Medicare Managed Care Manual
Chapter 5 - Quality Improvement Program

Contents

10 Introduction

In early 2010, the Centers for Medicare & Medicaid Services (CMS) developed a Quality Improvement Strategy for the Medicare Advantage (MA) and Prescription Drug Plan (PDP) Programs based on the 2001 Institute of Medicine (IOM) report. That strategy was expanded in 2011 to reflect the Department of Health and Human Services' (HHS) National Strategy for Quality Improvement in Health Care.

Based on the HHS strategy and the Affordable Care Act, HHS developed the National Quality Strategy (NQS) and the National Prevention Strategy (NPS) and CMS developed and released in June, 2012 its MA and PDP Quality Strategy, entitled "Medicare Advantage and Prescription Drug Plan Quality Strategy: A Framework for Improving Care for Beneficiaries." CMS' MA and PDP Quality Strategy was the culmination of a coordinated staff effort and leadership across CMS.

The MA and PDP Quality Strategy is expected to serve as a framework to advance CMS' continuous quality improvement efforts, establish a culture of improving quality of care and services in the MA and PDP programs and improve the quality of care for Medicare beneficiaries enrolled in those programs.

The MA and PDP Quality Strategy include a vision, mission, five core values, and six goals as outlined below. The vision is to ensure that Medicare beneficiaries enrolled in MAOs receive efficient, high quality care and services every time. The mission is to lead and develop the infrastructure, tools, and performance measures for MAOs to provide integrated coordinated care and the best services for every beneficiary across all plan types. The five core values are Robust, Consumer Friendly, Comparable, Comprehensive, and Transparent. These core values provide the necessary foundation in support of the MA and PDP Quality Strategy. Specific MA and PDP Quality Strategy goals are as follows:

1. *Build Solid and Dedicated Medicare Leadership and Infrastructure;*
2. *Foster Communications and Partnerships Across All Levels of Government;*
3. *Lead the Health Care Industry in Providing Cutting Edge, Integrated Coordinated Care;*
4. *Monitor and Assess the Quality of Health Care Services;*
5. *Provide Incentives for Improving and/or Excelling on Quality Assessments; and,*
6. *Improve Beneficiaries' Ability to Use Quality Measures to Evaluate and Compare Health Plans and Services*

The MA and PDP Quality Strategy's vision, mission, core values, and goals collectively drive the quality of healthcare and ongoing quality improvement initiatives for all plans.

All Medicare Advantage Organizations (MAOs) are required, as a condition of their contract with CMS, to develop a Quality Improvement program that is based on care coordination for enrollees. The MA and PDP Quality Strategy support that requirement by providing a framework for MAOs and PDPs as they work to improve care and patient health outcomes. The foundation of the MA and PDP Quality Strategy and the Quality

Improvement program is improving care coordination and encouraging provision of health care using evidence-based clinical protocols.

The complete MA and PDP Quality Strategy report, as well as other pertinent MA quality-related documents, are available on the CMS MA Quality Website located at: http://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/Overview.html.

20 Medicare Quality Improvement Program

MAOs that offer one or more MA plans must have an ongoing Quality Improvement (QI) program for each of their plans. The purpose of a QI program is to ensure that MAOs have the necessary infrastructure to coordinate care, promote quality, performance, and efficiency on an ongoing basis. The requirements for the QI program are based in regulation at 42 CFR§ 422.152. For each plan, an MAO must:

1. *Develop and implement a chronic care improvement program (CCIP) 42 CFR §422.152(c);*

2. *Develop and implement a quality improvement project (QIP) 42 CFR §422.152(d);*

3. *Develop and maintain a health information system (42 CFR §422.152(f)(1));*
4. *Encourage providers to participate in CMS and HHS QI initiatives (42 CFR §422.152(a)(3));*

5. *Implement a program review process for formal evaluation of the impact and effectiveness of the QI Program at least annually (42 CFR §422.152(f)(2));*

6. *Correct all problems that come to its attention through internal surveillance, complaints or other mechanisms (42 CFR §422.152(f)(3));*

7. *Contract with an approved Medicare Consumer Assessment of Health Providers and Systems (CAHPS®) vendor to conduct the Medicare CAHPS® satisfaction survey of Medicare enrollees (42 CFR §422.152(b)(5)); and,*

8. *Measure performance under the plan using standard measures required by CMS and report its performance to CMS (42 CFR §422.152(e)(i)).*

All MAOs, as part of their application to offer new MA products or expand the service area of an existing product, must submit a written Quality Improvement Program Plan (QIPP). The QIPP outlines the elements of an MAO's QI Program and provides a framework for how a plan will execute each of the QI program requirements stipulated above.

20.1 Chronic Care Improvement Program (CCIP) and Quality Improvement Projects (QIP)

42 CFR §422.152(c) – (d)

As required by regulation, each MAO must develop and implement a CCIP and QIP as part of its required QI Program. MAOs must conduct the same CCIP and QIP for all their non-SNP coordinated care plans offered under a specified contract, including employer group plans and Medical Savings Account plans (MSA) and Private Fee for Service (PFFS) plans that have contracted networks. MAOs must implement a unique CCIP and QIP for each SNP plan offered, including when an MAO offers multiple SNPs of the same type under a contract. Only PFFS plans that do not have contracted networks, section 1833 and 1876 cost plans, and Program of All-Inclusive Care for the Elderly (PACE) plans are exempted from the CCIP and QIP requirements.

The quality improvement model adopted by CMS for the CCIP/QIPs is based on The Plan-Do-Study-Act (PDSA) quality improvement model. PDSA is an iterative, problem-solving model used for improving a process or carrying out change. The four steps of the PDSA cycle provide a systematic, step-by-step, ongoing approach for quality improvement initiatives. Components of the PDSA are as follows:

- *Plan: Describes the processes, specifications, and output objectives used to establish the CCIP/QIP;*
- *Do: Describes the progress of the implementation and the data collection plan;*
- *Study: Describes the analysis of data to determine what impact the program has had on members.*
- *Act: Summarizes action plan(s) based on findings; describes, in particular, the differences between actual and anticipated results, and describes specific actions or steps taken or planned based on current results.*

The MAO's first step in implementing a QIP or CCIP is submitting a complete, stand-alone "Plan" section of the PDSA model for approval by CMS. Once that Plan is approved and implemented, MAOs are required to submit Annual Updates that are comprised of the Do, Study, and Act components of the PDSA model to report on the ongoing operations of that approved Plan.

The Plans and Annual Updates for both CCIPs and QIPs are submitted to CMS through the "Quality and Performance" module of the Health Plan Management System (HPMS). CMS's expectations regarding the information that is to be included in the Plan and Annual Update submittals are discussed in greater detail below.

MAOs have access to detailed information about the submission requirements for the CCIP and QIP Plan and Annual Updates can be found in the CCIP and QIP User Guides available within the HPMS Quality and Performance module.

20.1.1 Chronic Care Improvement Program (CCIP)

A CCIP is a clinically focused initiative designed to improve the health of a specific group of enrollees with chronic conditions. Beginning CY 2012, CMS required that each MA plan conduct, over a 5 year period, a CCIP focused on reducing and/or preventing cardiovascular disease.

CCIP Plan Section Description

The CCIP Plan section describes all aspects of the proposed CCIP initiative, including, but not limited to: the opportunity for improvement, target goal, what specific interventions will be introduced to achieve the identified goal, members targeted for receipt of the intervention(s), and the expected results. Below is a general summary of the required components of the CCIP Plan.

- *Basis for Selection - An overall description of the QIP and rationale for selection that includes impact on the member, anticipated outcomes, and rationale for selection.*
- *Program Design - Outlines the process used to identify the target population, risk stratification, and enrollment method.*
- *Evidence-Based Medicine - Includes the clinical practice guidelines and standards of care to be employed.*
- *Care Coordination Approach - Describes the expected collaboration and communication among a multidisciplinary team that may include providers, MAO staff and the targeted member.*
- *Education - The method of education and the topics that will be addressed. Includes education directed to applicable providers and/or targeted members.*
- *Outcome Measures and Interventions - Setting objectives in measurable terms; identifying the appropriate data source(s) to measure; and the methodology used to analyze the data to determine whether the initiative impacted the health status of the targeted population.*
- *Communication Sources - Methods used to inform patients, physicians, and other providers on what is occurring in the CCIP and any changes necessary over time.*

MAOs with contracts that were operational in CY 2012 were required to submit the Plan Section of the CCIP for the first time through HPMS in 2012. In subsequent years, newly operating MAO contracts and SNPs must submit the Plan section of the PDSA during the CMS-determined submission window in the fall of their first year of operation; the first Annual Update for those plans will be submitted the following year.

CCIP Annual Update Section

The CCIP Annual Update is due during the CMS-determined submission window in the fall of the first year of implementation following approval of the CCIP Plan Section and annually thereafter, until program completion. The Annual Update should include the results or findings to date, based on the intervention(s); any barriers encountered during the update period; risk mitigation activities implemented to address barriers

encountered; impact on the established goal or benchmark; and, next steps for the project. Below is a general summary of the components of the CCIP Annual Update.

- *Educational components - Includes the actual method(s) of education and the topics that were covered. The education may be patient and/or provider focused.*
- *Intervention(s) - Specific actions/approaches implemented to achieve the stated goal.*
- *A description of barriers encountered, if applicable, and the specific actions taken to mitigate those barriers.*
- *Discussion of findings and analysis of the initial results in relation to the target goal, benchmark, timeframe, results.*
- *Identification of next steps based on internal evaluation and ongoing assessment of the CCIP, whether or not the goals were met, and any revisions to the intervention(s), methodology, goal, or other aspects of the initiative.*
- *Best Practices - Any identified approaches that are proven to be reliable and appear to contribute to the success of the CCIP.*
- *Lessons Learned - Description of pertinent knowledge gained through the CCIP experience.*

20.1.2 Quality Improvement Project (QIP)

QIPs are initiatives focused on one or more clinical and/or non-clinical areas with the aim of improving health outcomes and beneficiary satisfaction. Beginning CY 2012, each MAO is required to conduct, over a 3 year period, a QIP focused on reducing 30-day all cause hospital readmission rates.

QIP Plan Section Description

The QIP Plan section describes all aspects of the proposed CCIP initiative, including, but not limited to: the opportunity for improvement, target goal, what specific interventions will be introduced to achieve the identified goal, members targeted for receipt of the intervention(s), and the expected results. Below is a general summary of the required components of the CCIP Plan.

- *Basis for Selection – An overall description of the QIP and rationale for selection that includes impact on the member, anticipated outcomes, and rationale for selection. (Note: The QIP Plan Section specific to a SNP may include, if applicable, any Model of Care elements which form the basis for the QIP, e.g., the Individualized Care Plan, the Interdisciplinary Care Team, etc.)*
- *Program Design – An outline of the process used to identify the target population, risk stratification, and enrollment method.*
- *Prior Focus – A description of any previous attempts to address the problem that the QIP will be addressing. This includes intervention-specific information about the previous attempt(s), including any outcomes achieved.*
- *Examination of any anticipated barriers and the potential impact on the success of the QIP.*

- *Outcome Measures and Interventions - Setting objectives in measurable terms; identifying the appropriate data source(s) to measure; and the methodology used to analyze the data to determine whether/how the initiative affected the health status of the targeted population.*

QIP Annual Update Section Description

The QIP Annual Update is due during the CMS-determined submission window in the fall of the first year of implementation following approval of the QIP Plan Section, and annually thereafter, until project completion. The Annual Update should include the results or findings to date, based on the intervention(s); any barriers encountered during the update period; risk mitigation activities implemented to address barriers encountered; the impact on the established goal or benchmark, and next steps for the project. Below is a general summary of the components of the QIP Annual Update.

- *Intervention(s) - Specific actions/approaches implemented to achieve the stated goal.*
- *A description of Barriers encountered, if applicable, and the specific actions taken to mitigate those barriers.*
- *Discussion of Findings and analysis of the initial results in relation to the target goal, benchmark, timeframe, sample size, numerator, denominator, and other data results.*
- *Identification of Next Steps based on internal evaluation and ongoing assessment of the QIP, whether or not the goals were met, and any revisions to the intervention(s), methodology, goal, or other aspects of the initiative.*
- *Best Practices - Any identified approaches that are proven to be reliable and appear to contribute to the success of the QIP.*
- *Lessons Learned - Description of pertinent knowledge gained through the QIP experience.*

20.2 Additional Quality Improvement Program Requirements for Special Needs Plans (SNPs)

20.2.1 Model of Care (MOC)

(Please note that the SNP MOC element guidelines and scoring criteria will be moved from their current location in Chapter 16b of the Medicare Managed Care Manual, "Special Needs Plans," to this chapter. We believe that this information appropriately resides in this chapter, as it reflects the fundamental purpose of the MOC as an essential quality improvement tool for SNPs. We have proposed revisions to the existing MOC elements as part of the information collection request titled, "Part C -Medicare Advantage and 1876 Cost Plan Expansion Application" published in the Federal Register on June 28, 2013 (OMB Control No. 0938-0935).

New MOC guidance, along with the modified scoring criteria, will be incorporated into this chapter as soon as the revised MOC elements are finalized.

20.2.2 Structure & Process (S&P) Measures

In 2007, CMS contracted with the National Committee for Quality Assurance (NCQA) to develop a strategy to evaluate the quality of care provided by SNPs. That strategy resulted in development of a tool to collect information that is meant to provide CMS with a better understanding of how SNPs perform on a set of standardized national performance measures that assess internal SNP processes and operations that affect the enrolled Medicare beneficiaries' quality of care (see Section 30.1 of this chapter for information regarding SNP-specific HEDIS measures). S&P measures address the SNP structures, systems and processes in place to address quality of care in the following 6 areas:

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.

The S&P measures rely on a review of plan policies and procedures, data reports, prepared materials and other documentation the plans use to implement their programs, analyze internal data, document processes and convey information to members and practitioners.

NCQA collects S&P measure data from SNPs annually and provides an overview of performance results in a report submitted to CMS. For additional information regarding S&P measures, please see the NCQA website at: http://www.ncqa.org/Programs/OtherPrograms/SpecialNeedsPlans.aspx.

30 Standard Reporting Requirements for MAOs for HEDIS®, HOS, and CAHPS®

42 CFR §417.106(a)(3)
42 CFR §417.418
42 CFR §422.152(b)(5)
42 CFR §422.152(e)(i)
42 CFR §422.516

General

This section provides information regarding the annual Medicare HEDIS®, HOS, and CAHPS® reporting requirements. *Performance measures that are derived largely from MA plan*

and beneficiary information from these data form the basis of the CMS Star Ratings used to assess the quality of MA plans. (Additional information regarding the Star Ratings may be found at[*http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html*](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html)*.* In addition, CMS makes summary, contract-level performance measures available to the public through media that are beneficiary-oriented including the Medicare Plan Finder tool at http://www.medicare.gov.

30.1 HEDIS® Reporting Requirements

HEDIS® is a trademark product of NCQA. All Medicare Advantage plans must submit audited summary-level HEDIS® data to NCQA. 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 patient-level 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 van 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 of 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.

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.

11. *Demonstration Projects – Specific waivers contained in demonstration contracts supersede any requirements specified in this chapter.*

If the Health Plan Management System (HPMS) contract status is listed as a consolidation, a merger, or a novation during the measurement year, the surviving contract must report HEDIS® data for all members of all contracts involved. If a contract status is listed as a conversion in the measurement year, the contract must report if the new organization type is required to report.

In August of each year, CMS issues a HPMS memorandum that provides guidance for the

upcoming reporting year. The HPMS memorandum, entitled "Updated Requirements for Reporting of (reporting year) HEDIS®, HOS, and CAHPS® Measures." All contracts that are required to report HEDIS® are identified by specific organization type. There is no minimum enrollment requirement for submitting MA HEDIS®. The HPMS Memo provides information about required HEDIS® measures for reporting, changes in the data specifications, data submission schedule and deadlines, and instructions about data submission. All MA contracts shall 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 Health Plans" for each reporting year. *The Manual has instructions on data collection for each measure and general guidelines for calculations and sampling.*

Medicare Advantage 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.

Reporting HEDIS® for Medicare

All members covered under the contracts listed below are included in Medicare HEDIS® reporting. CMS communicates directly with all contracted organizations and benefit plans on HEDIS® reporting requirements (e.g., plan type, enrollment criteria). HEDIS® reporting is required for:

- *Medicare Advantage (MA contracts);*
- *Section 1876 cost contracts with active enrollment;*
- *Medical Savings Account (MSA) contracts;*
- *Private Fee-for-Service (PFFS) contracts;*
- *Employer/Union Only Direct Contract PFFS contracts;*
- *Special Need Plans (SNPs);*
- *SNPS are required to submit a subset of HEDIS® measures and some SNP-specific measures such as Care of Older Adult measures that are outlined in our annual HPMS memorandum regarding reporting requirements; and*
- *Certain demonstration projects.*

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.

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 the previous section of this chapter must report summary data for all required HEDIS® measures except for the HOS measure, which is not a *Data Submission Tool* (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.

30.1.1 HEDIS® Compliance Audit Requirements

Because of the critical importance of ensuring accurate data, CMS continues to require an external audit of the HEDIS® measures before public reporting. MAOs 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.

30.1.2 Final Audit Reports, Use and Release

Following the receipt by the MAO of the Final Audit Report from the NCQA-licensed audit firm, the MAO must make available a copy of the complete final report to the CMS ROs as needed. CMS ROs may request the report upon completion or as part of the pre-site monitoring visit package. In addition, the reports should be available for review onsite during monitoring visits. CMS will use the Final Audit Reports to support contract monitoring and quality improvement activities. CMS may use the assessment of the MAO's administrative and information systems capabilities that are contained in the audit report and may use the data to conduct post-submission validation. Final Audit Reports are subject to the Freedom of Information Act (FOIA). CMS will follow the FOIA 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.

30.2 Medicare HOS Requirements

30.2.1 HOS Survey Process Requirements

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 as of February 1 of the current year. In addition, all continuing MAOs that participated in the Baseline survey two years prior are required to administer a Follow- survey regardless of whether they meet the current year's enrollment threshold.

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, including health maintenance organizations (HMOs), local and regional PPOs and contracts with exclusively SNP plan benefit packages;
- Section 1876 cost contracts with open enrollment;
- PFFS and MSA contracts;
- Employer/union only direct PFFS contracts.

Additionally, MAOs sponsoring fully integrated dual eligible (FIDE) SNPs may elect to report HOS-M (section 30.2.2 below) at the FIDE SNP level to determine eligibility for a frailty adjustment payment under the Affordable Care Act, similar to those payments provided to PACE programs. Voluntary reporting will be in addition to the standard HOS requirements for quality reporting at the contract level. *For additional information regarding FIDE SNPs, please see Chapter 16b of the Medicare Managed Care Manual.*

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 and1, 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 the 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 wellbeing 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.

30.2.2 HOS-Modified

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.

30.2.3 HOS Data Feedback

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.

30.3 Medicare CAHPS® Requirements

30.3.1 Information Regarding the CAHPS® Survey

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 of 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.

40 – Medicare Advantage (MA) Deeming Program *Overview*

42 CFR §422.156, 422.157, 422.158

Under section 1852(e)(4) of the Act, CMS established and oversees a program which allows private, national accrediting organizations (AOs) to *deem compliance with certain Medicare requirements. The AOs may only grant deemed status for MAOs that it has fully accredited (and periodically re-accredited).*

Accreditation is an evaluative process (usually involving both on and off site surveys) in which a health care organization chooses to undergo an examination of its policies, procedures and performance by an external organization ("accrediting body"). . In addition to the standard accreditation process, an MAO may pay an additional

fee to have the AO conduct various reviews that allow the AO to "deem" that the MAO is compliant with certain Medicare requirements.

To deem an MAO, the AO must use standards (and the process for monitoring compliance) that CMS determines are no less stringent than the applicable Medicare requirements.

Additionally, the AO is responsible for enforcing compliance on the accredited MAO when deficiencies are found in those areas to which the deemed status applies. AOs who obtain deeming authority are responsible for ensuring that MAOs meet the deeming requirements established by CMS.

Organizations that seek the authority to deem must meet CMS's definition of a private, national AO, by demonstrating the following:

1. *It is recognized as an accrediting body by the managed care industry and relevant national associations;*

2. *It has accredited and/or re-accredited MAOs in multiple states;*

3. *It contracts with or employs staff who are appropriately trained and have experience with monitoring managed care plans for compliance with the AOs specific accrediting standards; and*

4. *It contracts with or employs sufficient staff to provide accreditation services nationwide.*

40.1 - Deeming Requirements

42 CFR §422.156 (a), (b), *and (c); §423.165(b) (1), (2) and (3)*

As provided under section 1852(e)(4) of the Act, MAOs may seek deeming for certain 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;

Additionally, under 1860D-4(j) of the Act, Part D plan sponsors may seek deeming for certain Medicare requirements in the following areas:

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.[1]

The 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 *deemed* by the AO.

40.2 - Deemed MAOs

40.2.1 – Deeming Process

42 CFR §422.156 (d)

MAOs receive benefits by choosing to seek deemed status. For example, being accredited and deemed increase a MAOs marketability. Also, MAOs that seek deemed status via accreditation by a CMS-approved AO can include the cost of accreditation as an administrative cost in the construction of its 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.

1. *If an MAO decides to pursue deeming, the AO conducts its review of the MAO.*
   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.

[1] *Please note that items 7-9 have not yet been implemented into the deeming program.*

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).

2. The AO notifies CMS that the MAO has been approved for deemed status. The AO will provide the date of the deemed status accreditation, the MAO's contract number, and any additional information that CMS may require.

3. CMS enters the deemed status into HPMS.

40.2.2 - Deemed Status and Surveys

42 CFR §422.156(d) (1), *(2)*

As noted in section 40.1 of this chapter, to be granted deemed status, an MAO must be 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 are accredited by CMS-approved AOs are still subject to CMS surveys. As noted, an approved accrediting organization may only deem an MAO for one or more of the nine areas described in section 40.1 of this chapter. *If the AO only has deeming authority in one of the nine deemable areas, such as access to services, then CMS may conduct a survey to assess the other 8 areas, as well as non-deemable requirements* such as grievances and appeals, beneficiary disclosure, marketing, enrollment, and organization determinations. CMS always retains the authority to investigate complaints about an MAO.

40.2.3 - Removal of an MAO's Deemed Status

42 CFR §422.156(e)

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

1. CMS determines, based on its own *evaluation*, 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 *40.2.2* of this chapter.

CMS will not overrule an AO's decision without doing its own investigation. However, if CMS' *evaluation* 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.

Additionally, if CMS withdraws its approval of deeming authority from an AO, all MAOs with deemed status *provided by that AO*, 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 resumes responsibility for ensuring that the organization meets *Medicare program requirements*.

40.3 - CMS' Role in Deeming

42 CFR §422.157(a)(d)

CMS has many different roles in the deeming program. For example, CMS approves the applications of the organizations that are applying for the authority to deem. CMS may approve the organization for deeming authority if it demonstrates that its accreditation program is at least as stringent as CMS' and it meets the application requirements described in section 40.4.1 of this chapter. CMS must approve an AO by deeming area, rather than by individual requirement. However, an AO must have a comparable standard for every one of the MAO requirements within a deeming area.

As mentioned above, CMS conducts validation surveys and other audits to ensure compliance with Medicare program requirements. CMS also conducts monitoring of non-deemable requirements. If, during the course of monitoring for non-deemable requirements, CMS staff determines that an MAO is not in compliance with a *requirement for which it has been deemed, it will notify the* AO *of the failure; to ensure the AO* initiates a corrective action process, when and if appropriate. *CMS* will not issue the corrective action requirement for deficiencies found in deemed areas.

40.3.1 - Oversight of AOs

42 CFR §422.157(d)

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 *CMS* staff detects a pattern of complaints in deemed areas, they contact the appropriate AO.

40.3.2 - Enforcement Authority

42 CFR §422.156(f)

CMS retains the authority to initiate enforcement actions against any MAO that it determines, on the basis of its own evaluation, no longer meets the Medicare requirements for which deemed status was granted. *Enforcement actions may include the imposition of intermediate sanctions and civil money penalties (42 CFR §422 Subpart O) or the termination or non-renewal of the MAOs contract (42 CFR §422 Subpart K).*

40.3.3 - Withdrawal of Approval

42 CFR §422.157(d)(4)

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 *40* and 40.4 of this chapter.

40.4 - Obligations of AOs with Deeming Authority

42 CFR §422.157

AOs must apply and enforce the standards that CMS determines, as a condition of approval, are at least as stringent as the applicable Medicare requirements. To be approved, an AO must comply with the application and reapplication procedures that are addressed in section 40.4.1 of this chapter.

To prevent conflicts of interest, AOs must ensure the following:

- *When the AO deems an MAO, any individual associated with the AO who is also associated with the MAO*, does not influence the deeming decision concerning that MAO;

- That the majority of the membership of the AOs governing body is not comprised of managed care organizations or their representatives;

- *The AOs* governing body *acts without bias* and has a broad and balanced representation of interests.

To avoid actual conflicts of interests (or the appearance of conflicts of interests), CMS encourages any personnel involved in a conflict to recuse themselves from the deeming process for the MAO in conflict.

Additionally, if CMS takes an adverse action based on accreditation findings, the approved AO must permit its surveyors to serve as witnesses.

40.4.1 - Reporting Requirements

42 CFR §422.157(c)

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 accreditation 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.

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.

40.4.2 - Application Requirements

42 CFR §422.158

A private, national AO may seek deeming authority for any or all of the 9 categories listed in section 40.1 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 *40* 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.

40.4.3 - Application Notices

42 CFR §422.158(e)

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.

Within 210 days of receipt of its completed application, *CMS must provide the AO with* a formal notice that:

1. *Approves or denies the request*;
2. Provides a *detailed* rationale *in the case* of a denial; and
3. Describes the reconsideration and reapplication procedures.

For information regarding reconsideration of adverse determinations refer to section *40.4* of this chapter.

40.4.4 - Withdrawing an Application

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

40.5 - Reconsideration of a Decision to Deny, Remove or Not Renew Deeming Authority

42 CFR §422.158

An AO that has received a notice of denial of its request for deeming authority (or specific deeming categories) may request reconsideration in accordance with the Subpart D of part 488. CMS will reconsider any determination to deny, remove, or not 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 the 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.

40.5.1 - Informal Hearing Procedures

42 CFR §488.158(g), §§488.201-488.211

CMS will provide written notice of the time and place of the informal hearing at least10 calendar days before the scheduled date. The hearing will be conducted in accordance with the following procedures:

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

    - *Authorized representatives;*
    - *Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and*
    - *Legal counsel;*

2. *The hearing 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.*

40.5.2 - Informal Hearing Findings

42 CFR §488.209

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.

40.5.3 - Final Reconsideration Determinations

The hearing officer's decision is final unless the CMS Administrator, within 30 days of the hearing officer's decision, chooses to review that decision. The CMS Administrator may accept, reject, or modify the hearing officer's findings. Should the CMS Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the 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.

50 Definitions

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

Accreditation

An evaluative process (usually involving both on and off site surveys) in which a health care organization chooses to undergo an examination of its policies, procedures and performance by an external organization ("accrediting body").

Accreditation Cycle for Medicare Advantage (MA) Deeming

The duration of CMS's recognition of the validity of an accrediting organization's determination that a MAO is "fully accredited."

Accrediting Organization (AO)

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

Annual Update
The Annual Update is comprised of the information required in the components of the Do, Study, and Act sections of the Plan-Do-Study-Act quality improvement model specific to the CCIP and QIP initiatives.

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

Chronic Care Improvement Program (CCIP)
An initiative with a clinical focus that includes interventions designed to improve the health of individuals who live with multiple or sufficiently severe chronic conditions, and includes 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 one or more CMS requirements. The CAP may result from an audit or result from other ad-hoc compliance events unrelated to an audit.

Deemed Status

A designation granted to an MAO which concludes that the MAO has been reviewed by an AO for those standards within the categories that the AO has the authority to deem on behalf of CMS.

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 certain Medicare requirements.

Equivalency Review

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

Fully Accredited

Fully accredited is a designation that all the elements within the accreditation standards 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 in QIPs and CCIPs.

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.

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.

Quality
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 Organization (QIO)
Formerly known as Peer Review Organization, this is an entity that CMS contracts with 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 initiative that focuses on specified clinical and/or non-clinical areas.

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