;
- QI program requirements for special needs plans (SNPs);

- Quality Improvement Organizations (QIOs);
- The MA deeming program; and
- Standard MAO reporting requirements.

10.2 Definitions

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Unless otherwise stated in this chapter, the following definitions apply:

Accreditation

An evaluative process under which a health care 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.

Accreditation Cycle for Medicare Advantage (MA) Deeming

The duration of CMS’ recognition of the validity of an accrediting organization’s determination that a MAO is “fully accredited.”

Accreditation Organization (AO)

A private, national accreditation organization approved by CMS and authorized to deem that an MAO is in compliance with Medicare accreditation requirements.

Baseline Data

The 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 Healthcare Providers and Systems (CAHPS®)

A patient’s perspective of care survey, administered annually, in which a sample of members

from provider organizations (e.g., MAOs, PDPs, PFFS) are asked for their perspectives of care that allow meaningful and objective comparisons between providers on domains that are important to consumers; create incentives for providers to improve their quality of care through public reporting of survey results; and enhance public accountability in health care by increasing the transparency of the quality of the care provided in return for the public investment.

Corrective Action Plan (CAP)

A formal process where CMS informs an MAO that it is out of compliance with CMS requirements. The CAP may result from an audit or result from other ad-hoc compliance events unrelated to an audit.

Cost Benefit Analysis

The weighing of known costs against probable benefits; the objective is to have potential benefits to exceed (additional) costs.

Deemed Status

Deemed status is a designation that an 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 AOs to determine, on CMS’ behalf, whether a MAO evaluated by the accrediting organization is in compliance with corresponding Medicare regulations.

Equivalency Review

The process CMS employs to compare an AO’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 limit.

Fully Accredited

Fully accredited is a designation that all the elements within the accreditation standards for which the AO 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.

Goal

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

Healthcare Effectiveness 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.

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 VR-12, to assess both physical and mental functioning. A sample of members from each MAO health plan is surveyed. Two years later these same members are surveyed again in order to evaluate changes in health status.

Health Outcomes Survey - Modified (HOS-M)

The HOS-M is a modified version of the Medicare HOS. The HOS-M is administered to Medicare beneficiaries enrolled in Programs of All Inclusive Care for the Elderly (PACE). The instrument assesses the physical and mental health frailty level of the Program members to generate information for payment adjustment.

Health Plan Management System (HPMS)

Facilitates data and information exchanges between CMS and Part C and D plan sponsors. HPMS plays an important role in CMS' efforts to communicate critical Part C and D program announcements to plans.

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.

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).

National Committee for Quality Assurance (NCQA)

A private, 501(c)(3) not-for-profit organization that has contracted with CMS to develop a set of measures to evaluate the structure, processes, and performance of SNPs.

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 MAO's

enrollees.

Quality

As defined by the Institute of Medicine (IOM) defines quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

Quality Improvement

As defined by the Agency for Healthcare Research and Quality (AHRQ) defines quality improvement as “doing the right thing at the right time for the right individual to get the best possible results.”

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 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.

Quality Improvement Project (QIP)

An organization’s initiative that focuses on specified clinical and non-clinical areas.

Sample

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

Subgroup

A sample selected from a large population.

Unit of Analysis for Deeming

For deeming, CMS will recognize the deemed status of MAOs if they are accredited at the same jurisdictional level (whether contract, state, or multi-state) that CMS would have used it, rather than the AO, had conducted the survey.

Variation

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

10.3 Quality Data Reporting Requirements

42 CFR §422.152(f); §422.516(a)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Each MAO must have effective procedures to develop, compile, evaluate, and report certain measures and other information to CMS, its enrollees, and the general public. In doing so, MAOs are responsible for safeguarding the confidentiality of the doctor-patient relationship. MAOs must report, at the times and in the manner that CMS requires, the following information:

- Cost of operations;
- Patterns of utilization of services;
- Availability, accessibility, and acceptability of Medicare approved and covered services;
- To the extent practical, developments in the health status of its enrollees;
- Information demonstrating that the MAO has a fiscally sound operation; and
- Other information that CMS may require.

Specifically, with respect to health information, MAOs must:

- Maintain a health information system that collects, analyzes, and integrates the data necessary to implement their QI program;
- Ensure that the information it receives from providers of services is reliable and complete; and
- Make all information collected in response to required reporting measures and other reportable information available to CMS.

Section 90 of this chapter provides detailed descriptions of all quality reporting requirements for CAHPS®, HEDIS®, and HOS measures.

20 - Quality Improvement (QI) Program

42 CFR §422.152

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

MAOs that offer one or more MA plans must have an ongoing QI program for each of their plans. The QI program must meet the applicable requirements for the services that it furnishes to its MA enrollees. Because access to care is a key element for the QI program, MAOs should also address this focus area in their QI programs.

This section describes the overall QI program requirements for MA plans. Subsequent sections of this chapter provide the details for MA plans that have additional or unique QI program requirements.

20.1 QI Program Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

MAOs that offer one or more MA plans must have for each of their plans a QI program under which it meets the following requirements:

1. Has a chronic care improvement program (CCIP), that meets the requirements of 42 CFR §422.152(c), and addresses populations identified by CMS based on a review of current quality performance;
2. Conducts quality improvement projects (QIP) that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meets the requirements of 42 CFR §422.152(d), and addresses areas identified by CMS;
3. Encourages providers to participate in CMS and Health and Human Service (HHS) QI initiatives;
4. Develops and maintains a health information system;
5. Contracts with an approved Medicare CAHPS® vendor to conduct the Medicare CAHPS® satisfaction survey of Medicare enrollees;
6. Includes a program review process for formal evaluation that addresses the impact and effectiveness of its QI programs at least annually; and
7. Corrects problems for each plan.

For certain types of MAOs, there may be additional requirements for the QI program; these specific requirements are described in sections 30, 40, 50 and 60 of this chapter.

20.2 Chronic Care Improvement Program (CCIP)

42 CFR §422.152(c)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Each MAO must have a CCIP and must establish criteria for participation in the program. The CCIP must be relevant to and target the MAO's plan population. Although plans have the flexibility to choose the design of their CCIPs, CMS may require MAOs to address specific topic areas. In addition, the CCIP must include a method for identifying MA enrollees with multiple or sufficiently severe chronic conditions who would benefit from participating in the program. Furthermore, MAOs

must have a mechanism for monitoring the MA enrollees who are participating in the CCIP.

20.2.1 Types of CCIPs

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

As noted in the section 20.2 of this chapter, designing a CCIP that is relevant to the specific target population for the MA plan is a critical component of the program. The Care Continuum Alliance (formerly the Disease Management Association of America (DMAA)) is a useful resource for identifying diseases that require care coordination and addressing related quality improvement strategies. In addition, the Agency for Healthcare Research and Quality (AHRQ) is a helpful resource for identifying evidence-based practice models and guidelines.

20.2.2 Evaluation of CCIPs and Scoring Criteria

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The evaluation methodology used for review of CCIPs is based on the degree to which the program improves and impacts the health status of the plan members. MAOs can expect to submit and utilize outcome measures for all CCIPs.

Following are 7 compliance indicators used for the evaluation of the CCIPs:

1. Target population and method of identifying the eligible enrollees;
2. Method for enrolling participants and participation rates;
3. Whether the CCIP is designed to improve health outcomes;
4. Data sources used to identify need for CCIP;
5. Intervention;
6. Program monitoring and delegation oversight; and
7. Outcome measures.

The definitions of each of the compliance indicators and the weights and scoring criteria for each are described in this section. Table 1 summarizes the weights that are assigned to each of the 7 compliance indicators. The score for each compliance indicator is based on how well the CCIP meets the specific criteria for that indicator. Tables 3 through 9 summarize the criteria for each specific indicator. The specific criteria are scored from a scale of 0 to 4, where 4 is the best score that can be attained and 0 is the poorest score.

Table 1: CCIP Compliance Indicators and Assigned Weights

Compliance Indicator	Weight
Target population and method of identifying eligible enrollees	15%
Method for enrolling participants and participation rates	15%
Whether the CCIP is designed to improve health outcomes	15%
Data sources used to identify need for CCIP	10%
Intervention	15%
Program monitoring and delegation oversight	15%
Outcome measures	15%

In order for a CCIP to be considered acceptable, the final score must be a 70 percent or greater. A CCIP with a score of 69 percent or lower is scored as “Unmet.” Unless otherwise directed by CMS, MAOs with CCIPs that have a score of 69 percent or below are required to complete a corrective action plan (CAP). Table 9 provides a summary of the final scoring and rating for the CCIPs.

Final CCIP Score and Rating

The weight of the indicator is multiplied by the points (on the 0-4 scale) given to the indicator to yield a weighted score for each indicator. These are then summed to create an overall score for the CCIP.

Table 2: Final CCIP Scoring and Rating

Range of Points	Compliance Rating	Action
70-100	MET	Requirements MET – Comments, Recommendations.
0- 69	NOT MET	Requirements NOT MET – Corrective Action Plan required.

20.2.2.1 CCIP Compliance Indicator 1 - Target Population and Method of Identifying Eligible Enrollees

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The CCIP must target the appropriate Medicare population with a clearly defined numerator, denominator, and exclusion criteria. In addition, the CCIP must demonstrate high, meaningful participation.

Table 3: Criteria for CCIP Compliance Indicator 1: Target Population and Method of Identifying Eligible Enrollees

Score	Criteria
4	Criteria for participation are thoroughly identified. Method of identifying eligible enrollees is designed for high, meaningful participation.
3	Criteria for participation are appropriately identified but could be more complete or method of identifying eligible enrollees could be improved.
2	Criteria for participation are somewhat appropriately identified the and method of identifying eligible enrollees is incomplete.
1	Criteria for participation are clearly not identified OR the method of identifying eligible enrollees is flawed.
0	Criteria for participation are not clearly described AND the method of identifying eligible enrollees is flawed or not explained.

20.2.2.2 CCIP Compliance Indicator 2 - Method for Enrolling Participants and Participation Rates

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The CCIP must demonstrate a rigorous enrollment method that reaches a significant segment of the targeted population while exhibiting robust participation in the program.

Table 4: Criteria for CCIP Compliance Indicator 2: Method for Enrolling Participants and Participation Rates

Score	Criteria
4	Enrollment method reaches a significant segment of the targeted population; participation is robust.

3	Enrollment method reaches a good, realistic portion of the target population; participation level is appropriate.
2	Enrollment method reaches part of the target population; participation could be improved.
1	Enrollment method reaches only part of the target population; participation is low.
0	Enrollment method reaches a few of the target population; participation is very low or not reported.

20.2.2.3 CCIP Compliance Indicator 3 – Whether the CCIP is Designed to Improve Health Outcomes

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The CCIP must be relevant, important, and developed with a strong evidence-based chronic care improvement process.

Table 5: Criteria for CCIP Compliance Indicator 3: Whether the CCIP is Designed to Improve Health Outcomes

Score	Criteria
4	CCIP is relevant, important, and developed with a strong QI process, based on evidence. Strong rationale for targeting condition is given.
3	CCIP is important to the population, good rationale is given.
2	Rationale for CCIP is appropriate, could be stronger.
1	CCIP is of minor importance to members or rationale is weak.
0	CCIP is not likely to help members and rationale is very weak or absent.

20.2.2.4 CCIP Compliance Indicator 4 - Data Sources Used to Identify the Need for a CCIP

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The plan must use multiple and reliable data sources and processes to identify and demonstrate the need for the CCIP.

Table 6: Criteria for CCIP Compliance Indicator 4: Data Sources Used to Identify the Need for a CCIP

Score	Criteria
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4	Multiple sources and QI processes are used to identify need for CCIP. Data sources are valid and reliable.
3	Strong sources and QI processes are used to identify need for CCIP. Data sources are valid and reliable.
2	Adequate sources and QI processes are used to identify need for CCIP. Data sources are valid and reliable.
1	Sources and QI processes used to identify need for CCIP are not clearly defined, are not clearly relevant or appropriate, or are not adequate.
0	Sources and QI processes used to identify need for CCIP are not defined or are not relevant, or data collection methodology is flawed. Data sources are not valid or reliable.

20.2.2.5 CCIP Compliance Indicator 5 – Intervention

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The intervention must reach a significant segment of the targeted population and concurrently address health literacy and cultural needs of participants

Table 7: Criteria for CCIP Compliance Indicator 5: Intervention

Score	Criteria
4	Intervention reaches a significant segment of the targeted population; impacts multiple aspects of problem, addresses health literacy and cultural needs of members.
3	Intervention is well planned to address most of the problem for most of the members.
2	Intervention reaches part of the target population; participation could be improved.
1	Intervention reaches only part of the target population; intervention does not address the spectrum of issues involved.
0	Intervention does not address the problem well or is not described.

20.2.2.6 CCIP Compliance Indicator 6 - Program Monitoring and Delegation Oversight

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

There should be a systematic process to monitor the CCIP. The program’s progress should be reviewed at least annually to reveal opportunities for improvement that need to be addressed.

Table 8: Criteria for CCIP Compliance Indicator 6: Program Monitoring and Delegation Oversight

Score	Criteria
4	Systematic program monitoring is integrated into the program; program progress of enrollee is reviewed at least annually and opportunities for improvement are addressed.
3	Program progress of enrollees is monitored by a small group but is not integrated into overall health plan operations and quality improvement.
2	Program progress of enrollees monitoring is occurs at least annually with some measures and some opportunities for improvement are addressed.
1	Program progress of enrollee is monitored less frequently than annually or opportunities for improvement are not addressed.
0	No program progress of enrollees is monitored or no oversight is described.

20.2.2.7 CCIP Compliance Indicator 7 - Outcome Measures

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The CCIP must have specific and appropriate performance measures to illustrate the success of the program.

Table 9: Criteria for CCIP Compliance Indicator 7: Outcome Measures

Core	Criteria
4	Specific, appropriate Outcome/performance measures provided.
3	General Outcome/performance measures provided.
2	Vague Outcome/performance measures provided.

1	Inappropriate Outcome/performance measures provided.
0	Outcomes/performance measures are not addressed at all.

20.3 Quality Improvement Projects (QIPs)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

QIPs are an MAO’s initiatives that focus on specified clinical and non-clinical areas. QIPs should be designed to address clinical or non-clinical areas of health care that would improve the health outcomes for the enrollees in the MAO. Unless otherwise directed by CMS, the MAOs may select the topic areas for their QIPs and these topic areas should be based on weaknesses identified by the MAOs. The specific characteristics for the QIPs are described in section 20.4.1 below.

20.3.1 Characteristics of QIPs

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

QIPs, whether they are clinical or non-clinical in nature, must:

1. Measure performance;
2. Improve performance;
3. Address system interventions, including the establishment or alteration of practice guidelines;
4. Provide systematic and periodic follow-up on the effect of the interventions;
5. Implement interventions that achieve demonstrable improvement;
6. For each project, use quality indicators to assess performance that meet the criteria outlined below. The quality indicators must be:
 - Objective;
 - Defined clearly and unambiguously;
 - Based on current clinical knowledge or health services research;
 - Capable of measuring outcomes such as (but not limited to):
 - Changes in health status;
 - Functional status;
 - Enrollee satisfaction; and

- Valid proxies for these and/or other outcomes.
7. Assess performance based on systematic ongoing collection and analysis of valid and reliable data; and
 8. Ensure that the status and results of each project are reported to CMS as requested.

20.3.2 Evaluation of QIPs and Scoring Criteria
(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The evaluation methodology that is used for the QIPs is similar to that for the CCIPs described in section 20.2.2 of this chapter. However, in contrast to the CCIPs, the QIPs may be either clinical or non-clinical in design. Therefore, the compliance indicators used to assess the QIPs have been modified to address this distinction.

CMS uses the following 6 compliance indicators to evaluate QIPs:

1. Target population;
2. Topic and focus relevant to the Medicare population;
3. QIP data sources and collection methodology;
4. Participation;
5. Results; and
6. Intervention

The definition for each of the compliance indicators and the weights and scoring criteria for each are described in this section. Table 10 summarizes the weights that are assigned to each of the 6 compliance indicators. In addition, the score achieved for each compliance indicator is based on how well the QIP meets the specific criteria for that indicator. Tables 12 through 17 summarize the criteria for each specific indicator. The specific criteria are scored from a scale of 0 to 4, where a score of 4 is the best score that can be attained and 0 is the poorest score. Each indicator is weighted according to its impact on overall quality as well as the independence of the indicator.

Table 10: QIP Compliance Indicators and Weights

Compliance Indicator	Weight
Target population	20%
Topic focus and relevance to Medicare Population	20%

QI indicators, data source and collection methodology	15%
Participation	10%
Results	15%
Interventions	20%

In order for a QIP to be considered acceptable, the final score must be a 70 percent or greater. A QIP with a score of 69 percent or lower is scored as “Unmet.” Unless otherwise directed by CMS, MAOs with QIPs that have a score of 69 percent or below are required to complete a CAP. Table 10 provides a summary of the final scoring and rating for the QIPs.

Final QIP Scoring, Rating, and Report

The weight of the indicator is multiplied by the points (on the 0-4 scale) given to the indicator to yield a weighted score for each indicator. These are then summed to create an overall score for the QIP.

Table 11: Final QIP Score and Rating Standards

Range of Points	Compliance Rating	Action
70-100	MET	Requirements MET – Comments, Recommendations.
0- 69	NOT MET	Requirements NOT MET – Corrective Action Plan required.

Plans that submit the QIP will receive a summary report that provides a score on each of the criteria and a description of the compliance indicators that will need to be addressed through a corrective action (CAP) plan if the score is a 69 percent or below.

20.3.2.1 QIP Compliance Indicator 1 - Target Population

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The QIP must be targeted at the appropriate Medicare population with a clearly defined numerator, denominator, and exclusion criteria.

Table 12: Criteria for QIP Compliance Indicator 1: Target Population

Score	Criteria
4	Target population is appropriate to the topic and is clearly defined, with clear numerator, denominator, and exclusion criteria.

3	Target population is appropriate to the topic and has defined numerators and denominators, and exclusions criteria but could be more complete.
2	Target population is somewhat appropriate and/or inclusion criteria are incomplete.
1	Target population is not appropriate <u>or</u> not clearly defined.
0	Target population is not appropriate <u>and</u> not clearly defined.

20.3.2.2 QIP Compliance Indicator 2 - Topic Focus and Relevance to the Medicare Population

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The topic of the QIP must be based on evidence with a clinical or non-clinical focus and should be developed with a strong QI process.

Table 13: Criteria for QIP Compliance Indicator 2: Topic Focus and Relevance to the Medicare Population

Score	Criteria
4	Topic is relevant, important, and developed with a strong QI process, based on evidence with a clinical or non-clinical focus.
3	Topic is important to the population with a clinical or non-clinical focus.
2	Topic is appropriate, could be stronger with a clinical or non-clinical focus.
1	Topic is of minor importance to members with a clinical or non-clinical focus.
0	Topic is not likely to help members.

20.3.2.3 QIP Compliance Indicator 3- QI Indicators, Data Sources and Collection Methodology

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The QIP must outline robust QI indicators that are objective, clearly and unambiguously defined, based on current clinical knowledge, and measurable. Data sources and collection methodology must be valid and reliable.

Table 14: Criteria for QIP Compliance Indicator 3: QI Indicators, Data Sources and Collection Methodology

Score	Criteria
4	Robust QI indicators are: objective, clearly and unambiguously defined; based on current clinical knowledge; and measurable. Data source and collection methodology are valid and reliable.
3	Strong QI indicators are used with reliable data and collection methodology.
2	Adequate QI indicators are used with valid and reliable data and collection methodology.
1	QI indicators are not clearly defined, are not clearly relevant or appropriate, or are not adequate.
0	QI indicators are not defined at all or are not relevant or weak and/or data collection methodology is flawed.

20.3.2.4 QIP Compliance Indicator 4 – Participation

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Interventions must reach a significant segment of the targeted population and beneficiary participation should be robust.

Table 15: Criteria for QIP Compliance Indicator 4: Participation

Score	Criteria
4	Intervention reaches a significant segment of the targeted population; participation is robust.
3	Intervention reaches a good, realistic portion of the target population; participation level is appropriate.
2	Intervention reaches part of the target population; participation could be improved.
1	Intervention reaches only part of the target population; participation is low.
0	Intervention reaches a few of the target population; participation is very low or not reported.

20.3.2.5 QIP Compliance Indicator 5 – Results

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

For the purpose of reviewing QIPs, meaningful improvement occurs when there is quantitative improvement that meets certain parameters. In order to be considered meaningful the quantitative improvement needs to be evaluated relative to:

1. The relevance to the organization’s population;
2. The effect on a significant portion of the population or of a high-risk population;
3. The likelihood of resulting in better outcomes for the population;
4. Attribution to the strength, duration, and quality of the organization’s actions (not to confounders, such as chance or random variation);
5. Support by valid study design with quantitative and qualitative analyses;
6. The ability of the organization to sustain the improvement(s) over time; and
7. Whether the improvement represents a reasonable gain beyond baseline performance.

While it is good to have a high baseline performance rate it may be more difficult to improve upon an already high level of performance than it is to improve on a lesser level of performance. For example, it may take more effort to move from a performance rate of 92 percent to a performance rate of 93 percent than it does to move from a performance rate of 20 percent to 40 percent.

Plans should set realistic performance targets based on an achievable goal or performance benchmark. The target should be reasonable and not unacceptably low. Although the ultimate goal is for the organization to reach its performance goals, even if performance goals are not met, an improvement can be considered meaningful if it meets the tests described above.

Results of the QIP’s interventions must show demonstrable quality improvement.

Table 16: Criteria for QIP Compliance Indicator 5: Results

Score	Criteria
4	Results show demonstrable improvement.
3	Results show improvement but not enough time has lapsed for an annual measure.

2	Results show no improvement but strategy for improvement is presented.
1	Results show no improvement and no strategy for improvement is presented.
0	Results are not addressed at all.

20.3.2.6 QIP Compliance Indicator 6 – Intervention

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The QIP must outline strong, realistic interventions that address multiple aspects of the problem, based on root cause analysis.

Table 17: Criteria for QIP Compliance Indicator 6: Intervention

Score	Criteria
4	Strong, realistic interventions address multiple aspects of the problem, based on root cause analysis.
3	Realistic interventions address multiple aspects of the problem.
2	Interventions are adequate but do not fully address multiple aspects of the problem.
1	Interventions are described but are not appropriate for the identified problem.
0	Interventions are not described.

**20.4 CMS and Department of Health and Human Service (DHHS) QI Initiatives
42 CFR §422.152**

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

20.4.1 General

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Each MAO must encourage its providers to participate in CMS and DHHS quality improvement initiatives, PFFS and MSA plans are required to meet the requirements only for their contracted providers (i.e., providers who have a contract with the plan). CMS will develop guidance as needed on the priorities for a QI initiative.

20.4.2 CMS-Directed Special Projects

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS may require an organization to conduct a particular QIP that is specific to the organization. There may be instances in which CMS believes that some aspects of care require greater emphasis, either because of the organization's relationship to populations with special health care needs or because the organization's performance is in need of greater improvement in some areas than in others. In such an instance, CMS may require the organization to conduct a particular project.

This type of project may be required in response to a remedial or corrective action request or if a previous QIP did not meet CMS' expectations. An MAO will be informed by CMS if it will be required to conduct this type of project.

20.5 QI Program Health Information Systems

42 CFR §422.152

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

MAOs must maintain a health information system that collects, integrates, analyzes, and reports data necessary to implement their QI programs. MAOs' health information system is central to their efforts to manage patient care and to assess and improve health care quality and outcomes. All MA plan types must meet the requirements of this section and must, as part of their health information systems:

1. Have the ability to collect, analyze and integrate data necessary to implement their QI program;
2. Ensure that the information they receive from providers of services is reliable and complete; and
3. Make all collected information available to CMS.

20.6 QI Program Benchmarks

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS is developing benchmarks for the overall QI program. These benchmarks will be designed to include all aspects of the QI program as described in this chapter. In the interim, MAOs must be able to document the basis on which they selected benchmarks that were used for their QI program.

Some benchmarks for the Medicare population such as HEDIS® results are available as public use files at <http://www.cms.gov> and are appropriate for use. Additional resources for benchmarking have been developed from the U.S. Preventive Services Task Force

(USPSTF) and the National Quality Forum (NQF). Information on both of these organizations can be found on the AHRQ website. If Medicare specific data are not available, commercial measures may be appropriate to use.

20.7 QI Program Remedial Action

42 CFR §422.152

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

For each plan, an MAO must correct all problems that come to its attention. These problems may be identified through:

1. Internal surveillance;
2. Complaints; and
3. Other mechanisms

30 - QI Program Requirements for MAOs Using Physician Incentive Plans (PIPs)

42 CFR §422.208

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

In addition to the QI program requirements described in section 20 of this chapter, MA plans with a physician incentive plan (PIP) that places a physician or physician group at substantial financial risk (as defined in 42 CFR §422.208(d)) for the care of Medicare or Medicaid enrollees should include in their QI program continuous monitoring of the potential effects of the incentive plan on access or quality of care.

MAOs should review utilization data to identify patterns of possible under-utilization of services that may be related to the incentive plan, (e.g., 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 the development of the organization's focus areas for QIPs.

40 –QI Program Requirements for Medicare Advantage Regional and Local Preferred Provider Organizations (PPOs)

42 CFR §422.152(e)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

In addition to the QI program requirements specified in section 20.1 of this chapter, the QI programs of regional and local PPO plans must:

1. Measure their performance under the plan using standard measures required by CMS, and report their performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.
2. Collect, analyze, and report quality performance data identified by CMS that are of the same type of data we currently collect as part of the HEDIS®, HOS and CAHPS® processes.
3. Evaluate the continuity and coordination of care furnished to enrollees. If the MAO uses written protocols for utilization review, the MAO 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.

50 – QI Program Requirements for Private-Fee-For Service (PFFS) and Medicare Medical Savings Account (MSA) Plans

42 CFR §422.152(h)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

In addition to the QI program requirements specified in section 20.1 of this chapter, PFFS and MSA plans must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. As provided under 42 CFR §422.152(e) data collection is limited to providers who are under direct contract with the plan. Similar to MA local plans that are PPO plans, PFFS and MSA plans are required to collect, analyze, and report health outcomes and quality data to the extent those data are furnished by providers who have a contract with the PFFS or MSA plan.

60 – QI Program Requirements for Special Needs Plans (SNPs)

42 CFR §422.152, §422.153, and §480.140

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

All SNPs are required to have a QI program to measure health outcomes and other indices of quality at the plan level and to monitor and evaluate the performance of its MOC. As an MA product, SNPs have the same performance improvement requirements as their parent MA organizations, but SNP QI requirements are tailored to the special needs individuals that the SNP serves. Additionally, SNPs and other MA-PD plans must participate in the Part D MTM program, which examines multi-drug therapy for specific chronic conditions. A SNP can use the MTM program to satisfy the requirements under Medicare and Medicaid that pertain to assessing the quality and appropriateness of care and services, as outlined in 42 CFR §438.204, §438.208, §438.240 and §422.152.

As provided under 42 CFR §422.152(c) and §422.152(d), MA organization QI programs must include a CCIP and QIP that measures and demonstrates improvement in health outcomes and beneficiary satisfaction.

CMS has reframed the QI program as a continuous performance improvement program for all MA organization products that includes collection, reporting, and analysis of data that:

1. Assists beneficiaries in selecting plans that meet acceptable performance levels
2. Assists CMS in monitoring plan performance; and
3. Sets minimum requirements for MA plans to assess their own performance through a robust internal performance improvement program.

All SNPs must also adhere to MA organization CCIP and QIP requirements, and must use CAHPS®/HEDIS®/HOS for performance measurement and reporting on QI for each SNP type they offer. SNP PPOs are not required to report HEDIS® measures that rely on medical record review to calculate the numerator or denominator.

60.1 Additional SNP QI Program Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

In addition to the QI program requirements specified in section 20.1 of this chapter, the QI programs for SNPs, as defined in section 30.2.4 of Chapter 1, are subject to the requirements detailed in this section.

As specified in section 90 of Chapter 16b, Special Needs Plans, SNPs must include the model of care (MOC) as part of their QI program. All information about the program must be available for submission to CMS or for review during monitoring visits. Data collected, analyzed, and reported as part of the SNP's QI program must be used to measure health outcomes and other indices of quality at the plan level and to monitor and evaluate the performance of its MOC.

The SNP QI program should be implemented as a three-tiered system of performance improvement that meets the following criteria:

1. The first tier consists of data on quality and outcomes that are collected and analyzed to enable beneficiaries to compare and select from among health coverage options. The data include selected HEDIS® measures and other structure and process measures. Each year, CMS provides guidance on the HEDIS® measures that plans are required to report on for the contract year.
2. The second tier consists of collection, analysis, and reporting data that measure the performance SNP MOCs.
3. The third tier consists of monitoring of the implementation of care management through the collection and analysis of selected data that measure the effectiveness of SNP MOCs. The SNP-specific QI measures for assessing the effectiveness of the MOCs are described in section 60.3.

60.2 SNP Model of Care (MOC) Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

SNPs must implement evidence-based MOCs and evaluate the effectiveness of the care management process. SNPs may evaluate one or more of the eleven components of the MOC through their QIP or CCIP. Section 90 of Chapter 16b provides detailed guidance on the eleven elements of the MOC.

60.3 SNP Quality Data Reporting Requirements

42 CFR §422.152(g)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

60.3.1 General

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

In addition to the MAO data reporting requirements outlined in section 90 of this chapter, MAOs that offer a SNP must provide for the collection, analysis, and reporting of data that measure health outcomes and indices of quality pertaining to their targeted special needs population (i.e., chronic condition, dual-eligible, institutionalized or institutional-equivalent) at the plan level.

These reviews focus on how the SNPs have implemented their MOCs and how their QI programs have affected care management, as structured by the MOC. SNPs can meet both QI measurement requirements and the care management requirements described in this section and in section 90.8 of this chapter by making the collection and analysis of health outcomes and quality indices pertaining to special needs individuals the focus of their QIP and CCIPs. For example, some SNPs have indicated that they collect and analyze data from a variety of sources (e.g., claims, medical record reviews, pharmacy records, surveys) to measure service utilization rates (e.g., preventive care visits, hospitalizations, emergency room visits), functional status changes, complaints and grievances, disease management outcomes, and beneficiary satisfaction in an effort to improve service delivery and health status among their enrollees.

60.3.2 SNP Reporting Measures Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The specific SNP HEDIS® reporting requirements for each contract year are provided to the plans on an annual basis. SNPs with 30 or more enrollees are required to report those measures to CMS. (Refer to section 90.2 of this chapter.)

60.3.2.1 SNP Structure and Process Measures

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS, together with the National Committee for Quality Assurance (NCQA), has developed a set of measures to evaluate the structure, processes, and performance of SNPs. Through these measures, SNPs must demonstrate that they are providing quality health care for the beneficiaries. Performance information for structure and process measures will be collected via NCQA's Interactive Survey system.

There are six structure and process measures:

1. Complex case management;
2. Improving member satisfaction;
3. Clinical quality improvements;
4. Care transitions;
5. I-SNP relationships with facility; and
6. Coordination of Medicare and Medicaid coverage.

60.3.2.2 SNP-Specific Medicare HOS Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

All coordinated care plans, including contracts with exclusively SNP plan benefit packages (PBPs) are required to report the Baseline HOS, provided the contracts have a minimum enrollment of 500 members. Since the baseline and follow-up surveys collected during the same year involve different cohorts, information about specific annual requirements will be announced through HPMS.

60.3.2.3 SNP-Specific Medicare CAHPS® Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

All coordinated care contracts with exclusively SNP PBPs and at least 600 enrollees are required to collect CAHPS® data.

60.3.2.4 Medicare and Medicaid Quality Reporting Requirements for D-SNPs
42 CFR §438.200, §438.242

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

State contracts with D-SNPs must include a written strategy for assessing and improving the quality of managed care services. D-SNPs should begin discussing these quality requirements with the State during the contracting process. The State will ensure that D-SNPs comply with these standards, and will submit a copy of its initial quality strategy, and any necessary revisions, to its CMS Regional Office.

In the case of D-SNPs that enroll only dual-eligible individuals, the State has the option under §438.360 of relying on Medicare information for all three mandatory external quality review (EQR) activities described in §438.358(b)(3). A State may also exempt a D-SNP from the EQR altogether if the plan meets the requirements of §438.362.

States have flexibility in defining the performance measures and performance improvement projects for their Medicaid contracts. A State may additionally choose to build its medication therapy management program into its D-SNP contract requirements. While a State may agree to use Medicare performance measures or performance improvement projects, States are not required to do so, or to limit the requirements solely to the Medicare requirements. CMS does not permit SNPs to use Medicaid measures as a proxy for Medicare measures when those measures differ from the Medicare requirements.

70 - Quality Improvement Organizations (QIOs)
42 CFR §422.153

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS may coordinate with QIOs, whose role is described in 42 CFR §480, to obtain information and data on utilization and quality control for the Medicare program. The QIOs have a significant role in providing data to CMS for monitoring and assessing MAO quality improvement.

CMS may acquire data from the QIOs as needed for quality improvement and monitoring plan performance. The data may be used for the following limited functions:

1. To enable beneficiaries to compare health coverage options and select among them;
2. To evaluate plan performance;
3. To ensure compliance with plan requirements

4. To develop payment models; and
5. For other purposes related to MA plans as specified by CMS.

80 – Medicare Advantage (MA) Deeming Program

42 CFR §422.156, 422.157, 422.158

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS is required, under section 1852(e)(4) of the Act, to establish and oversee a program that allows private, national accreditation organizations (AOs) to “deem” that an MAO is in compliance with certain Medicare requirements.

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

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

Currently CMS has entered into agreements with NCQA, URAC (formerly the Utilization Review Accreditation Commission), and the Accreditation Association for Ambulatory Healthcare (AAAHC) for deeming AOs.

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

80.1 Deeming Requirements

42 CFR §422.156(b)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

As provided under section 1852 (e)(4) of the Act, CMS may deem Medicare requirements in the following areas:

1. Quality assessment and improvement;
2. Confidentiality and accuracy of medical or other enrollee health records;
3. Anti-discrimination;
4. Access to services;
5. Information on advance directives;
6. Provider participation rules;
7. Access to covered drugs;
8. Drug utilization management, quality assurance measures and systems, medication therapy management, and a program to control fraud, waste and abuse; and
9. Confidentiality and accuracy of enrollee prescription drug records.

We note that items 7-9 are not being implemented at this time in the deeming program.

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

An MAO's deemed status is effective on the later of:

1. The date on which the AO is approved by CMS; or
2. The date the MAO is accredited by the AO.

An MAO's deemed status will be effective on the date the AO is approved if the AO uses the same standards and methods of evaluation approved by CMS at the time of the survey. For example, if the MAO is accredited on January 5 by an organization that is approved by CMS on March 1 of the same year, on January 5 the AO 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 MAO's deemed status effective date would be March 1.

80.2 Obligations of Deemed MAOs

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

80.2.1 General

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

As noted in section 80.1 of this chapter, to be granted deemed status, an MAO must be fully accredited and periodically re-accredited by a CMS-approved AO. In addition, an MAO deemed to meet Medicare requirements must submit to surveys to validate its AO'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 MAO that seeks deemed status must also agree to authorize its AO to release to CMS a copy of its most current accreditation survey, as well as any survey-related information that CMS may require (including CAPs and summaries of unmet CMS requirements).

MAOs that seek deemed status via accreditation by a CMS-approved AO 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 an MAO's Medicare and non-Medicare lines of business using an appropriate cost allocation method, consistent with the bid instructions.

The steps demonstrating the process that an MAO must follow to initiate deemed status are:

1. The MAO inquires about the AO's MA deeming program:
 - a. This is the opportunity for the MAO to learn more about AO's deeming program.
 - b. The AO sends informational materials pertaining to its MA deeming program to the MAO. 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 MAO reviews the information and contacts the AO with any questions or additional information that it may require.
 - d. CMS Regional Office (RO) staff should continue to work with the MAOs to coordinate the CMS performance assessment review because: (1) many of the CMS requirements are not deemable, and (2) the MAO may decide that it does not want to pursue deeming.
2. The MAO makes a decision on seeking deemed status via accreditation.
- a. If the Decision is No: The RO Reviews All Monitoring Guide Elements. The RO will schedule and conduct a performance assessment visit using the most current version of the monitoring guide.
 - b. If the Decision is Yes: The MAO 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 MAO to seeking deemed status.
3. An agreement committing the MAO seeking deemed status is sent to and confirmed by the AO.
- a. If the MAO 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 its application for MA deeming authority, an agreement that relates specifically for MAO deemed status is signed. The AO will only review 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 MAO by using the AO's entire accreditation program for managed care plans (its regular accreditation program plus the MAO supplement).
 - c. The MAO sends the agreement to the AO with all the applicable processing fees.
 - d. At this point it is determined that the MAO is seeking deemed status via accreditation.
 - e. The RO continues to work with MAO to coordinate the performance assessment review for all the requirements that are not deemed. If the AO 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. The AO notifies CMS that the MAO has been approved for deemed status. Once the agreement has been signed, the AO will notify CMS' CO contact via e-mail that the MAO has been deemed. The AO will provide the date of the deemed status accreditation, the MAO's contract number, and any additional information that CMS may require.
5. CMS' CO enters the deemed status into HPMS:
 - a. Once the AO notifies CMS that it has a signed agreement that the MAO has been deemed via accreditation, CO staff will enter the deemed status into the HPMS system.
 - b. Before any pre-visit information request is sent to an MAO by RO staff, the HPMS system must be checked for deemed status.
 - c. CO staff will initiate the indicator in HPMS which will alert RO staff that the MAO has been deemed 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 MAO 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. RO staff review all of the non-deemed elements. Once it has been established that the MAO is deemed the RO staff will only review non-deemed elements.

80.2.2 Deemed Status and CMS Surveys

42 CFR §422.156(d)(1)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

An MAO that is accredited by a CMS-approved AO is still subject to CMS surveys. As noted in section 80.1 of this chapter, an approved accrediting organization may only deem an MAO for one or more of the nine areas described in section 80.1 of this chapter.

Thus, CMS' ROs and CO 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 AO 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 8 areas, as well as non-deemable requirements. CMS will also retain the authority to investigate “serious” complaints about an MAO.

80.2.3 Removal of an MAO’s Deemed Status

42 CFR §422.156(e)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS will remove part or all of an MAO’s deemed status if:

1. CMS determines, based on its own survey, that the MAO does not meet the Medicare requirements for which deemed status was granted;
2. CMS withdraws its approval of the AO that accredited the MAO; and/or
3. The MAO fails to meet the obligations of a deemed MAO, which are addressed in section 80.2.1 of this chapter.

CMS will not overrule an AO’s survey decision without doing its own investigation. However, if CMS’ investigation reveals that a condition is not met, CMS reserves the right to remove deemed status even though the AO has not removed accreditation with respect to that condition.

In addition, when CMS withdraws its approval of deeming authority from the AO, the MAO’s deemed status will also be withdrawn. The MAO will be notified of the withdrawal of deemed status via a public notice. The AO must notify all its accredited MAOs within 10 days. Upon removal of an MAO’s deemed status, CMS immediately assumes responsibility for ensuring that the organization meets MA standards.

80.3 CMS’ Role in Deeming

42 CFR §422.157(a)(d)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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 described in section 80.4.1 of this chapter. CMS must approve an AO by deeming subset (area), rather than by individual requirement. However, an AO must have a comparable standard for every one of the MAO requirements within a deeming subset (area).

If, during the course of monitoring for non-deemable requirements, CMS’ RO staff determines that an MAO is not in compliance with a deemable requirement, RO staff must notify CMS CO deeming staff who will ensure that the AO 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.

80.3.1 Oversight of AOs

42 CFR §422.157(d)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

After approving an AO for deeming authority, CMS provides oversight of the AOs' performance. CMS has a number of mechanisms available to fulfill its oversight responsibilities, including:

1. Conducting equivalency reviews if CMS or the AO adds or changes requirements;
2. Conducting validation surveys to examine the results of the AO's survey;
3. Conducting onsite observations of the AO'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 MAOs in response to serious complaints.

If RO staff detects a trend (or pattern) of complaints in deemed areas, they will refer the matter to CO deeming staff who will, in turn, contact the appropriate AO.

80.3.1.1 Equivalency Review

42 CFR §422.157(d)(1)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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

1. CMS imposes new requirements or changes its survey process;
2. An AO proposes to adopt new standards or changes in its survey process; or
3. The term of an AO's approval expires.

80.3.1.2 Validation Review

42 CFR §422.157(d)(2)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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 MAOs.
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 AO 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 AO 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 AO performance. CMS will later phase in a combination of desk reviews, concurrent observational, and look behind surveys.

80.3.1.3 Onsite Observation of an AO

42 CFR §422.157(d)(3)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS may conduct an onsite survey of the AO'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 MAO deeming program, CMS will conduct the AO survey during the application and reapplication process.

80.3.2 Enforcement Authority

42 CFR §422.156(f)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS retains the authority to initiate enforcement action (including intermediate sanctions that are detailed in 42 CFR §422, Subpart O) against any MAO that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

80.3.3 Notice of Intent to Withdraw Approval

42 CFR §422.157(d)(4)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

If an equivalency review, validation review, onsite observation, or CMS' daily experience with the AO suggests that the AO is not meeting the requirements specified in 42 CFR §422, Subpart D, CMS will give the AO written notice of its intent to withdraw approval.

CMS may withdraw an AO's approval for deeming authority at any time, if CMS determines that:

- Deeming based on accreditation no longer guarantees that the MAO meets the requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitutes a significant hazard to the public health,
- Or,
- The AO has failed to meet the obligations specified in sections 80.1 and 80.4 of this chapter.

80.4 Obligations of AOs with Deeming Authority

42 CFR §422.157(c)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

AOs must apply and enforce the standards that CMS determines, as a condition of approval, are at least as stringent as Medicare requirements with respect to the standard or standards in question. To be approved, an AO must comply with the application and reapplication procedures that are addressed in section 80.4.1 of this chapter.

AOs must also ensure the following:

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

80.4.1 Application Requirements

42 CFR §422.158

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

A private, national AO may seek deeming authority for any or all of the 9 categories listed in section 80.1 of this chapter. For each deeming category for which the AO is applying for deeming authority, it must demonstrate that its standards and processes meet or exceed Medicare requirements within that particular category.

A private, national AO 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;
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 MAO it is 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 MAOs of deficiencies and the

- procedures to monitor the correction of those deficiencies; and
- 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 MAO 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; and
 - 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. A 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. A description of all the types (full, partial, or denial) and categories (provisional conditional, or 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 MAOs that the organization has currently accredited, by State an type, and the category of accreditation and expiration date of accreditation held by each organization;
11. A list of all the managed care organizations (MCOs) 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 MCO is an MAO;
13. The name and address of each person with an ownership or controlling interest in the AO;
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; and
16. A statement acknowledging that, as a condition of approval, the organization agrees to comply with the ongoing responsibility requirements that are addressed in section 80 of this chapter.

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

As part of the application process, CMS may visit the AO'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.

80.4.2 Application Notices

42 CFR §422.158(e)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Each application will be reviewed for completeness. Approximately 60 days after an application has been determined to be complete, CMS will publish a proposed notice in

the Federal Register. This notice will announce that CMS has received an application from the AO and is considering granting the organization's application for MAO deeming authority. The proposed notice will also describe the criteria that CMS will use in evaluating the applications. CMS will provide a 30-day period for the public to comment on the proposed notice.

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

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

1. States whether the request for approval has been granted or denied;
2. Provides the rationale for any denial; and
3. Describes the reconsideration and reapplication procedures.

For information regarding reconsideration of adverse determinations refer to section 80.4 of this chapter.

80.4.3 Withdrawing an Application

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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

80.4.4 Reporting Requirements

42 CFR §422.157(c)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

When an AO is approved by CMS for deeming authority, the AO agrees to certain ongoing activities, including:

1. Providing 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 CAPs and summaries of unmet CMS requirements);

- b. Notice of all accreditation decisions;
 - c. Notice of all complaints related to deemed MAOs;
 - d. Information about any MAO against which the AO has taken remedial or adverse action, including revocation, withdrawal or revision of the MAO's within 30 days of taking the action; and
 - e. Notice of any proposed changes to its accreditation standards or requirements or survey process. If an AO implements any changes before or without CMS approval, CMS may withdraw its approval.
2. If an AO finds a deficiency in an MAO 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 it is withdrawing its approval for deeming authority, the AO must notify all its accredited MAOs within 10 days.
 4. AOs 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 MAO requirement, the AO 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 of 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. AOs must have a mechanism for publicly disclosing the results of an MAO's accreditation survey.
 7. AOs must report their assessment of accredited MAO QIPs and results of deemed surveys and any corrective actions, if required, to CMS via HPMS.

Accreditation surveys of MAOs performed by private AOs under section 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. AOs must, however, have methods to disclose the accreditation status of deemed MAOs.

80.5 Reconsideration of Application Denials, Removal of Approval of Deeming Authority and Non-Renewals of Deeming Authority

42 CFR §422.158

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

An AO that has received a notice of denial of its request for deeming authority (or specific deeming categories) may request reconsideration. CMS will reconsider any determination to deny, remove, or non-renew the approval of deeming authority to private AOs, if the AO files a written request for reconsideration. The request must be filed within 60 days of the receipt of notice of an adverse determination. The request for reconsideration must specify the findings or issues with which the AO disagrees, and the reasons for the disagreement.

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

80.5.1 Informal Hearing Procedures

42 CFR §488.158(g), §§488.201-488.211

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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

1. The hearing is open to CMS and the organization requesting the reconsideration, including:
 - Authorized representatives;
 - Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and
 - Legal counsel;
2. The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;
3. The hearing officer may accept testimony and other evidence even though it would be inadmissible under the usual rules of court procedures;
4. Either party may call witnesses from among those individuals specified in this section.

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

80.5.2 Informal Hearing Findings

42 CFR §488.209

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the AO that requested the reconsideration. The written report of the hearing officer will include separately numbered findings of fact and the legal conclusions of the hearing officer.

80.5.3 Final Reconsideration Determinations

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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

90 - Standard Reporting Requirements for MAOs for HEDIS®, HOS, and CAHPS®

42 CFR §422.152

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

90.1 General

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

This section provides information regarding the annual Medicare HEDIS®, HOS, and CAHPS® reporting requirements. CMS makes summary, contract-level performance measures available to the public through media that are beneficiary-oriented, such the Medicare Plan Finder tool at <http://www.medicare.gov>.

90.2 HEDIS® Reporting Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

HEDIS® is a trademark product of NCQA. MAOs meeting CMS's minimum enrollment requirements must submit audited summary-level HEDIS® data to NCQA. Contracts with 1,000 or more members enrolled as reported in the July Monthly Enrollment by Contract

Report (which can be found at <http://www.cms.hhs.gov/MCRAdvPartDEnrolData/MEC/list.asp#TopOfPage>) must collect and submit HEDIS® data to CMS. Closed cost contracts are required to report HEDIS® as long as they meet the enrollment threshold in the reporting year. Patient-level data must be reported to the CMS designated data contractor. Information about HEDIS® reporting requirements is posted in HPMS. During the contract year, if an HPMS contract status is listed as a consolidation, a merger, or a novation, the surviving contract must report HEDIS® data for all members of the contracts involved. If a contract status is listed as a conversion in the data year, the contract must report if the new organization type is required to report.

CMS collects audited data from all benefit packages designated as SNPs and contracts with ESRD Demonstration Plans that had 30 or more members enrolled as reported in the SNP Comprehensive Report (which can be found at <http://www.cms.hhs.gov/MCRAdvPartDEnrolData/SNP/list.asp#TopOfPage>).

The data collection methodologies for HEDIS® are either the administrative or hybrid types. The administrative method is from transactional data for the eligible populations and the hybrid method is from medical record or electronic medical record and transactional data for the sample. PFFS contracts are required to collect and report HEDIS summary-level data and patient-level data as outlined each year in the annual notice through HPMS.

MAOs new to HEDIS® must become familiar with the requirements for data submissions to NCQA, and make the necessary arrangements as soon as possible. The organization should request an application for a HEDIS® Audit from an NCQA Licensed Organization (www.ncqa.org/audit.aspx), and is responsible for determining fees and entering into contracts. HEDIS® Compliance Audits result in audited rates or calculations at the measure level and indicate if the HEDIS® measures can be publicly reported. All HEDIS® measure selected for public reporting must have a final, audited result. The auditor approves the rate or report status of each HEDIS® measure and survey included in the audit. For HEDIS® measures, the auditor approves the rate or report status of each measure and survey included in the audit as follows:

- A rate of numeric result. The organization followed the specifications and produced a reportable rate or result for the measure.
- Small Denominator (NA). The organization followed the specifications but the denominator was too small (<30) to report a valid rate.
- Benefit Not Offered (NB). The organization did not offer the health benefit required by the measure (e.g., mental health, chemical dependency).
- Not Reportable (NR). The organization calculated the measure but the rate was materially biased, or the organization chose not to report the measure or was not required to report the measure.

Following are requirements for MAOs with special circumstances:

1. MAOs with Multiple Contract Types - An MAO cannot combine small contracts of different types, e.g., risk and cost, into a larger reporting unit.
2. MAOs with contract conversions: For HEDIS® measures with a continuous enrollment requirement and for enrollees who converted from one type of contract to another (within the same organization), enrollment time under the prior contract will not be counted.
3. 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 an MAO’s commercial product line to the MAO’s Medicare product line are considered continuously enrolled. Please read the General Guidelines of HEDIS® Volume 2: Technical Specifications for a discussion of “age-ins” (see “Members who switch product lines”) and continuous enrollment requirements.
4. 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 1 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.
5. 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.
6. 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 Data Submission Tool (DST), an Excel-based application developed and maintained by 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.
7. Non-renewing/Terminating MAOs - Entities that meet the HEDIS® reporting requirements 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 Medicare CAHPS® or Medicare HOS surveys.

- 8 MAOs with Continuing Section 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, skilled nursing facilities (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.
9. Section 1876 Cost Contracts: 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.
10. Mergers and Acquisitions - The entity surviving a merger or acquisition must report both summary and patient-level HEDIS® data only for the enrollment of the surviving company. 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.

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.

90.2.1 Additional Information Regarding HEDIS®

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

CMS annually provides guidance for every reporting year that provides details about required HEDIS® measures, changes in the data specifications, data submission schedule and deadlines, and instructions about data submission. All contracts should use the annual guidance regarding the HEDIS® requirements for the upcoming reporting year. The details of all of the measures can be found in the NCQA annual publications, in HEDIS®, Volume Two, "Technical Specifications" for the corresponding reporting year. Medicare managed care contracts that are required to report HEDIS® summary-level data must also provide the patient-level data used to calculate the summary-level data for each

MA contract. Submission of the patient-level HEDIS® data is not required for the SNP-specific HEDIS® measures.

CMS collects patient-level data with patient-level identifiers for the numerator and the denominator of each required HEDIS® measure because this 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.

90.3 HEDIS® Submission Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

90.3.1 Summary and Patient-Level Data

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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 and §1876 cost contracts must submit summary measures, after completing the NCQA HEDIS® Compliance Audit required by Medicare, by mid-June of each reporting year. MAOs, including PPO, PFFS, and §1876 cost contracts must submit HEDIS® patient-level data at the same time. CMS requires the submission of the following patient-level data on the same date as summary data to ensure that the patient-level data match the summary data. Auditors will review patient-level data for the numerator and denominator of audited measures when checking for algorithmic compliance during the HEDIS® audit. The summary data are sent to NCQA and the patient-level data are sent only through the designated CMS secure data submission system to the CMS contractor.

1. Summary Data

- a. Required Measures - MAOs that held Medicare contracts in the measurement year and meet the criteria in section 90.2 of this chapter must report summary data for all required HEDIS® measures except for the HOS measure, which is not a DST item. 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. 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 annually post Healthcare Organization Questionnaires (HOQ) on the NCQA Web site in late February. MAOs must accurately complete the HOQ in order to have an appropriate HEDIS® DST posted on the NCQA web site each April. 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. 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.
 - 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.
 - b. Data Submission – Patient-level HEDIS® data are submitted via the CMS Enterprise FTP client system that contract use to submit other beneficiary specific information to CMS. Contracts use their existing system that connects to the designated CMS secure data transmission system to upload patient-level data files. The CMS contractor accesses the patient-level data through the same secure system to perform data validations. Contracts must retain the data used for reporting for six years. As specified in 42 CFR §422.504 and §423.505, all MA contracts are required to maintain the privacy and security of protected health information and other personally identifiable information of Medicare enrollees. There have been questions expressed about the provision of behavioral health measures in the patient-level data files. Contracts are accountable for providing patient-level data, unless prohibited by State laws. In such cases, contracts must notify CMS with appropriate documentation of the legal prohibition for consideration.

90.3.2 HEDIS® Compliance Audit Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Because of the critical importance of ensuring accurate data, CMS continues to require an external audit of the HEDIS® measures before public reporting. MAOs and §1876 cost contracts are responsible for submitting audited data, according to the “Full Audit” methodology outlined in Volume Five: HEDIS® Compliance Audit: Standards, Policies and Procedures.

CMS requires each MAO and §1876 cost contract to contract with an NCQA licensed organization for an NCQA HEDIS® Compliance Audit. The licensed audit firms are listed on NCQA’s Web site at <http://www.ncqa.org/>. CMS requires that the licensed organizations follow the established standards, policies and procedures in NCQA’s HEDIS®, Volume Five. All contracts 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.

90.3.3 Final Audit Reports, Use and Release

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

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 requirements 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.

90.4 Medicare HOS Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

90.4.1 HOS Survey Process Requirements

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

HOS reporting requirements specify that MAOs with Medicare contracts in effect on or before January 1 of the preceding year report the Baseline HOS, provided they have a minimum enrollment of 500 members. In addition, all continuing MAOs that participated in the Baseline survey two years prior are required to administer a Follow-Up survey.

The following organizations with plan contracts in effect on or before January 1 of the previous year are included in the HOS:

- All coordinated care contracts;
- Section 1876 cost contracts with open enrollment;
- PFFS and MSA contracts.

The Veterans RAND 12-Item Health Survey (VR-12), supplemented with additional case-mix adjustment variables and four HEDIS® Effectiveness of Care measures, will be used to solicit self-reported information from a sample of Medicare beneficiaries for the

HEDIS® functional status measure, HOS. This measure is the first "outcomes" measure for the Medicare managed care population. Because it measures outcomes rather than the process of care, the results are 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 1,200 beneficiaries per reporting unit (i.e., contract) will be surveyed. If the contract-market has fewer than 1,200 eligible members, all will be surveyed.

Additionally, each year a cohort measured two years previously at baseline 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. Beneficiary level results are aggregated to derive the MAO, state, and HOS national percent better, same, and worse than expected values.

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 January of each reporting year to ensure survey implementation by early-April of the reporting year. Further details will be provided by NCQA regarding administration of the survey the preceding fall.

90.4.2 HOS-Modified

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The HOS-Modified (HOS-M) is a shorter, modified version of the Medicare HOS and contains 6 ADL items as the core items used to calculate an annual frailty adjustment factor for PACE organizations. The survey also includes 12 physical and mental health status questions from the VR-12. The HOS-M survey is cross-sectional, measuring the physical and mental health functioning of beneficiaries at a single point in time.

HOS-M reporting requirements specify that all PACE organizations with a Medicare contract in effect on or before January 1st of the previous year and a minimum enrollment of 30 report the HOS-M for current year reporting.

Similar to the HOS, the HOS-M design is based on a randomly selected sample of individuals from each participating PACE Organization. For plans with at least 1,400 enrollees, 1,200 members are randomly selected for HOS-M. All eligible members are included in the sample for plans with populations of less than 1,400.

The survey protocols for the HOS and HOS-M data collection efforts are similar. The HOS and HOS-M technical specifications are updated annually by NCQA and published each February in HEDIS® Volume 6: Specifications for the Medicare Health Outcomes Survey. Additional information is available from NCQA's web site at <http://www.ncqa.org> under HEDIS® and Quality Measurement.

90.4.3 HOS Data Feedback

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

Individual member level data will not be provided to plans after baseline data collection. However, organizations will receive the following from CMS:

1. HOS Baseline Profile Report - This profile will be made available 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 each MAO's Medicare enrollees, was developed and extensively tested to ensure that MAOs would find the data useful and actionable. Each MAO's QIO will also receive electronic copies of the baseline profiles and is available to collaborate with MAOs on interpreting the data, identifying opportunities to improve care, assisting with planning effective, measurable interventions, and evaluating and monitoring the results of your interventions. Using data from the HOS to plan and conduct a quality improvement project may fulfill one of the QI program requirements. All report distribution occurs electronically through HPMS. MAOs are also alerted of all HOS report and data availability through HPMS.
2. 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.
3. HOS-M Summary Reports - After each yearly administration of the Medicare HOS-M, a plan specific report is produced and is available for each organization participating in the survey. The HOS-M report focuses on PACE plans serving frail and elderly beneficiaries, and provides a summary of demographic information, physical and mental health status, and selected health status measures. The corresponding beneficiary level data for a report are also made available to participating PACE plans.

All distribution of HOS-M reports occurs electronically to participating PACE organizations through HPMS. Plans are also alerted of report and data availability through HPMS.

4. Survey 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.

MAOs should not ask their survey 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 each MAO's State QIO.

90.5 Medicare CAHPS® Requirements

42 CFR §§417.106(a)(3), 417.418, 422.152.(b)(3)

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

90.5.1 Information Regarding the CAHPS® Satisfaction Survey

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

The following organizations types of MAOs are included in the CAHPS® survey administration provided that they have a minimum enrollment of 600 eligible members as of July 1st of the previous year.

- All MA organizations, including all coordinated care contracts, PPOs, PFFS, and MSA contracts.
- §1876 cost contracts even if they are closed for enrollments.
- Employer/union only contracts.

The Programs of All Inclusive care for the Elderly (PACE), and HCPP-1833 cost contracts, are excluded from the CAHPS administration.

Medicare Advantage organizations, and §1876 cost contracts, are required to contract with an approved MA & PDP CAHPS vendor for the survey administration. A list approved survey vendors is available on www.MA-PDPCAHPs.org. All approved survey vendors are trained by the CMS CAHPS® Survey Coordination team.

CMS issues HPMS memorandums about the CAHPS® survey each year.

If an approved CAHPS® vendor does not submit a contract's CAHPS® data by the data submission deadline, the contract will automatically receive a rating of one star for the required CAHPS® measures for the data that are updated on Medicare Plan Finder (in the fall) which also impacts the MA quality bonus payments.

For additional information on the CAHPS® survey, please email mp-cahps@cms.hhs.gov.

90.6 MAOs with Special Circumstances

(Rev. 100, Issued: 08-05-11, Effective: 08-05-11, Implementation: 08-05-11)

As provided under 42 CFR §§422.152 and 422.516, MAOs must submit performance measures as specified by CMS. These performance measures include the CAHPS® survey measures.

CMS also requires demonstration projects to meet the CAHPS®, and HEDIS® reporting requirements, in accordance with applicable laws, 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 chapter. For further information on the requirements for specific demonstrations, contact the CMS project officer.