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Pub. 100-16 Medicare Managed Care

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

Transmittal 79 Date: February 17, 2006

SUBJECT: Changes in MCM Chapter 11, Medicare Advantage Application Procedures and Contract Requirements

I. SUMMARY OF CHANGES: This revision makes the following changes:

The Title – is revised to read as Chapter 11, Medicare Advantage Application Procedures and Contract Requirements;

Section 20.1. – Added section on "Application Procedures and Conditions for Entering an MA Contract;"

Section 20.2 – Added section on "Evaluation and Determination of Applications,"

Section 20.3 – Added information related to the fraud, waste, and abuse provisions that MA-PDs must follow;

Section 60 –Added information on other operational guidance affecting the contract renewal process;

Section 70.1 – Updated the contract renewal section to reflect new timelines;

Section 70.2 – Specified the kinds of records subject to financial audits; updated §70.2.5 to reflect new quality improvement provisions;

Section 100.2 – Added section on payments to Federally Qualified Health Centers;

Section 110.4.3 – Updated the maintenance and access to MA-related records section by including the 10 year/current contract period and 10 prior contract period language;

Section 120 – Specified that MA organizations must comply with other laws and regulations designed to prevent fraud, waste, and abuse; specified that MA-PDs must follow the Part 423 requirements governing the Medicare prescription drug benefit for a comprehensive fraud, waste, and abuse program;

Section 150 – Removed employer/union plan sections. These are being developed into a stand alone chapter;

Appendix A – Replaced the previous risk adjustment data certification with a "Certification of Monthly Enrollment and Payment Data Relating to CMS Payment to an MA Organization;" and

General – Revised nomenclature and references throughout the Chapter to reflect new bidding and payment processes; quality improvement changes; Part D fraud, waste, and abuse requirements; and the reorganization/revision of several sections of the previous Medicare + Choice regulations.

NEW/REVISED MATERIAL/EFFECTIVE DATE: February 17, 2006

***Disclaimer for manual changes only*- - The revisions in this Chapter resulted in changes to every section. Therefore, this Chapter is being published without the usual red italic font to identify changed sections and text.**

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	11/01/Introduction
R	11/10/Definitions
R	11/20/General Medicare Advantage Application and Contract Provisions
R	11/20.1/Application Procedures and Conditions for Entering an MA Contract
R	11/20.2/Evaluation and Determination of Applications
R	11/20.3/Monitoring and Promoting Staff and Affiliated Provider Compliance with Policies
R	11/30/Minimum Enrollment Requirements for MA Organizations
R	11/30.1/Minimum Enrollment Waiver
R	11/40/Term and Effective Date of an MA Contract
R	11/50/Contracting Prohibitions under the Medicare Advantage (MA) Program
R	11/60/MA Contract Renewal
R	11/70/Contract Nonrenewal
R	11/70.1/Nonrenewal of MA Contract: MA Organization-Initiated
R	11/70.2/Responsibilities of Nonrenewing MA Organizations
R	11/70.3/Nonrenewal of MA Contract: CMS-Initiated
R	11/80/Contract Terminations
R	11/80.1/When CMS Terminates an MA Contract
R	11/80.2/Termination Process When CMS Initiates Contract Termination
R	11/80.3/Immediate MA Contract Termination by CMS

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	11/80.4/When an MA Organization Terminates an MA Contract
R	11/80.5/Termination Process When MA Organization Initiates Contract Termination
R	11/90/Modification or Termination of an MA Contract by Mutual Consent
R	11/100/MA Contract Provisions
R	11/100.1/Material Provisions of an MA Contract
R	11/100.2/Other Provisions of the MA Contract
R	11/100.3/Beneficiary Financial Protections
R	11/100.4/Provider and Supplier Contract Requirements
R	11/100.5/Administrative Contracting Requirements
R	11/100.6/Implementation of Written Policies With Respect to the Enrollee Rights
R	11/110/MA Organization Relationship with Related Entities, Contractors, Subcontractors, First-Tier and Downstream Entities
R	11/110.1/General Requirements
R	11/110.2/Delegation Requirements
R	11/110.3/MA Oversight and Beneficiary Protection Guidance
R	11/110.4/Policies and Procedures for Assessing Contracting Provider Groups' Administrative and Fiscal Capacity to Manage Financial Risk
R	11/110.4.1/Access to and Continuity of Care
R	11/110.4.2/Prevention of Member Billing
R	11/110.4.3/Maintenance of and Access to MA-Related Record Requirements
R	11/110.4.4/Disclosure Requirements
R	11/110.4.5/Additional MA Reporting Requirements
R	11/110.4.6/Reporting Requirements for Combined Financial Statements
R	11/110.4.7/Reporting and Disclosure Requirements under Employment Retirement Income Security Act of 1974 (ERISA)
R	11/120/Compliance with Other Laws and Regulations
R	11/130/Certification of Data That Determine Payment Requirements
R	11/140/Special Rules for Religious Fraternal Benefit (RFB) Societies
R	11/ Appendix A/Certification Of Monthly Enrollment and Payment Data

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
	Relating to CMS Payment to a Medicare Advantage Organization

III. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Special Notification

Medicare Managed Care Manual

Chapter 11 - Medicare Advantage Application Procedures and Contract Requirements

This Chapter Last Updated - (Rev. 79, 02-17-2006)

NOTE: This chapter addresses Medicare Advantage contract requirements only, and does not address Medicare cost-based managed care contract requirements. Information on Medicare cost-based contract requirements can be found in Chapter 17.

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01 - Introduction

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

These guidelines reflect CMS' current interpretation of the provisions of the Medicare Advantage statute and regulations (Chapter 42 of the Code of Federal Regulations, Part 422) pertaining to application procedures and contract requirements. These guidelines were developed after careful evaluation by CMS of industry practices and changes to the Medicare Advantage program enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Significant changes brought about by the MMA include a new bidding process, changes in contracting, and new health plan options. The guidance set forth in this document may be subject to change.

10 - Definitions

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The term **business transaction** means any of the following kinds of transactions:

1. Sale, exchange, or lease of property;

2. Loan of money or extension of credit; or
3. Goods, services, or facilities furnished for a monetary consideration, including management services, but not including:
    - Salaries paid to employees for services performed in the normal course of their employment; or
    - Health services furnished to the MA organization's enrollees by hospitals and other providers, and by MA organization staff, medical groups, or independent practice associations, or by any combination of those entities.

The term **clean claim** means a claim that has no defect, impropriety, lack of any required substantiating documentation - including the substantiating documentation needed to meet the requirements for encounter data - or particular circumstance requiring special treatment that prevents timely payment; and a claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

The term **downstream entity** means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA organization (and contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of health and/or administrative services.

The term **first tier entity** means any party that enters into a written arrangement with an MA organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

The term **party in interest** includes the following:

1. Any director, officer, partner, or employee responsible for management or administration of an MA organization;
2. Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization;
3. In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;
4. Any entity in which a person described in paragraph (1), (2), or (3) of this definition:
    - Is an officer, director, or partner; or
    - Has the kind of interest described in paragraphs (1), (2), or (3) of this definition;

5. Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization; or

6. Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

The term **related entity** means any entity that is related to the MA organization by common ownership or control and:

1. Performs some of the MA organization's management functions under contract or delegation;

2. Furnishes services to Medicare enrollees under an oral or written agreement; or

3. Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period;

The term **significant business transaction** means any business transaction or series of transactions of the kind specified in the above definition of "business transaction" that, during any fiscal year of the MA organization, have a total value that exceeds $25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

20 - General Medicare Advantage Application and Contract Provisions

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

CMS may enter into contracts with organizations without regard to provisions of law or regulations relating to the making, performance, amendment or modification of contracts of the United States that the Secretary of the Department of Health and Human Services (DHHS) determines to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, CMS may enter into contracts with MA organizations without regard to the Federal and Departmental acquisition regulations set forth in Title 48 of the CFR. The regulations governing MA contracts are set forth in the requirements for the MA program in Title 42 of the CFR.

Medicare Advantage Organizations may agree to operate coordinated care plans (as defined in 42 CFR 422.4(a)(1)) so long as they do so in compliance with the requirements of their contract and applicable Federal statutes, regulations, and policies.
For all MA organizations offering MA or MA-PD plans, the MA contract is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations or policies implementing or interpreting such statutory provisions. However, any regulations or policy statements issued by CMS after the date on which final bid proposals must be submitted for a calendar year, and which create significant new operational costs of which the MA organization did not have reasonable notice prior to such date, shall not become effective before the next contract year for which these requirements can be taken into account in making bid submissions, unless earlier implementation is required by statute or in connection with litigation challenging CMS policies.

20.1 - Application Procedures and Conditions for Entering an MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Organizations that seek to offer an MA or MA-PD plan must enter into a contract with CMS. A single MA contract may cover more than one MA plan offered by the contracting MA organization. An applicant entity, however, must meet certain requirements before CMS can consider entering into a contract with the organization. In addition, an applicant entity must have an acceptable bid before it may enter into a contract to offer an MA or MA-PD plan (see Subpart F of 42 CFR Part 422 for information on the bidding process). An application can be found at http://www.cms.hhs.gov/healthplans/applications/.

- The applicant must document that it is authorized under State law in the requested service area (SA) to operate as a risk bearing entity that may offer health benefits. If the applicant offers a continuation area in another State, then the applicant must show that it is authorized by the State to offer health benefits. As such, before an applicant entity may apply to become a Medicare Advantage organization, it must first submit a completed MA State Certification Form to CMS. This form, which is available on our Web site, must be provided by the MA organization to the State. The State, in turn, will certify that the organization is authorized to bear risk associated with the plan(s) it is offering in the State. The form may be acquired at. http://new.cms.hhs.gov/MedicareAdvantageApps/05_MAApplicationsandsupplementalmaterials.asp. Existing §1876 cost contractors do not have to complete this form. Please note that the revised coordinated care plan (CCP), regional preferred provider organization (PPO), private fee-for-service (PFFS), medical savings account (MSA), and service area expansion (SAE) applications include this form.

- Except in the case of a provider sponsored organization granted a waiver under 422.370 of Part 422 of the CFR the applicant entity must be licensed (or if the State does not license such entities, hold a certificate of authority/operation) as a risk-bearing entity in the State in which it wishes to operate as an MA organization.

- The applicant must meet certain minimum enrollment requirements. The applicant entity must have at least 5,000 (or 1,500 if it is a PSO) individuals receiving health benefits from the organization or at least 1,500 (or 500 if it is a PSO) individuals receiving benefits in a rural area. CMS has the authority to waive the minimum enrollment requirements for the first 3 contract years;

- An MA organization must demonstrate certain administrative and managerial capabilities. They include:

    - A policy making body that exercises oversight and control over the MA organizations policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees;

- Personnel and systems sufficient for the MA organization to organize, plan, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization (to include systems/capabilities to provide data and/or reports to CMS, in the manner and formats requested);

- At a minimum, an executive manager whose appointment and removal are under the control of the policy making body;

- A fidelity bond or bonds procured and maintained by the MA organization, in an amount fixed by its policy making body, but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. (The bond may have reasonable deductibles, based upon the financial strength of the MA organization.);

- Insurance policies or other arrangements, secured and maintained by the MA organization and approved by CMS to insure the MA organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

- A commitment to compliance, integrity, and ethical values as demonstrated by the following:

    - Written policies, procedures, and standards of conduct that articulate the organizations commitment to comply with all applicable Federal and State standards;

    - The designation of a compliance officer and compliance committee that are accountable to senior management;

    - Effective training and education between the compliance officer and organization employees;

    - Effective lines of communication between the compliance officer, the organization's employees, and MA-related contractors that at a minimum, includes a mechanism for employees or contractors to ask questions, seek clarification, and report potential or actual noncompliance without fear of retaliation;

    - Enforcement of standards through well-publicized disciplinary guidelines;

    - Provision for internal monitoring and auditing that includes a risk assessment process to identify and analyze risks associated with failure to comply with all applicable Medicare Advantage compliance standards; and

- Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's MA contract.

NOTE: MA organizations offering a prescription drug benefit under Part D must also follow the fraud, waste and abuse requirements at 42 CFR Part 423. Please see

§ 423.504(b)(4)(vi)(H) of 42 CFR Part 423 for a description of these requirements.

20.2 - Evaluation and Determination of Applications

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

In order to obtain a determination on whether it meets the requirements to become an MA organization and will be qualified to provide a particular type of MA plan, an entity or an individual authorized to act for the entity must complete a certified application in the form and manner required by CMS, including the following:

A. Documentation of appropriate State licensure or State certification that the entity is eligible, as a risk-bearing entity, to offer health insurance or health benefits coverage in the state or states in which it offers one or more plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or documentation of a Federal waiver; or

B. For regional plan, documentation of application for State licensure in any State in the region that the organization is not already licensed.

C. The authorized individual must describe thoroughly how the entity and MA plan meet, or will meet the requirements for meeting its obligations under 42 CFR Part 422.

NOTE: An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act (FOIA), or because of exceptions provided in 45 CFR Part 5 (the Department of Health and Human Service's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR Part 5. The foregoing is not a pledge of confidentiality, and the applicant's labeling of material as confidential or privileged does not exempt such material from undergoing FOIA review by CMS.

Other requirements concerning the evaluation of applications include the following:

A. CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plan(s) meet(s) the requirements for obtaining a contract under 42 CFR Part 422.

B. A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under 42 CFR Part 422 Subpart F and such negotiation is not subject to the appeals provisions included in Subpart N of that part.

C. An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, public hearings, and any other appropriate procedures.

If the application is incomplete, CMS will make all efforts to notify the entity and allows 2 days from the date of the notice for the entity to furnish the missing information. Please note, however, that such notification is not required of CMS and, if the entity does not respond within the 2 days, the entity risks receiving an intent to deny notice as described below.

After evaluating all relevant information, CMS determines whether the entity's application meets the requirements in section of 42 CFR §422.501.

CMS notifies each entity that applies for an MA contract of its determination and the basis for the determination. The determination may be approval, intent to deny or denial. If CMS approves the application, it gives written notice to the MA organization, indicating that it meets the requirements for an MA contract.

If CMS finds that the entity does not appear to meet the requirements to be an MA contracting organization, and/or has not provided enough information to enable CMS to evaluate the application, CMS gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding. Within 10 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and may revise its application to remedy any defects CMS identified.

If CMS denies the application, it gives written notice to the entity indicating:

a. That the entity is not qualified to contract as an MA organization under Part C of Title XVIII of the Act;

b. The reasons why the entity does not meet the contract requirements; and

c. The entity's right to request reconsideration in accordance with the procedures specified in Subpart N of the MA regulations at 42 CFR Part 422.

CMS oversees an entity's continued compliance with the requirements for an MA organization. If an entity no longer meets those requirements CMS terminates the contract in accordance with procedures described in Subpart K at 42 CFR Part 422.

NOTE: If an entity has failed to comply with the terms of a previous year's contract with CMS under Title XVIII of the Social Security Act as an HMO, competitive medical plan, health care prepayment plan, or MA organization, or if an entity has failed to complete a corrective action plan during the term of its contract, CMS may deny a future application based on the entity's failure to comply with that prior contract with CMS, even if the entity meets all of the current requirements.

20.3 - Monitoring and Promoting Staff and Affiliated Provider Compliance with Policies

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The organization should monitor compliance through analysis of complaints or grievances, requests to change providers, enrollee satisfaction surveys, rapid disenrollment surveys, and other sources of enrollee input. Issues in compliance should be addressed through education or counseling of the staff or providers or other corrective action, and information on compliance with the policies should be considered during the recredentialing and staff evaluation process and within the quality improvement program. The organization ensures compliance with Federal and State laws affecting the rights of enrollees.

Applicable Federal laws include, but are not limited to:

- Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse to include but not limited to:

  - Applicable provisions of Federal criminal law;

  - The False Claims Act (31 U. S.C. 3729 et seq.);

  - The Anti-Kickback statute (§1128B(b) of the Act); and

- HIPAA administrative simplification rules at 45 CFR Parts 160, 162, and 164.

In general, agencies other than CMS or the State Medicaid Agency enforce these laws, and reviews conducted under these standards will not include detailed assessment of an organization's compliance. However, CMS or States will report any observed violations and refer any enrollee complaints to the appropriate agency for resolution.

The organization must include provisions relating to compliance with Federal and State laws in subcontracts with providers. Assessment of compliance should be included in the organization's credentialing procedures to the extent feasible and appropriate. For example, if site visits to individual providers' offices are conducted, they should include a general assessment of physical accessibility. Compliance issues identified may be addressed through the organization's Quality Improvement Program.

Each MA contract is for a period of at least 12 months. The contract is effective on the date specified in the contract between the MA organization and CMS.

An MA organization's MA contract with CMS will contain a provision specifying inspection and auditing rights, along with CMS' rights to inspect or evaluate the quality, appropriateness, and timeliness of services performed under the contract; CMS' rights to inspect or evaluate the facilities of the organization when evidence of the need to do so exists; and CMS' right to inspect books, contracts, and records of the MA organization that pertain to the organization's ability to bear financial risk, perform services, and determine amounts payable.

An MA organization's MA contract will contain a severability provision that provides that upon CMS' request: (1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS, and (2) A separate contract would be deemed to be in place for the plan removed from the MA contract, when such a request is made.

An MA organization's MA contract will contain a provision stating that any regulations or policy statements issued by CMS after the date on which final bid proposals must be submitted for a calendar year, and which create significant new operational costs of which the MA organization did not have reasonable notice prior to such date, will not become effective before the next contract year for which these requirements can be taken into account in making bid submissions, unless earlier implementation is required by statute or in connection with litigation challenging CMS" policies.

> **NOTE**: MA organizations offering prescription drug benefits under Part D must follow the fraud, waste, and abuse requirements at 42 CFR Part 423. Please see §423.504(b)(4)(vi)(H) for these requirements.

30 - Minimum Enrollment Requirements for MA Organizations

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Unless an organization has a minimum enrollment waiver as explained below, CMS does not enter into a contract with an entity unless it meets the following minimum enrollment requirements:

- At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or
- At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in 42 CFR §412.62(f) (or, in the case of a PSO, the PSO meets the requirements at 42 CFR §422.352(c)).

Except when an organization has a minimum enrollment waiver, the organization must maintain the minimum enrollment standards above for the duration of its contract.

30.1 - Minimum Enrollment Waiver

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

For an organization that does not meet the applicable enrollment requirements when it applies for an MA contract or during the first 3 years of its MA contract, CMS may waive the minimum enrollment requirement. To receive a waiver, an organization must demonstrate to CMS' satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract.

CMS considers the following factors when making this evaluation:

- The organization management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity;
- The organization has the financial ability to bear financial risk under an MA contract including experience managing an organization and stop-loss insurance that is adequate and acceptable to CMS; and
- The organization is able to establish a marketing and enrollment process that will allow it to meet the applicable enrollment requirement prior to completion of the third contract year.

If the MA organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization requests an additional minimum enrollment waiver no later than 120 days before the end of the first year, continues to demonstrate it is capable of administering and managing an MA contract and is able to manage the level of risk, and demonstrates an acceptable marketing and enrollment process.

Enrollment projections for the second year of the waiver become the organization's transitional enrollment standard. If an organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard established based on its enrollment projections for the second year.

CMS may elect to not renew its contract with an MA organization that fails to meet the applicable enrollment requirement.

40 - Term and Effective Date of an MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

An MA contract is effective on the date specified in the contract between the MA organization and CMS.

Each MA contract is for a period of at least 12 months.

50 - Contracting Prohibitions Under the Medicare Advantage (MA) Program

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

An MA organization will be subject to a 2-year contracting prohibition when the organization leaves the MA program entirely by non-renewing all of its MA contracts. As long as an MA organization continues to offer at least one MA plan, the prohibition will not apply. If an MA organization that non-renews all of its MA contracts proposes to return to Medicare contracting within the 2-year time period, the organization must provide a written request to CMS asking for an exemption to the prohibition based on special circumstances. The MA organization will automatically be permitted to re-enter the program as of the beginning of the next calendar year if, during the 6-month period beginning on the date the organization notified CMS of the intention to non-renew all of its MA contracts, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue. The MA organization will also be permitted to re-enter the program if "circumstances. . .warrant special consideration." CMS will evaluate proposed special circumstance requests on a case-by-case basis. However, there are certain special circumstances under which CMS generally will grant an exemption to the 2-year contracting prohibition to allow the MA organization to offer an MA or MA-PD plan as of the beginning of the next calendar year. These circumstances are:

1. The organization is proposing to introduce an MA plan(s) in a geographic area(s) currently served by two or fewer MA plans;
2. The organization is proposing to introduce MA plans in counties other than the counties they had previously withdrawn from when they ended their earlier contract with the Medicare program;
3. The organization proposes to offer a different MA plan type than they had previously offered. For example, an organization that had offered a health maintenance organization may want to reenter the program and offer a preferred provider organization;
4. The organization has undergone a significant change such as a merger or acquisition and could thereby demonstrate that the new entity is essentially a different organization from the one that severed its contracting relationship with CMS. CMS reserves the right to make a determination whether the nature and extent of the organizational change is sufficient to consider the organization as a new entity, and therefore, no longer subjected to the 2-year contracting prohibition.

In addition, CMS may grant an exception based on other "special circumstances" than those above, at CMS' discretion.

60 - MA Contract Renewal

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

MA contracts are renewed annually only if:

- CMS informs the MA organization that it authorizes a renewal;
- The MA organization has not provided CMS with a notice of intention not to renew; and
- Agreement is reached on the bid submitted by the MA organization.

CMS will notify each MA organization of its decision whether to authorize the renewal of its MA contract, along with applicable appeal rights, by May 1 of the current contract year.

> **NOTE**: CMS annually issues a call letter specifying information concerning the contract renewal process. For information for 2006 contracts, as well as information concerning the transition to plans with contracts beginning in 2006, view our call letter at http://www.cms.hhs.gov/HealthPlansGenInfo. The call letter includes the HPMS plan crosswalk which specifies MA plan renewal guidelines and operational instructions by designating the relationships between plans offered in 2005 to those being offered in 2006.

70 - Contract Nonrenewal

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

70.1 - Nonrenewal of MA Contract: MA Organization-Initiated

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

An MA organization may elect not to renew its contract with CMS at the end the contract for any reason provided it meets specified time frames for doing so. If an MA organization does not intend to renew its contract, it must notify:

- CMS in writing by the first Monday of June of the year in which the contract would end, or a later date specified by CMS as described below;
- Each Medicare enrollee at least 90 days before the date on which the nonrenewal is effective. The CMS approved-notice to the enrollee must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and Original Medicare; and
- The general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the MA organization's service area. This notice must be pre-approved by CMS;

CMS may accept a nonrenewal notice submitted after the first Monday in June if:

- The MA organization notifies its Medicare enrollees and the public as specified above; and
- Acceptance of the delayed non-renewal notice would not be inconsistent with the effective and efficient administration of the Medicare program.

NOTE: For more information concerning non-renewals view our 2006 call letter at.http://www.cms.hhs.gov/HealthPlansGenInfo.

70.2 - Responsibilities of Nonrenewing MA Organizations

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

MA organizations non-renewing their MA contracts must continue to meet the following requirements through the remainder of their final contract year.

1. **Financial Audits -** CMS is required by statute to audit at least one-third of MA organizations' financial records each year. Such records include all pertinent financial records (including data relating to Medicare utilization, costs, and development of the bid). Therefore, those audits started for the current year must be completed. This will assure that Medicare beneficiaries received appropriate benefits at proper price levels.

2. **Corrective Action Plans (CAP)** - MA organizations operating under a corrective action plan must continue to fulfill the requirements of the plan through December 31 of the final contract year.

3. **Health Employer and Data Information Set (HEDIS®) / Consumer Assessment of Health Plans Study (CAHPS) -** Non-renewing MA organizations will not be required to submit HEDIS® data results from their final MA contract year. (For example, MA organizations non-renewing their MA contract January 1, 2001, would not be required to submit HEDIS® results from the year 2000 measurement year.) Non-renewing MA organizations are similarly not required to participate in the CAHPS survey for the final year of their MA contract by submitting names and telephones numbers for telephone follow-up on non-respondents.

4. **Physician Incentive Plan (PIP) Requirements -** Non-renewing organizations must continue to provide assurances satisfactory to CMS that they are meeting the requirements specified at §422.208 and must continue to disclose to beneficiaries who request it the information specified AT §422.210. Organizations with incentive arrangements at substantial financial risk must assure that physicians have adequate stop-loss protection.

5. **Quality Improvement) -** MA organizations are required by regulation and contract to operate quality improvement programs as specified in 42 CFR 422.152 of the regulations and Chapter 5 of the manual. These requirements include chronic care improvement programs, quality improvement projects as well as measuring performance, and reporting on performance, as requested.

- For Projects in Their Third Year - During the MA organization's final contract year, the MA organizations must complete the project data collection and continue any quality improvement initiatives;
- For Projects in their Second Year (unless the second year of a Quality Improvement project is the project's completion year) - During the MA organization's final contract year, the organization must continue its quality improvement initiatives but need not continue data collection; and
- For Projects in Their First Year - During the MA organization's final contract year, the organizations may discontinue the project altogether. However, if a health care intervention has been started designed to improve the health status of enrollees, the MA organization must continue to provide that care until the actual end of the MA contract.

The following are MA requirements for which non-renewing organizations remain responsible beyond December 31 of the final contract year:

1. **Maintenance of Records -** MA organizations are required to maintain and provide CMS access to books, records, and other documents related to the operation of an MA contract. Under 42 CFR 422.504(d) and (e), MA organizations are to maintain these records, and allow CMS access to them, for 10 years from the termination date of the contract or the date of the completion of any audit. In the case of service area reductions, MA organizations must maintain these records, and allow CMS access to them, for 10 years from the date from which service in a particular county was discontinued. This also includes contract terminations that result from a decision by an MA organization not to renew its MA contract with CMS.

2. **Continuation of Care -** Terminating MA organizations and those plans reducing their service areas may, in certain situations, be responsible for costs incurred for Medicare beneficiaries hospitalized beyond the last day of the contracts. If a Medicare beneficiary is hospitalized in a prospective payment (PPS) hospital, the MA organization is responsible for all Part A inpatient hospital services until the beneficiary is discharged, as stated at 42 CFR 422.318(c). Original Medicare or the beneficiary's next Medicare-contracting managed care organization will assume payment for all services covered under Part B after the terminating MA organization's MA contract ends. If a Medicare beneficiary is in a non-PPS hospital, your organization is responsible for the covered charges through the last day of your contract or, for plans reducing their service areas, the last day in which service in a particular county are discontinued.

   With respect to enrollees receiving care in a skilled nursing facility (SNF) upon the termination of the MA contract, terminating MA organizations are financially liable for such care through December 31 of the final contract year. After that date, Medicare beneficiaries continuing a SNF stay may receive coverage through either fee-for-service Medicare or enrollment in another MA plan. Assuming that the SNF stay is Medicare covered, the number of days of the beneficiary's SNF

stay while enrolled in the MA plan will be counted toward the 100-day Medicare limit. For example, if a beneficiary entered a SNF on December 1, 2005, and was disenrolled on December 31, 2005, 31 days of the stay would be covered by the MA organization, leaving 69 days of fee-for-service coverage beginning January 1, 2006. Those beneficiaries who enroll in another MA plan will receive SNF coverage beginning January 1, 2006, according to the CMS-approved benefit package offered by that plan. MA organizations reducing their service areas must apply this SNF coverage policy to their enrollees who reside in the discontinued portion of the service area.

For more information on the kinds of facilities that trigger the continuation of care provisions see 42 CFR 422.318(a).

3. **Pending Appeals -** The MA contract and the regulations at 42 CFR 422.504(a)(3) require MA organizations to provide access to benefits for the duration of their contracts. Also the language at 42 CFR 422.618(b) requires MA organizations to "pay for, authorize, or provide" the services that the Center for Health Dispute Resolution (CHDR) determines should have been covered by the organization. As such, MA organizations are obligated to process any appeals for services which would have been provided or paid for while Medicare beneficiaries were enrolled in the plan. Reconsiderations and appeals decided in favor of the Medicare beneficiary after the date that the MA organization's contract terminates are the obligation of the (former) MA organization – regardless of when the decision is effectuated.

4. **Retroactive Payment Adjustments -** For terminating MA organizations, once the MA contract has been terminated and the MA organization is no longer receiving payments from CMS, the organization will still be required to reimburse CMS for any overpayments. Also, the MA organization will still have the right to seek reimbursement from CMS for any previously identified underpayments to the extent permitted by applicable law. MA organizations seeking payment adjustments should report corrected information within 45 days of the contract termination date to the CMS contractor responsible for retroactive payment adjustment data processing. These data include, but are not limited to, adjustments based on changes to enrollments, Medicaid status, and institutional status for Part C demographic payment which date from the period during which the contract was effective. The reporting of corrected information will trigger the CMS retroactive payment adjustment process. The reported corrections will be verified and applied to your (former) members' records. These corrections will be included as a part of your final payment reconciliation.

   CMS will complete final reconciliation of its accounts with the MA organization within approximately nine months of the termination date of the MA contract. However, it is important to note that completion of final reconciliation may be delayed in the event that the organization fails to comply with remaining data submission requirements.

70.3 - Nonrenewal of MA Contract: CMS-Initiated

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

CMS may elect not to authorize renewal of an MA contract. CMS must notify the MA organization of its intent to nonrenew by May 1 of the contract year, except in the event of paragraph (d), below, in which case notice will be sent by September 1. Reasons for CMS non-renewal of a contract include the following:

a. The MA organization has not fully implemented or shown discernable progress in implementing quality improvement projects;

b. For any of the same reasons that CMS would terminate a contract;

c. The MA organization has committed any of the acts that would support imposition of intermediate sanctions or civil money penalties; or

d. The MA organization did not submit a benefit and price bid or the benefit and price bid was not acceptable.

80 - Contract Terminations

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

80.1 - When CMS Terminates an MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Medicare Advantage contract terminations differ from Medicare Advantage contract non-renewals in that the Secretary may initiate a contract termination at any time for reasons set forth in the Medicare statute. In contrast, Medicare Advantage contract non-renewals occur according to a prescribed time-schedule, whereby in most cases CMS must notify an MA organization of its intention to non-renew the MA organization's MA contract by May 1 of the final contract year.

CMS may terminate an MA contract for any of the following reasons:

- The MA organization fails substantially to carry out the terms of its contract with CMS;
- The MA organization carries out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of the MA program;
- The MA organization no longer meets the requirements of this manual for being a contracting organization;
- The MA organization commits or participates in fraudulent or abusive activities affecting the Medicare program including the submission of fraudulent data (see 423.504(b)(4)(vi)(H) of 42 CFR Part 423 for additional requirements MA organizations must follow when offering a prescription drug benefit under Part D);

- The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists. When this occurs, CMS may immediately terminate its contract with an MA organization;
- The MA organization substantially fails to comply with the grievances and appeals requirements described in Chapter 13 of this manual, when published;
- The MA organization fails to provide CMS with valid risk adjustment data;
- The MA organization fails to implement an acceptable quality improvement program;
- The MA organization substantially fails to comply with the prompt payment requirements;
- The MA organization fails to comply with the service access requirements;
- The MA organization fails to comply with the requirements regarding physician incentive plans; and
- The MA organization substantially fails to comply with the marketing requirements.

In determining whether a failure is "substantial," CMS considers both the frequency and the seriousness of the noncompliance. In the case of a serious violation that could put the health of an enrollee at risk, even a single violation might be considered substantial. In the case of a less serious violation, the noncompliance would have to be more pervasive or systematic in order to be considered substantial.

80.2 - Termination Process When CMS Initiates Contract Termination

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

If CMS decides to terminate a contract for reasons other than the grounds precipitating immediate termination, it gives notice of the termination as follows:

- CMS notifies the MA organization in writing at least 90 days before the intended date of the termination;
- CMS requires that the MA organization notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination. CMS pre-approves such member notifications; and
- CMS requires that the MA organization notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area. CMS pre-approves these notices to the general public.

80.3 - Immediate MA Contract Termination by CMS

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

In instances where the MA organization experiences financial difficulties so severe that life and physical well being of beneficiaries is in jeopardy, or otherwise fails to make services available to the extent that such a risk to health exists, CMS can immediately sever its relationship with an MA organization in order to protect beneficiaries and to safeguard taxpayer confidence in CMS's administration of the Medicare program. When this occurs, CMS:

1. Notifies the MA organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination;

2. Notifies the MA organization's Medicare enrollees in writing of CMS's decision to immediately terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare;

3. Notifies the general public of the termination no later than 30 days after notifying the plan of CMS' decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

If a contract is immediately terminated by CMS, the MA organization will not have the opportunity to submit a corrective action plan to correct the finding that precipitated CMS's contract termination action. However, affected MA organizations do maintain appeal rights that become effective following the effective date of the termination. See Chapter 14 for a full discussion of the MA contract appeal rights afforded MA organizations.

80.4 - When an MA Organization Terminates an MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

An MA organization may terminate its MA contract if CMS fails to substantially carry out the terms of the MA contract.

80.5 - Termination Process When an MA Organization Initiates Contract Termination

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

- The organization must give CMS notice at least 90 days before the intended date of termination which specifies the reasons the MA organization is requesting contract termination.

- The organization's Medicare enrollees must be given a CMS-approved notice at least 60 days before the proposed termination effective date and include a description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, original fee-for-service Medicare.
- The MA organization must also notify the public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area;

The effective date of the termination is determined solely by CMS and is at least 90 days after the date CMS receives the MA organization's notice of its intent to terminate the contract. CMS' liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract was in effect. If termination occurs, CMS will not contract with the same organization for 2 years from the date of termination of the previous contract unless the organization meets specified exceptions (see §50 of this chapter).

90 - Modification or Termination of an MA Contract by Mutual Consent

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

There are circumstances under which an MA organization may agree to a termination by mutual consent. Further, CMS may decide that it is in the best interests of tax payers, Medicare beneficiaries and the Medicare program to agree to let an MA organization terminate its contract midyear.

An MA contract may be modified or terminated by CMS or an MA organization at any time by written mutual consent of both parties. MA organizations must provide notice to their Medicare enrollees and the general public when mutually agreeing to terminate an MA contract as follows:

- To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options, original Medicare, and it must receive CMS approval.
- To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

The general exception to these notice requirements occurs when an MA contract that is terminated by mutual consent, is replaced the day following such termination by a new MA contract covering the same population. If the new contract is effective during a calendar year, it must include benefits under the same terms as the old contract for this exception to apply.

100 - MA Contract Provisions

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

100.1 - Material Provisions of an MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The contract between the MA organization and CMS will contain the following material requirements and conditions.

The MA organization shall:

- Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments as provided in Chapter 2 of this manual;
- Not discriminate in regards to beneficiary enrollment;
- Provide the basic benefits and to the extent applicable, supplemental benefits;
- Provide access to services in accordance with the standards set forth at 42 CFR 422.112 (for a coordinated care plan) or 42 CFR 422.114 (for a private fee-for-service plan);
- Provide health care services in a manner consistent with professionally recognized standards of health care;
- Disclose information to beneficiaries in the manner and the form prescribed by CMS;
- Operate a quality improvement program in accordance with 42 CFR 422.152;
- Comply with all applicable provider requirements and specific physician requirements ;
- Comply with all requirements governing coverage determinations, grievances, and appeals;
- Comply with all reporting requirements including the submission of data;
- Accept payment;
- Develop and submit an annual bid proposal and submit all the required information on premiums, benefits, and cost-sharing by the due date specified in the statute, which is the first Monday in June;
- Acknowledge that CMS may not renew or may terminate its MA contract;
- Comply with all the requirements that are specific to a type of MA plan;

- Comply with the confidentiality, privacy, and enrollee record accuracy requirements;
- Submit to CMS certified financial information demonstrating that the organization has a fiscally sound operation; and
- Submit to CMS information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

An MA organization's noncompliance with material requirements of its MA contract are grounds for contract termination by CMS.

100.2 - Other Provisions of the MA Contract

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Provisions Necessary to Implement MA Program - The MA organization agrees that a provision will be included in its contract with CMS that specifies such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements of the MA program.

Severability of Contracts - The MA contract will provide that, upon CMS's request:

- The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and
- A separate contract will be deemed to be in place for any such organization or entity that is removed from its former MA contract when such a request is made.

Electronic Communication - An MA organization must have the capacity to communicate with CMS electronically which includes notifying CMS of appropriate e-mail addresses for contact individuals within the organization (and receiving and sending e-mail), accessing the Internet to receive instructions and communications, and sending individual or batch information to CMS or its contractors such as encounter and enrollment/disenrollment information;

Prompt Payment - The MA organization must comply with the following prompt payment of claims provisions for claims that have been submitted by providers for services and supplies rendered to Medicare enrollees when these services and supplies are furnished by non-contracted providers:

- The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the "clean claims" within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider;
- The MA organization must pay interest on clean claims that are not paid within 30 days; and

- All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request for payment.

If a Medicare Advantage organization chooses to use non-contracting providers to provide services "in lieu of" executing contracts with providers to provide such services, the Medicare Advantage organization must pay the provider the amount it would have received under original Medicare for the services.

In the case of "unforeseen" services furnished by a provider that Medicare pays under a prospective payment system (PPS), e.g., emergency or urgently needed care or certain post-stabilization care service(s) - a Medicare Advantage organization must pay the lesser of the hospital's billed charges or the PPS rate, but no more than would have been paid under original Medicare.

If CMS determines that the MA organization fails to make payments promptly to non-contracting providers and suppliers, CMS may, following an opportunity for a hearing:

- Provide for direct payment of the sums owed to providers, or MA private fee-for-service plan enrollees; and
- Provide for appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

Agreements with Federally Qualified Health Centers

Under the contract, if an MA enrollee receives a service from a Federally Qualified Health Center (FQHC) that has a written agreement with the MA organization:

- The MA organization must pay a FQHC a similar amount to what it pays other providers for similar service;
- The FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect; and
- Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments by CMS under 42 CFR 422.316(a) (requirements for the MA program).

100.3 - Beneficiary Financial Protections

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must:

- Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

- Indemnify the enrollee for any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's beneficiary enrollees.

The MA organization must provide for continuation of enrollee health care benefits for:

- All enrollees, for the duration of the contract period for which CMS payments have been made; and

- Enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

To meet this continuation of benefits requirements, an MA organization may use:

- Contractual arrangements (see MA contract requirements described at §20 and §§100.1 - 100.2);

- Insurance acceptable to CMS;

- Financial reserves acceptable to CMS; or

- Any other arrangement acceptable to CMS.

100.4 - Provider and Supplier Contract Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Contracts or other written agreements between MA organizations and providers and suppliers of health care or health care-related services must contain the following provisions:

- Contracting providers agree to safeguard beneficiary privacy and confidentiality and assure accuracy of beneficiary health records;

- Contracts must specify a prompt payment requirement, the terms and conditions of which are developed and agreed-to by the MA organization and its contracted providers and suppliers;

- Contracts must hold Medicare members harmless for payment of fees that are the legal obligation of the MA organization to fulfill. Such provision will apply, but will not be limited to insolvency of the MA organization, contract breach, and provider billing;

- Contracts must contain accountability provisions specifying:

    - That first tier and downstream entities must comply with Medicare laws, regulations, and CMS instructions (422.504(i)(4)(v)), and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records a minimum of 10 years;

- That the MA organization oversees and is accountable to CMS for any functions and responsibilities described in the MA regulations (422.504(i)(4)(iii)); and
- That MA organizations that choose to delegate functions must adhere to the delegation requirements - including all provider contract requirements in these delegation requirements - described in the MA regulations (422.504(i)(3)(iii); 422.504(i)(4)(i)-(v)).

- Contracts must specify that providers agree to comply with the MA organization's policies and procedures;

In addition to the provisions mentioned above, MA organizations must include certain MA-related provisions in the policies and procedures that are distributed to providers and suppliers that constitute the organizations' health services delivery network. The following table summarizes these provisions. Access the CFR online.

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Safeguard privacy and maintain records accurately and timely	422.118
Permanent "out of area" members to receive benefits in continuation area	422.54(b)
Prohibition against discrimination based on health status	422.110(a)
Pay for emergency and urgently needed services	422.100(b)
Pay for renal dialysis for those temporarily out of a service area	422.100(b)(1)(iv)
Direct access to mammography and influenza vaccinations	422.100(g)(1)
No copay for influenza and pneumococcal vaccines	422.100(g)(2)
Agreements with providers to demonstrate "adequate" access	422.112(a)(1)
Direct access to women's specialists for routine and preventive services	422.112(a)(3)
Services available 24 hrs/day, 7 days/week	422.112(a)(7)
Adhere to CMS marketing provisions	422.80(a), (b), (c)
Ensure services are provided in a culturally competent manner	422.112(a)(8)
Maintain procedures to inform members of follow-up care or provide training in selfcare as necessary	422.112(b)(5)

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Document in a prominent place in medial record if individual has executed advance directive	422.128(b)(1)(ii)(E)
Provide services in a manner consistent with professionally recognized standards of care	422.504(a)(3)(iii)
Continuation of benefits provisions (may be met in several ways, including contract provision)	422.504(g)(2)(i); 422.504(g)(2)(ii); 422.504(g)(3)
Payment and incentive arrangements specified	422.208
Subject to applicable Federal laws	422.504(h)
Disclose to CMS all information necessary to (1) Administer & evaluate the program (2) Establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services	422.64(a): 422.504(a)(4) 422.504(f)(2)
Must make good faith effort to notify all affected members of the termination of a provider contract 30 calendar days before the termination by plan or provider	422.111(e)
Submission of data, medical records and certify completeness and truthfulness	422.310(d)(3)-(4), 422.310(e), 422.504(d)-(e), 422.504(i)(3)-(4), 422.504(l)(3)
Comply with medical policy, QI and MM	422.202(b); 422.504(a)(5)
Disclose to CMS quality & performance indicators for plan benefits re: disenrollment rates for beneficiaries enrolled in the plan for the previous two years	422.504(f)(2)(iv)(A)
Disclose to CMS quality & performance indicators for the benefits under the plan regarding enrollee satisfaction	422.504(f)(2)(iv)(B)
Disclose to CMS quality & performance indicators for the benefits under the plan regarding health outcomes	422.504(f)(2)(iv)(C)
Notify providers in writing for reason for denial, suspension & termination	422.202(c)(1)
Provide 60 days notice (terminating contract without cause)	422.202(c)(4)
Comply with Federal laws and regulations to include, but not limited to: Federal criminal law, the False Claims Act (31	422.504(h)(1)

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
U.S.C. 3729 et. Seq.) and the anti-kickback statute (section 1128B(b) of the Act)	
Prohibition of use of excluded practitioners	422.752(a)(8)
Adhere to appeals/grievance procedures	422.562(a)

100.5 - Administrative Contracting Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The MA administrative contracting requirements apply both to first tier contracts and to downstream contracts in the manner specified for provider contracts, as described above. At the same time, the responsibility of the MA organization is to assure that its contractor and any downstream contractors have the information necessary to know how to comply with the requirements under the MA program.

These requirements do not apply to administrative contracts that do not directly relate to the MA organization's core functions under its contract with CMS. For example, a contract between the MA organization and a clerical support firm would not need to contain these provisions. Similarly, a contract between the MA organization and a real estate broker to identify rental properties for office space would not be required to address these areas. CMS would, however, view contracts for administration and management, marketing, utilization management, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, and credentialing to be administrative contracts subject to MA requirements as articulated in the MA regulation and related guidance.
The following provisions must be addressed in the administrative service contracts:

- The person or entity must agree to comply with all applicable Medicare laws, regulations, and CMS instructions;
- The person or entity must agree to comply with all State and Federal confidentiality requirements, including the requirements established by the MA organization and the MA program;
- The person or entity must agree to grant DHHS, the Comptroller General, or their designees the right to inspect any pertinent information related to the contract during the contract term, for up to 10 years from the final date of the contract period, and in certain instances described in the MA regulation, periods in excess of 10 years, as appropriate;

- The contract must clearly state the responsibilities of the administrative services provider and its reporting arrangements;
- The contract must provide that the MA organization and any first tier and downstream entities has/have the right to revoke the contract if MA organizations do not perform the services satisfactorily, and if requisite reporting and disclosure requirements are not otherwise fully met in a timely manner;
- If the written arrangement provides for credentialing activities by a first-tier or downstream entity, the first-tier or downstream entity must meet all applicable MA credentialing requirements;
- If the written arrangement provides for the selection of providers by a first-tier or downstream entity, written arrangements must state that the MA organization retains the right to approve, suspend, or terminate any such arrangement;
  - Contracts between MA organizations and first tier entities, and first tier entities and downstream entities must contain provisions specifying MA delegation requirements specified at 422.504(i)(3)(iii) and 42 CFR 422.504(i)(4)(i)-(v). A written agreement specifies the delegated activities and reporting responsibilities of the entity and provides for revocation of the delegation or other remedies for inadequate performance. Contracts must indicate what functions have been delegated and must require the entity to comply with the requirements of these standards and of applicable law and regulations. When a function is only partially delegated, contract provisions must clearly delineate which responsibilities have been delegated and which remain with the organization. In the Quality Improvement area, for example, the organization might develop topics for projects in consultation with an affiliated medical group, but delegate the actual conduct of a specific project to the group. The agreement must specify how the delegate is to conduct Quality Improvement activities, at what points in the process decisions by the delegate (for example, on data collection methodologies) are subject to the organization's review, and how the delegate's activities will be integrated into the organization's overall Quality Improvement program (for example, through participation in an organization-wide committee).

100.6 - Implementation of Written Policies With Respect to the Enrollee Rights

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The organization must articulate enrollees' rights, promote the exercise of those rights, ensure that its staff and affiliated providers are familiar with enrollee rights, and treat enrollees accordingly. While most of the standards in this domain address basic procedural protections for enrollees, they are closely related to quality of care. Interpersonal aspects of care are highly important to most patients. Enrollees' interactions with the organization and its providers can have an important bearing on their willingness and ability to understand and comply with recommended treatments, and hence, on

outcomes and costs. Policies are communicated to enrollees in the enrollee statement furnished in accordance with Chapter 2 of this manual, and to the organization's staff and affiliated providers, at the time of initial employment or affiliation, and annually thereafter.

Material on enrollee rights must be included in provider contracts or provider manuals, and in staff handbooks or other training materials.

110 - MA Organization Relationship with Related Entities, Contractors, Subcontractors, First-Tier and Downstream Entities

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Organizations likely to apply for MA contracts commonly enter into business relationships with entities that they place under contract to perform certain functions that otherwise would be the responsibility of the organization to perform, including management and provision of services.

110.1 - General Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The MA organization agrees to take ultimate responsibility for all services provided and terms of the contract and otherwise fulfilling all terms and conditions of its contract with CMS regardless of any relationships that the organization may have with entities, contractors, subcontractors, first-tier or downstream entities.

The MA organization agrees to require all related entities, contractors, or subcontractors, first-tier and downstream entities to agree that:

- DHHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s), first-tier and downstream entities involving transactions related to the MA contract as specified above under §110.4.4 of this chapter;

- DHHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later; and

- All contracts or written arrangements between MA organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the contract language requirements described in §100 of this chapter.

NOTE: All MA organizations offering a Part D prescription drug benefit must also comply with requirements of Part 423 (the requirements for the Part D prescription drug benefit) concerning a comprehensive fraud and abuse plan. This requirement applies only to the Part D benefit offered by the

MA organization. See 42 CFR 423.504(b)(4)(vi)(H) for Part D fraud, waste, and abuse requirements.

110.2 - Delegation Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The organization oversees and is accountable for any functions or responsibilities that are delegated to other entities.

With certain restrictions indicated below, an organization may, by written contract, delegate any activity required under or governed by these standards to another entity. However, an organization entering into a Medicare contract remains accountable to CMS or the State for performance of any such delegated function. It is the sole responsibility of the organization to ensure that the function is performed in accordance with applicable standards. (Note that this standard is not meant to imply that the organization is legally liable for the actions of its subcontractors. For example, in cases of malpractice any such liability is established by State or local law.)

Special note must be made of "carve-out" arrangements, under which a managed care organization contracts with an entity to assume entire responsibility for a given type or category of service and delegates to that entity a broad range of basic management functions. Such contracts are most common for mental health and substance abuse services, although some organizations use similar arrangements for prescription drugs, home health care, or other types of services. These arrangements are conceptually no different from those under which an organization capitates a single medical group to provide all physician and related ambulatory services and delegates management of those services to the group. Although the latter arrangements are never spoken of as "medical carve-outs," they are functionally comparable to "mental health/substance abuse carve-outs." The contractor assumes entire responsibility for management of a defined portion of the overall benefit package. Just as medical group contracts have never diminished the basic accountability of the organization directly contracting with Medicare or Medicaid, so with mental health or other carve-outs. The prime contractor remains wholly accountable for the activities of its subcontractors.

Because of the wide variety of organizational structures and contractual arrangements, it is difficult to develop simple guidelines for the review of delegated activities. In any given situation, the review methodology to be adopted should be that which is least burdensome for reviewers and for the organization, yet which provides positive assurance that the activity in question is being performed in compliance with these standards. For example, credentialing of providers might occur in several different ways:

1. The organization itself verifies the credentials of individual providers affiliated with its subcontractors. Review would focus directly on the organization's performance of this function;

2. An organization contracts with one or more independent physician groups, each of which is expected to verify the credentials of each affiliated provider. It would

be impractical for a CMS or State reviewer to review compliance by the independent contractor(s). Instead, the organization itself must document that it has periodically reviewed the performance of each contractor, for example by verifying that all required credentialing information is present in a sample of each contractor's provider records; or

3. An organization contracts with a single independent credentialing verification organization (CVO) to collect information about providers. The CVO, and not the organization, maintains documentation of verification of credentials from primary sources. If a single CVO provided services to multiple organizations in a State, a State Medicaid agency might review the CVO itself and deem in compliance all organizations that contracted with the CVO. Alternatively, the State might accept the findings of an independent body that accredits CVOs. For the purposes of Medicare, however, CMS does not at this time review CVOs or accept external accreditation of CVOs. It would, therefore, expect the organization to document that it has monitored the CVO's performance, again through a review of a sample of practitioner records. (Similarly, the organization would be required to review the credentialing performance of any "carve-out" contractor, such as a national managed behavioral health care organization.)

This example illustrates that the variety and complexity of contracting arrangements makes it impractical to suggest a uniform method for review of delegated functions. As part of the advance preparation for on-site reviews, the reviewer and the organization should negotiate the most expeditious procedure. However, the burden of documenting a delegate's compliance with applicable standards ultimately rests with the organization.
It is especially important to identify instances in which a delegation has been made implicitly. For example, a contract with a medical group may hold the group responsible for providing or arranging for a wide range of ambulatory services in return for a fixed monthly capitation payment. The group is left to develop its own procedures for approving requests for referral services by its own primary care providers. If so, the utilization management function has been delegated, and the organization must ensure that the group complies with the standards for that function, including standards related to requests for expedited review.

The following specific requirements apply to all delegated functions:

- Written arrangements must specify delegated activities and reporting responsibilities;

- The organization evaluates the entity's ability to perform the delegated activities prior to delegation. The organization must document that it has approved the entity's policies and procedures with respect to the delegated function. It also must verify that the contractor has devoted sufficient resources and appropriately qualified staff to performing the function; or

- The performance of the entity is monitored on an ongoing basis and formally reviewed by the organization at least annually. The organization must have written procedures for monitoring and review of delegated activities. The nature

of ongoing monitoring may vary according to the organization's past experience with the delegate and with the nature of the delegated activity. In the areas of grievance processing or utilization management, for example, monitoring may be more or less continuous, in as much as decisions by the delegate may be appealed to the organization. However, the organization must periodically verify that the delegate is in fact forwarding requests for reconsideration, and that its statistical or other reporting on these processes is accurate. In other areas, such as credentialing, annual review of the delegate's activities may be sufficient, particularly if the organization has ascertained in the past that the delegate is performing the activity properly.

The annual evaluation should be a comprehensive assessment of the delegate's performance, including both compliance with applicable standards and the extent to which the delegate's activities promote the organization's overall goals and objectives for the delegated function. If any problems or deficiencies are identified, the evaluation must specify any necessary corrective action and include procedures for assuring that the corrective action is implemented.

The organization must ensure that monitoring of delegates is carried out by staff of the organization who are qualified to assess the delegates' activities. For example, an organization that has delegated authorization of mental health and substance abuse services to an entity must use appropriately credentialed professionals to review the entity's authorization decisions.

The following requirements apply:

- Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily;
- Written arrangements must further specify that either:
  - The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA organization;
  - The credentialing process will be reviewed and approved by the MA organization and the MA organization must audit the credentialing process on an ongoing basis; or
  - The policies and procedures that an MA organization develops for its related entity, contractor, subcontractor, first-tier and downstream entities must state that these entities must comply with all applicable Medicare laws, regulations, and CMS instructions;
- If the organization delegates selection of providers to another entity, the organization retains the right to approve, suspend, or terminate any provider selected by that entity; and

- Written arrangements must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

110.3 - MA Oversight and Beneficiary Protection Guidance

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

MA organizations, provider groups, individual providers and CMS have a common interest in preventing delegated provider group financial difficulties that may negatively impact the well being of Medicare beneficiaries. Similarly, these parties share an interest in mitigating the impact that provider group failures might have upon Medicare beneficiaries enrolled in an MA product.

The following is a list of MA regulations that are relevant to MA organizations that have relationships with delegated entities. These requirements hold MA organizations responsible for providing care to Medicare beneficiaries, and for protecting Medicare beneficiaries in instances where delegated entities experience operational difficulties that may result in failure of the delegated entity to perform delegated functions.

- 422.100(a) - an MA organization offering an MA plan must provide enrollees in that plan with coverage of the (plan benefit package) by furnishing the services directly or through arrangements, or by paying for the benefits;
- 422.112(b) - The MA organization must ensure continuity of care and integration of services;
- 422.504(g)(1) - Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the MA organization;
- 422.504(i)(1) - Notwithstanding any relationship(s) that the MA organization may have with related entities, contractors, or subcontractors, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;
- 422.502(i)(4)(i)-(v) - If any of the MA organization's activities or responsibilities under its contract with CMS are delegated to other parties, written arrangements must specify that the performance of the parties is monitored by the MA organization on an ongoing basis, and either provide for revocation of the delegated activities or specify other remedies where CMS or the MA organization determines such parties have not performed satisfactorily.

The policies and procedures described in §110.4 are recommended but not required for MA Organizations to ensure the operational integrity of delegated entities, and to protect beneficiaries in the event of a delegated provider group(s) insolvency and/or termination. This additional guidance may prove helpful to MA organizations in their attempt to meet the aforementioned MA regulatory requirements.

110.4 - Policies and Procedures for Assessing Contracting Provider Groups' Administrative and Fiscal Capacity to Manage Financial Risk

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Before an MA organization contracts with an entity to perform functions that are otherwise the responsibility of the MA organization under its contract with CMS, the MA organization should develop, implement, and maintain policies and procedures for assessing contracting provider groups' administrative and fiscal capacity to manage financial risk prior to delegating MA-related risk to these groups. Suggested policies and procedures include:

- Establish minimum net worth, adequate liquidity and reserve requirements that the delegated entity must meet before the MA organization contracts with a group;
- Conduct on-site audits to assess the delegated entity's administrative capabilities. Audit activities would include, but are not limited to: assessment of claims processing capabilities; financial planning and oversight capabilities; assessing a group's capacity to measure and accurately report incurred but not reported (IBNR) claims estimates.

After an MA organization has entered a contract with an entity to perform delegated functions it must develop policies and procedures for monitoring the fiscal soundness of at-risk delegated entities on an ongoing basis. These policies and procedures should specify thresholds that trigger MA organization intervention. Suggested policies and procedures include:

- Periodic collection of at-risk entity's financial statements and claims timeliness reports;
- Periodic auditing of claims payment timeliness and accuracy;
- Periodic administrative performance assessments;
- Listing of interventions that the MA organization will take and corrective actions it will require when an at-risk delegated entity falls below minimum standards or other thresholds; and
- Develop, maintain, and implement contingency plans to enable the MA organization to quickly respond to delegated entity financial failures. Particular emphasis should be placed on assessing the availability, accessibility, and continuity of care for Medicare beneficiaries enrolled in an MA plan, and for preventing inappropriate beneficiary billing for services that are the legal obligation of the MA organization. See §110.4.1 for suggested elements of a contingency plan.

110.4.1 - Access to and Continuity of Care

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

MA organizations offering coordinated care plans must:

- Honor all open authorizations for care;
- Place outbound calls to affected Medicare beneficiaries scheduled for services and undergoing treatment plans to coordinate continuation of care;
- Maintain "network crossover reports," so Medicare beneficiaries can be quickly reassigned to other plan-contracted providers or groups within the approved service area; and
- Provide an opportunity for members undergoing a treatment plan to continue to see providers that are no longer in the network due to the group insolvency.

110.4.2 - Prevention of Member Billing

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The following procedures may help prevent member billing:

- Initiate internal audits of hold-harmless provisions in downstream provider contracts;
- Provide written notification to all Medicare beneficiaries assigned to or receiving care through insolvent provider groups instructing them not to pay bills (except applicable copayments and or deductibles) for provider group obligations and to forward any bills to the MA organization;
- Provide written notification to an insolvent group's downstream contractors informing them that billing Medicare members for an insolvent group's obligations is prohibited; and
- Develop and implement specific policies and procedures to prevent non-contracting providers from billing Medicare beneficiaries for insolvent provider group obligations.

110.4.3 - Maintenance of and Access to MA-Related Record Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

DHHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the MA organization or relating to the MA organization's MA contract. DHHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the MA contract.

The MA organization agrees to make available its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. Pursuant to these requirements, the MA organization further agrees that it must maintain the following types of books, records, documents, and other evidence of accounting procedures and practices for 10 years from the end date of an MA contract or the completion date of an audit, whichever is later.

- Records sufficient to accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, encounter data, and computation of the bid proposal);
- Records sufficient to enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract and the facilities of the organization;
- Records sufficient to enable CMS to audit and inspect any books and records of the MA organization that pertain to the ability of the organization to bear the risk of potential financial losses, to services performed, or determinations of amounts payable under the contract;
- Records sufficient to properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid proposal;
- Records sufficient to establish component rates of the bid proposal for determining additional and supplementary benefits;
- Records sufficient to determine the rates utilized in setting premiums for State insurance agency purposes, and for other government and private purchasers;
- Records relating to ownership and operation of the MA organization's financial, medical, and other record keeping systems;
- Financial statements for the current contract period and 10 prior periods;
- Federal income tax or informational returns for the current contract period and 10 prior periods;
- Asset acquisition, lease, sale, or other ownership issues;
- Agreements, contracts, and subcontracts;
- Franchise, marketing, and management agreements;
- Schedules of charges for the MA organization's fee-for-service patients;
- Documentation of matters pertaining to costs of operations;
- Documentation of amounts of income received by source and payment;
- Cash Flow statements; and
- Any financial reports filed with other Federal programs or State authorities;

This requirement includes allowing DHHS, the Comptroller General, or their designee to have access to facilities and records to evaluate through inspection or other means:

- The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;
- The facilities of the MA organization; and
- The enrollment and disenrollment records for the current contract period and 10 prior contract periods.

DHHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the final date of the contract period or completion of audit, whichever is later unless:

- CMS determines there is a special need to retain a particular record or group of records for a longer period. CMS notifies the MA organization at least 30 days before the normal disposition date;
- There has been a termination, dispute, or fraud or similar fault by the MA organization, in which case the retention may be extended to six years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or
- CMS determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the MA organization at any time.

NOTE: See 42 CFR 423.504(b)(4)(vi)(H) for additional requirements relating to fraud, waste, and abuse that MA organizations offering a prescription drug benefit under Part D must follow.

110.4.4 - Disclosure Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The MA organization agrees to disclose the following to CMS:

- Certified financial information that must include the following:
  - Such information as CMS may require demonstrating that the organization has a fiscally sound operation; and
  - Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.
- All information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:
  - The benefits covered under an MA plan;

    - The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA monthly MSA premium;

    - The service area and continuation area, if any, of each plan and the enrollment capacity of each plan; and

    - The plan quality and performance indicators for the benefits under the plan including:

        - Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

        - Information on Medicare enrollee satisfaction;

        - Information on health outcomes;

        - The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

        - Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

    - Information about beneficiary appeals and their disposition;

    - Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization; and

    - Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

- MA organizations must disclose to existing enrollees and to each new enrollee electing an MA plan it offers in clear, accurate, and standardized form; and at the time of enrollment and at least annually thereafter, information relating to the MA organization's MA plans, including:

    - The MA plan's service area and any enrollment continuation area;

    - The benefits offered under the plan, including applicable conditions and limitations, premiums, cost sharing (such as copayments, deductibles, and coinsurance), and any other conditions associated with receipt or use of benefits; and for purposes of comparison;

    - The benefits offered under original Medicare;

    - For an MA Medical Savings Account (MSA) plan, the benefits under other types of MA plans; and

    - The availability of the Medicare hospice option and any approved hospices in the service area, including those the MA organization owns, controls, or has a financial interest in.

- The number, mix, and distribution of providers from whom enrollees may obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets MA access to service requirements;

- Out-of-area coverage provided by the plan;

- Coverage of emergency services, including:

    - Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at 42 CFR 422.113;

    - The appropriate use of emergency services, stating that prior authorization cannot be required;

    - The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent;

    - The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the MA plan;

- Any mandatory or optional supplemental benefits and the premium for those benefits;

- Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The MA organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any;

- All grievance and appeals rights and procedures;

- A description of the MA organization's quality assurance program; and

- Enrollees' disenrollment rights and responsibilities.

Upon request of an individual eligible to elect an MA plan, an MA organization must provide to the individual the following information:

- Benefits under original Medicare, including covered services, beneficiary cost sharing, such as deductibles, coinsurance, copayment amounts and any beneficiary liability for balance billing;

- Information and instructions on how to exercise election options under this subpart;

- A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the MA program and the right to be protected against discrimination based on factors related to health status;
- The fact that an MA organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's MA plan;
- Benefits, including covered services beyond those provided under original Medicare, any beneficiary cost sharing, and any maximum limitations on out-of-pocket expenses, the extent to which an enrollee may obtain benefits through out-of-network health care providers, the types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers, and the coverage of emergency and urgently needed services. In the case of an MA MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to MA plans. In the case of a MA private fee-for-service plan, differences in cost sharing, enrollee premiums, and balance billing, as compared to MA plans;
- The MA monthly basic beneficiary premium and the MA monthly supplemental beneficiary premium (if any);
- The plan's service area;
- Quality and performance indicators for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):
    - Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines;
    - Medicare enrollee satisfaction;
    - Health outcomes;
    - Plan-level appeal data;
    - The recent record of plan compliance with the requirements of this part, as determined by the Secretary; and
    - Other performance indicators.
- Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits;
- The procedures the organization uses to control utilization of services and expenditures;

- The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as:
    - Grievances according to Subpart M of 42 CFR 422 and Chapter 13 of this manual, when published;
    - Appeals according to Subpart M of 42 CFR 422 and Chapter 13 of this manual, when published. A summary description of the method of compensation for physicians;
- Financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan. Other MA organizational financial information that must be disclosed:
    - The cost of its operations;
    - The patterns of utilization of its services;
    - The availability, accessibility, and acceptability of its services;
    - To the extent practical, developments in the health status of its enrollees;
    - Information demonstrating that the MA organization has a fiscally sound operation; and
    - Other matters that CMS may require.

110.4.5 - Additional MA Reporting Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Each MA organization must have a Management Information System to compile, evaluate, and produce reports for CMS, its enrollees, and the public as needed. This system must insure the confidentiality of the doctor-patient relationship and the privacy of individual's records. The system must be able to produce statistics and other information with respect to:

- The cost of the MA organization's operations;
- The patterns of utilization of its services;
- The availability, accessibility, and acceptability of its services;
- To the extent practical, developments in the health status of its enrollees;
- Information demonstrating that the MA organization has a fiscally sound operation; and
- And any other information required by CMS when it gives advance notice before the beginning of the contract year.

In addition, each MA organization, through its Management Information System, must report to CMS:

- With respect to Business Transactions as defined above, MA organizations must provide either:
  - A showing that the costs of the transactions listed do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
  - If they do exceed the limit of $25,000 or 5 percent of the MA organization's total operating expenses, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements;
- A combined financial statement for the MA organization and a party in interest if either 35 percent or more of the costs of operation of the MA organization go to a party in interest or 35 percent or more of the revenue of a party in interest is from the MA organization.

110.4.6 - Reporting Requirements for Combined Financial Statements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

The combined financial statements described at 42 CFR 422.516(b)(3) must display in separate columns the financial information for the MA organization and each of the parties in interest. Inter-entity transactions must be eliminated in the consolidated column, the statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes. Upon written request from an MA organization showing good cause that is determined at the discretion of CMS, CMS may waive the requirement that the organization's combined financial statement include the information required regarding combined financial statements.

110.4.7 - Reporting and Disclosure Requirements under Employment Retirement Income Security Act of 1974 (ERISA)

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

For any employees' health benefits plan that includes an MA plan in its offerings, the MA organization must furnish, upon request, the information the organization needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the ERISA. The organization must furnish the information to the employer or the employer's designee, or the plan administrator as defined under ERISA.

Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors, and related entities, and must make information reported to CMS regarding benefits, beneficiary cost sharing, service area and continuation area if any, plan quality and performance indicators, beneficiary appeals and

grievances, MSA demonstration project information, and all formal actions taken by regulatory/ licensing/ accrediting bodies available to its enrollees upon request.

120 - Compliance with Other Laws and Regulations

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

MA organizations are obligated to comply with other laws, specifically Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse including, but not limited to:

- Applicable provisions of Federal criminal law;
- The False Claims Act (31 U.S.C. 3729 et seq.);
- The Anti-kickback statute (Section 1128B(b) of the Act); and
- HIPAA administrative simplification rules at 45 CFR Part 160, 162, and 164.

MA organizations receiving Federal payments under MA contracts, and related entities, contractors, and subcontractors paid by an MA organization to fulfill its obligations under its MA contract are subject to certain laws that are applicable to individuals and entities receiving Federal funds. MA organizations must inform all related entities, contractors and subcontractors, first tier and downstream entities that payments they receive are, in whole or in part, from Federal funds.

MA organizations offering a Part D prescription drug benefit must follow additional requirements relating to fraud, waste, and abuse. Please see 42 CFR 423.504(b)(4)(vi)(H) for these requirements.

130 - Certification of Data That Determine Payment Requirements

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

As a condition for receiving a MA related monthly payment from CMS, the MAO agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that attests to (based on best knowledge, information and belief, as of the date specified on the certification form) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment/disenrollment information, changes in benefit packages, and other information that CMS may specify.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest to the fact that each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization, and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief as of the date specified on the attestation form) is accurate, complete, and truthful.

The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) that the data it submits are accurate, complete, and truthful. If such data are generated by a related entity, contractor, or subcontractor of an MAO, such entity, contractor, or subcontractor must similarly attest to (based on best knowledge, information, and belief, as of the date specified on the attestation form) the accuracy, completeness, and truthfulness of the data.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the bid proposal requirements.

This attestation requirement is applicable to all MA contractors, including those that are nonrenewing or terminating their contracts.

140 - Special Rules for Religious Fraternal Benefit (RFB) Societies

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

In order to participate as an MA organization, an RFB society may not impose any limitation on membership based on any factor related to health status and must offer in addition to the MA RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

Appendix A - Certification Of Monthly Enrollment and Payment Data Relating to CMS Payment to a Medicare Advantage Organization

(Rev. 79, Issued 02-17-06, Effective Date 02-17-06)

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (NAME OF MEDICARE ADVANTAGE ORGANIZATION), hereafter referred to as the "MA Organization," governing the operation of the following Medicare Advantage plans (PLAN IDENTIFICATION NUMBERS), the MA Organization hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization and that misrepresentations and omissions to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This certification shall not be considered a waiver of the MA Organization's right to seek payment adjustments from CMS based on information or data which does not become available until after the date the MA Organization submits this certification.

1. The MA Organization has reported to CMS for applications received in the month of (MONTH AND YEAR) all new enrollments, disenrollments, and changes in Plan Benefit Packages, as well as those beneficiaries who have met the qualifying institutional period with respect to the above-stated MA plans. Based on best knowledge, information, and belief, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The MA Organization has reviewed the CMS monthly membership report and reply listing for the month of _______________ (MONTH AND YEAR) for the above-stated MA plans and has submitted requests to the IntegriGuard, under separate cover, for retroactive adjustments to correct payment data when the MA Organization has more accurate information. This may include enrollment status, working aged status, institutional status, Medicaid status, and State and County Code related to specific beneficiary.

For those portions of the monthly membership report and the reply listing to which the MA Organization raises no objection, the MA Organization, through the certifying CEO/CFO, will be deemed to have attested, based on my best knowledge, information, and belief, to their accuracy, completeness, and truthfulness.

____
NAME
TITLE
on behalf of

____
(MA Organization)