

§ 417.428 Marketing activities.

The requirements and prohibitions set forth in § 422.80 of this chapter, for M+C organizations, apply also to HMOs and CMPs with contracts under section 1876 of the Act.

6. In § 417.472, paragraph (h) is revised to read as follows:

§ 417.472 Basic contract requirements.

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(h) *Collection of fees from risk HMOs and CMPs.* (1) The rules set forth in § 422.10 of this chapter for M+C plans also apply to collection of fees from risk HMOs and CMPs.

(2) In applying the part 422 rules, references to "M+C organizations" or "M+C plans" must be read as references to "risk HMOs and CMPs".

Subpart M—[Amended]

7. Sections 417.520, 417.522 and 417.523 of subpart M are redesignated as §§ 422.550, 422.522 and 422.553 in a new subpart L in part 422, and the heading for the new subpart L to part 44 is added to read "Change of Ownership and Leasing of Facilities: Effect on Medicare Contract, under part 422, Medicare+Choice Program".

8. A new § 417.520 is added to subpart M to read as follows:

§ 417.520 Effect on HMO and CMP contracts.

(a) The provisions set forth in subpart L of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying these provisions, references to "M+C organizations" must be read as references to "HMOs and CMPs".

(c) In § 422.550, reference to "subpart K of this part" must be read as reference to "subpart L of part 417 of this chapter".

(d) In § 422.553, reference to "subpart K of this part" must be read as reference to "subpart J of part 417 of this chapter".

9. In § 417.584, a new paragraph (e) is added to read as follows:

§ 417.584 Payment to HMOs or CMPs with risk contracts.

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(e) *Determination of rate for calendar year 1998.* For calendar year 1998, HMOs or CMPs with risk contracts will be paid in accordance with principles contained in subpart F of part 422 of this chapter.

Subpart Q—[Amended]

10. In subpart Q, §§ 417.600 through 417.638 are removed.

11. A new § 417.600 is added to subpart Q as follows:

§ 417.600 Beneficiary appeals and grievances.

(a) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act; and references to M+C organizations as references to HMOs and CMPs.

12. In § 417.800 paragraph (a) introductory text is republished and the definition for "Health care prepayment plan" is revised to read as follows:

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions:* As used in this subpart, unless the context indicates otherwise—

* * * * *

Health care prepayment plan (HCPP) means an organization that—

(1) Is union or employer sponsored;
 (2) Does not provide, or arrange for the provision of any in patient hospital services. Current HCPPs must meet this definition on January 1, 1999 and 1998 applicants must meet the definitions as of the effective date of the HCPP agreement. As of January 1, 1999, HCPPs are not required to meet Medigap requirements.

(3) Is responsible for the organization, financing and delivery of covered Part B services to a defined population on a prepayment basis;

(4) Meets the conditions specified in paragraph (b) of this section; and

(5) Elects to be reimbursed on a reasonable cost basis.

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F. Part 422

PART 422—MEDICARE+CHOICE PROGRAM

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1851 through 1857, 1859, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w-21 through 1395w-27, and 1395hh).

2. Subparts A through G are added as follows:

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Subpart A—General Provisions

§ 422.1 Basis and scope.

(a) *Basis*. This part is based on the indicated provisions of the following sections of the Act:

- 1851—Eligibility, election, and enrollment.
 1852—Benefits and beneficiary protections.
 1853—Payments to Medicare+Choice (M+C) organizations.
 1854—Premiums.
 1855—Organization, licensure, and solvency of M+C organizations.
 1856—Standards.
 1857—Contract requirements.
 1859—Definitions; enrollment restriction for certain M+C plans.

(b) *Scope*. This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare+Choice organizations through Medicare+Choice plans.

§ 422.2 Definitions.

As used in this part—
ACR stands for adjusted community rate.

Additional benefits are health care services not covered by Medicare, and reductions in premiums or cost-sharing for Medicare covered services, funded from adjusted excess amounts as calculated in the ACR.

Adjusted community rate (ACR) is the equivalent of the maximum amount allowed under § 422.310.

Arrangement means a written agreement between an M+C organization and a provider or provider network, under which—

- (1) The provider or provider network agrees to furnish for a specific M+C plan(s) specified services to the organization's M+C enrollees;
- (2) The organization retains responsibilities for the services; and
- (3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means all Medicare-covered benefits, except hospice services, and additional benefits.

Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the M+C organization incurs a cost or liability under an M+C plan, and that are approved in the Benefit/ACR process.

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an M+C enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an M+C plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

- (1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(2) Serious impairment to bodily functions; or

(3) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are—

- (1) Furnished by a provider qualified to furnish emergency services; and
- (2) Needed to evaluate or stabilize an emergency medical condition.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an M+C contract.

M+C stands for Medicare+Choice.

M+C eligible individual means an individual who meets the requirements of § 422.50.

M+C organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by HCFA as meeting the M+C contract requirements.

M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.

M+C plan enrollee is an M+C eligible individual who has elected an M+C plan offered by an M+C organization.

Mandatory supplemental benefits are services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.
MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes an M+C MSA. A trustee may be a bank, an insurance company, or any other entity that—

- (1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and
- (2) Meets the requirements of § 422.262(b).

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for-service payment system.

Optional supplemental benefits means health benefits normally not covered by Medicare purchased at the option of the M+C enrollee and that are

paid for directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Point of service (POS) is a benefit option that an M+C coordinated care plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the M+C plan allows members the option of receiving specified services outside of the M+C plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, where offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an M+C organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an M+C coordinated care or network MSA plan.

Religious and Fraternal (RFB) Society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means a coordinated care plan that is offered by an RFB society.

Service area means a geographic area approved by HCFA within which an M+C eligible individual may enroll in a particular M+C plan offered by the organization. For coordinated care plans and network medical savings account (MSA) plans only, the service area also is the area within which a network of providers exists that meets the access standards in § 422.112. The service area also defines the area where a uniform benefit package is offered. In deciding whether to approve a service area proposed by an M+C organization for an M+C plan, HCFA considers the M+C organization's commercial service area for the type of plan in question (if

applicable), community practices generally, whether the boundaries of the service area are discriminatory in effect, and, in the case of coordinated care and network MSA plans, the adequacy of the provider network in the proposed service area. HCFA may approve single county M+C non-network MSA plans even if the M+C organization has a different commercial service area.

Urgently needed services means covered services provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when such services are medically necessary and immediately required—

(1) As a result of an unforeseen illness, injury, or condition; and

(2) It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

§ 422.4 Types of M+C plans.

(a) *General rule.* An M+C plan may be a coordinated care plan, a combination of an M+C MSA plan and a contribution into an M+C MSA established in accordance with § 422.262, or an M+C private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by HCFA.

(i) The network is approved by HCFA to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include health maintenance organizations (HMOs), provider-sponsored organizations (PSOs) and preferred provider organizations (PPOs), RFBs, and other network plans (except network MSA plans).

(2) *A combination of an M+C MSA plan and a contribution into the M+C MSA established in accordance with § 422.262.* (i) *M+C MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee

has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d); and

(B) Meets all other applicable requirements of this part.

(ii) An M+C MSA plan may be either a network plan or a non-network plan.

(A) *M+C network MSA plan* means an MSA plan under which enrollees must receive services through a defined provider network that is approved by HCFA to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(B) *M+C non-network MSA plan* means an MSA plan under which enrollees are not required to receive services through a provider network.

(iii) *M+C MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by HCFA under the M+C program, or a trustee-to-trustee transfer or rollover from another M+C MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *M+C private fee-for-service plan.* An M+C private fee-for-service plan is an M+C plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Does not vary the rates for a provider based on the utilization of that provider's services; and

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(b) *Multiple plans.* Under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from HCFA a waiver of the State licensing requirement). If an M+C organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of M+C plan.

§ 422.6 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an M+C organization and is qualified to provide a particular type of M+C plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by HCFA, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to M+C 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 M+C contract; or

(ii) Federal waiver as described in subpart H of this part.

(2) The authorized individual must describe thoroughly how the entity and M+C plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* HCFA is responsible for determining whether an entity qualifies as an M+C organization and whether proposed M+C plans meet the requirements of this part.

(d) *Resubmittal of application.* An application that has been denied by HCFA may not be resubmitted for 4 months after the date of the notice from HCFA denying the application.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department'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.

§ 422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, HCFA determines whether

the entity's application meets the applicable requirements of § 422.6.

(b) *Use of information from a prior contracting period.* If an entity has failed to comply with the terms of a previous year's contract with HCFA under title XVIII of the Act as an HMO, competitive medical plan, health care prepayment plan, or M+C organization or an entity has failed to complete a corrective action plan during the term of the contract, HCFA may deny an application based on the entity's failure to comply with that prior contract with HCFA even if the entity meets all of the current requirements.

(c) *Notice of determination.* HCFA notifies each entity that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If HCFA approves the application, it gives written notice to the M+C organization, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If HCFA finds that the entity does not appear to meet the requirements of an M+C organization and appears to be able to meet those requirements within 60 days, HCFA gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding and may revise its application to remedy any defects HCFA identified.

(f) *Denial of application.* If HCFA denies the application, it gives written notice to the M+C organization indicating—

(1) That the M+C organization does not meet the contract requirements under part C of title XVIII of the Act;

(2) The reasons why the M+C organization does not meet the contract requirements; and

(3) The M+C organization's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.* (1) HCFA oversees an entity's continued compliance with the requirements for an M+C organization.

(2) If an entity no longer meets those requirements, HCFA terminates the contract in accordance with § 422.510.

§ 422.10 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing

in enrollment-related costs. It sets forth the procedures that HCFA follows to assess the required fees on M+C plans offered by M+C organizations.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes HCFA to charge and collect from each M+C plan offered by an M+C organization its pro rata share of fees for administering section 1851 of the Act, relating to dissemination of enrollment information; and section 4360 of the Omnibus Budget Reconciliation Act of 1990, relating to the health insurance counseling and assistance program.

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees—(1) Timing of collection.* HCFA collects the fees over nine consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of the following:

(i) The estimated costs to be incurred by HCFA in that fiscal year to carry out the activities described in paragraph (b) of this section.

(ii) The amount authorized in the DHHS appropriation for the fiscal year.

(e) *Assessment methodology.* (1) The amount assessed is a percentage of the total Medicare payments to each organization. HCFA determines the percentage rate using the following formula:

A times B divided by C where—

A is the total of the estimated January payments to all organizations subject to assessment;

B is the nine-month (January through September) assessment period; and

C is the total assessment amount authorized for the particular fiscal year in accordance with paragraph (d)(2) of this section.

(2) HCFA determines each organization's pro rata share of the annual fee on the basis of that organization's calculated monthly payment amount during the nine consecutive months beginning with January. HCFA calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in HCFA's payment system on the first day of the month.

(3) HCFA deducts the organization's fee from the amount of Federal funds otherwise payable to the organization for that month under the M+C program.

(4) If assessments reach the amount authorized for the year before the end of

September, HCFA discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section or the fee percentage rate specified in paragraph (e), HCFA may adjust the assessment time period and the fee percentage amount.

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Suppart B—Eligibility, Election, and Enrollment

§ 422.50 Eligibility to elect an M+C plan.

(a) An individual is eligible to elect an M+C plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who is (or was) enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the M+C organization may continue to be enrolled in the M+C organization as an M+C plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization offering an M+C plan in the service area or continuation area in which the individual resides may continue to be enrolled in the M+C organization as an M+C plan enrollee;

(3) Resides in the service area of the plan, except that an individual who resides in a continuation area of an M+C plan while enrolled in a health plan offered by the M+C organization may continue to be enrolled in the M+C organization as an M+C plan enrollee;

(4) Completes and signs an election form and gives information required for enrollment; and

(5) Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

(b) An M+C eligible individual may not be enrolled in more than one M+C plan at any given time.

§ 422.54 Continuation of enrollment.

(a) *Definition. Continuation area* means an additional area (outside the service area) within which the M+C organization furnishes or arranges for furnishing services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any plan.

(b) *Basis rule.* An M+C organization may offer a continuation of enrollment

option to enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the M+C organization as a continuation of enrollment area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as, driver's license, voter registration.

(c) *General requirements.* (1) An M+C organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain HCFA's approval of the continuation area, the marketing materials that describe the option, and the M+C organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the plan.

(d) *Specific requirements—(1) Basic benefits.* The M+C organization must, at a minimum, provide or arrange for the Medicare-covered benefits described in § 422.101(a).

(2) *Reasonable access.* The M+C organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet requirements in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) *Reasonable cost-sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to—

(i) The cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides) if provided by contract providers;

(ii) The cost-sharing amounts required by the continuation area plan if provided through agreements with another M+C plan; or

(iii) The amount for which a beneficiary would be liable under original Medicare if noncontracting providers furnish the services.

(4) *Protection of enrollee rights.* An M+C organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements

remain with the organization that is receiving payment from HCFA; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the marketing materials.

(e) *Capitation payments.* HCFA's capitation payments to all M+C organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

§ 422.56 Limitations on enrollment in an M+C MSA plan.

(a) *General.* An individual is not eligible to elect an M+C MSA plan—

(1) If the number of individuals enrolled in M+C MSA plans has reached 390,000;

(2) Unless the individual provides assurances that are satisfactory to HCFA that he or she will reside in the United States for at least 183 days during the year for which the election is effective; or

(3) On or after January 1, 2003, unless the enrollment is the continuation of an enrollment in effect as of that date.

(b) *Individuals eligible for or covered under other health benefits program.* An individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an M+C MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an M+C MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the M+C MSA plan may not enroll in an M+C MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice benefit, supplemental insurance policies not specifically permitted under § 422.103, and retirement health benefits.

§ 422.57 Limited enrollment under M+C RFB plans.

An RFB society that offers an M+C RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§ 422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an M+C MSA plan provided by § 422.62(d)(1) and except as specified in paragraph (a)(2) of this section, each M+C organization must accept without restriction (except for an M+C RFB plan as provided by § 422.57) individuals who are eligible to elect an M+C plan that M+C organization offers and who elect an M+C plan during initial coverage election periods, annual election periods, and special election periods specified in § 422.62 (a)(1), (a)(2), and (b).

(2) M+C organizations must accept elections during the open enrollment periods specified in § 422.62(a)(3), (a)(4), and (a)(5) if their M+C plans are open to new enrollees.

(b) *Capacity to accept new enrollees.* (1) M+C organizations must submit information on enrollment capacity of plans they offer by May 1 of each year as provided by § 422.306(a)(2).

(2) If HCFA determines that an M+C plan offered by an M+C organization has a capacity limit, and the number of M+C eligible individuals who elect to enroll in that plan exceeds the limit, the M+C organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the HCFA determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

(c) *Election forms.* (1) The election form must comply with HCFA instructions regarding content and format and have been approved by HCFA as described in § 422.80. The form must be completed and signed by the M+C eligible individual beneficiary (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary.

(2) The M+C organization must file and retain election forms for the period specified in HCFA instructions.

(d) *When an election is considered to have been made.* An election in an M+C plan is considered to have been made

on the date the election form is received by the M+C organization.

(e) *Handling of election forms.* The M+C organization must have an effective system for receiving, controlling, and processing election forms. The system must meet the following conditions and requirements:

(1) Each election form is dated as of the day it is received.

(2) Election forms are processed in chronological order, by date of receipt.

(3) The M+C organization gives the beneficiary prompt written notice of acceptance or denial in a format specified by HCFA.

(4) In a format specified by HCFA, a notice of acceptance—

(i) Promptly informs the beneficiary of the date on which enrollment will be effective under § 422.68; and

(ii) If the M+C plan is enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) A notice of denial explains the reasons for denial in a format specified by HCFA.

(6) Within 30 days from receipt of the election form (or from the date a vacancy occurs for an individual who was accepted for future enrollment), the M+C organization transmits the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

§ 422.62 Election of coverage under an M+C plan.

(a) *General: Coverage election periods—*(1) *Initial coverage election period.* The initial coverage election period is the period during which a new M+C eligible individual may make an initial election. This period begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement.

(2) *Annual election period.* (i) Beginning in 1999, the month of November is the annual election period for the following calendar year. Organizations offering M+C plans in January 1999 must open enrollment to Medicare beneficiaries in November 1998.

(ii) During the annual election period, an individual eligible to enroll in an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan.

(3) *Open enrollment and disenrollment opportunities through 2001.* From 1998 through 2001, the number of elections or changes that an M+C eligible individual may make is not limited (except as provided for in

paragraph (d) of this section for M+C MSA plans). Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan.

(4) *Open enrollment and disenrollment during 2002.* (i) Except as provided in paragraphs (a)(4)(ii) and (a)(4)(iii) of this section, an individual who is eligible to elect an M+C plan in 2002 may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 6 months of the year.

(ii) *Newly eligible M+C individual.* An individual who becomes an M+C eligible individual during 2002 may elect an M+C plan or original Medicare and then change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of such entitlement, or on December 31, whichever is earlier. The individual can change the election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan during this period.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual election period specified in (a)(2) of this section or during a special enrollment period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2003.* (i) For 2003 and subsequent years, except as provided in paragraphs (a)(5)(ii) and (a)(5)(iii) of this section, an individual who is eligible to elect an M+C plan may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 3 months of the year.

(ii) *Newly eligible M+C individual.* An individual who becomes an M+C eligible individual during 2003 or later may elect an M+C plan or original Medicare and then change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of such entitlement, or on December 31, whichever is earlier. The individual can change the election from an M+C plan to original Medicare or to a different

M+C plan, or from original Medicare to an M+C plan during this period.

(iii) The limitation to one election or change in paragraphs (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections or changes made during the annual election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(b) *Special election periods.* Effective as of January 1, 1999 for M+C plans, and as of January 1, 2002, for all MSA other types of M+C MSA plans, an individual may at any time (that is, not limited to the annual election period) discontinue the election of an M+C plan offered by an M+C organization and change his or her election, in the form and manner specified by HCFA, from an M+C plan to original Medicare or to a different M+C plan under any of the following circumstances:

(1) HCFA has terminated the organization's contract for that plan or the organization has terminated or discontinued offering the plan in the service area or continuation area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by HCFA but not including terminations resulting from a failure to make timely payment of an M+C monthly or supplemental beneficiary premium, or from disruptive behavior.

(3) The individual demonstrates to HCFA, in accordance with guidelines issued by HCFA, that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(4) The individual meets such other exceptional conditions as HCFA may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an M+C eligible individual who elects an M+C plan during the initial coverage election period, as defined under section 1837(d) of the Act, that

surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the M+C plan.

(d) *Special rules for M+C plans—(1) Enrollment.* An individual may enroll in an M+C plan only during an initial or annual election period described in paragraphs (a)(1) and (a)(2) of this section or during November 1998.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an M+C plan only during—

(A) November 1998;

(B) An annual election period; or

(C) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an M+C MSA plan during an annual election period and has never before elected an M+C MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the M+C MSA plan a signed and dated request in the form and manner prescribed by HCFA or by filing the appropriate disenrollment form through other mechanisms as determined by HCFA.

§ 422.64 Information about the M+C program.

(a) *Source of information.* Each M+C organization must provide, on an annual basis and in a format and using standard terminology that may be specified by HCFA, the information necessary to enable HCFA to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

(b) *Timing and recipients of the information.* HCFA mails a notice containing the information described in paragraph (c) of this section—

(1) At least 15 days before each annual election period, to each individual eligible to elect an M+C plan; and

(2) To the extent practicable, not later than 30 days before his or her initial coverage election period to each individual who will become eligible to elect an M+C plan.

(c) *Content of notice—(1) Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.*

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

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the M+C program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Medigap and Medicare Select.* A general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under section 1882 of the Act, and provisions relating to Medicare Select policies under section 1882(t) of the Act.

(5) *Potential for contract termination.* The fact that an M+C 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 M+C plan.

(6) *Comparative information.* A list of M+C plans that are or will be available to residents of the service area in the following calendar year, and, for each available plan, information on the aspects described in paragraphs (c)(7) through (c)(11) of this section, presented in a manner that facilitates comparison among the plans.

(7) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an M+C MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(v) In the case of a M+C private fee-for-service plan, differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(viii) The coverage of emergency and urgently needed services.

(8) *Premiums.* (i) The M+C monthly basic beneficiary premiums.

(ii) The M+C monthly supplemental beneficiary premium.

(9) *The plan's service area.*

(10) *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):

(i) 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 HCFA guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(11) *Supplemental benefits.* Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits.

(d) *Format and updating.* The information is written and formatted using language that is easily understandable, and is updated at least annually.

(e) *Mailing.* The mailing is coordinated, to the extent practicable, with the mailing of the annual notice of Medicare benefits under section 1804 of the Act.

§ 422.66 Coordination of enrollment and disenrollment through M+C organizations.

(a) *Enrollment.* An individual who wishes to elect an M+C plan offered by an M+C organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by HCFA.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an M+C plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by HCFA.

(ii) Submit a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by HCFA or file the appropriate disenrollment form through other mechanisms as determined by HCFA.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the disenrollment request is received by the M+C organization.

(3) *Responsibilities of the M+C organization.* The M+C organization must—

(i) Submit a disenrollment notice to HCFA within 15 days of receipt;

(ii) Provide the enrollee with a copy of the request for disenrollment; and

(iii) In the case of a plan where lock-in applies, also provide the enrollee with a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the M+C organization nor HCFA pays for services not provided or arranged for by the M+C plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in HCFA instructions.

(4) *Effect of failure to submit disenrollment notice to HCFA promptly.* If the M+C organization fails to submit the correct and complete notice required in paragraph (b)(3)(i) of this section, the M+C organization must reimburse HCFA for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* HCFA may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(c) *Election by default: Initial coverage election period.* An individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An M+C plan offered by an M+C organization must accept any individual (residing in the service area or continuation area of the M+C plan) who is enrolled in a health plan offered by an M+C organization (regardless of whether the individual has end-stage renal disease) during the month immediately preceding the month in which he or she is entitled to both Part A and Part B as provided by § 422.50(a)(2) and (a)(3).

(2) *Reserved vacancies.* Subject to HCFA's approval, an M+C organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other M+C eligible individuals.

(3) *Effective date of conversion.* Unless the individual chooses to disenroll from the health plan offered by the M+C organization, the individual's

conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B.

(4) *Prohibition against disenrollment.* The M+C organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election form.* The individual who is converting must complete and sign an election form as described in § 422.60(c)(1).

(6) *Submittal of information to HCFA.* The M+C organization must transmit the information necessary for HCFA to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* An individual who has made or is deemed to have made an election under this section is considered to have continued to have made that election until either of the following, whichever occurs first:

(1) The individual changes the election under this section.

(2) The elected M+C plan is discontinued or no longer serves the service area in which the individual resides, and the organization does not offer or the individual does not elect the option of continuing enrollment, as provided in § 422.54.

422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B.

(b) *Annual election periods.* For an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year.

(c) *Open enrollment periods.* For an election or change of election made during an open enrollment period as described in § 422.62(a)(3) through (a)(5), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the effective date of coverage shall be determined by HCFA, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in

§ 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

§ 422.74 Disenrollment by the M+C organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an M+C organization may not—

(1) Disenroll an individual from any M+C plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment—(1) Optional disenrollment.* An M+C

organization may disenroll an individual from an M+C plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behaviors specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An M+C organization must disenroll an individual from an M+C plan it offers in any of the following circumstances:

(i) The individual no longer resides in the M+C plan's service area as specified in paragraph (d)(4) of this section, and optional continued enrollment has not been offered or elected pursuant to § 422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(3) *Plan termination or reduction of service area or continuation area.* An M+C plan offered by an M+C organization that terminates with respect to all M+C individuals in the area where the individual resides or is terminated or reduces service area or continuation area must comply with the process for disenrollment set forth at paragraph (d)(7) of this section.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(3) of this section, that is, other than death or loss of entitlement to Part A or Part B, the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C

organization is planning to disenroll the individual.

(1) The notice must be mailed to the individual before submission of the disenrollment notice to HCFA.

(2) The notice must include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures.

(d) *Process for disenrollment—(1) Monthly basic and supplementary premiums are not paid timely.* An M+C

organization may disenroll an individual from the M+C plan for failure to pay any basic or supplementary premiums if the M+C organization—

(i) Makes a reasonable effort to collect unpaid premium amounts by sending a written notice of nonpayment to the enrollee within 20 days after the date that the delinquent charges were due—

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with an explanation of the disenrollment procedures and any lock-in requirements of the M+C plan; and

(C) Advising that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage;

(ii) Only disenrolls a Medicare enrollee when the organization has not received payment within 90 days after the date it has sent the notice of nonpayment to the enrollee; and

(iii) Gives the individual a written notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(2) *Disenrollment for disruptive behavior—(i) Basis for disenrollment.* An M+C organization may disenroll an individual from the M+C plan if the individual's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continued enrollment in the plan seriously impairs the M+C plan's ability to furnish services to either the particular individual or other individuals enrolled in the plan.

(ii) *Effort to resolve the problem.* The M+C organization must make a serious effort to resolve the problems presented by the individual, including the use (or attempted use) of the M+C organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the M+C organization.

(iii) *Consideration of extenuating circumstances.* The M+C organization must establish that the individual's behavior is not related to the use of medical services or to diminished mental capacity.

(iv) *Documentation.* The M+C organization must document the enrollee's behavior, its own efforts to resolve any problems, and any extenuating circumstances, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of this section.

(v) *HCFA review of the M+C organization's proposed disenrollment.* (A) HCFA decides after reviewing the documentation submitted by the M+C organization and any information submitted by the beneficiary (which the M+C organization must forward to HCFA) whether the M+C organization has met the disenrollment requirements.

(B) HCFA makes the decision within 20 working days after receipt of the documentation and notifies the M+C organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If HCFA permits an M+C organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the M+C organization gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Individual commits fraud or permits abuse of enrollment care. (i) Basis for disenrollment.* An M+C organization may disenroll the individual from an M+C plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the M+C plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the M+C plan.

(ii) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to HCFA.* The M+C organization must report to HCFA any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the M+C plan's service area—(i) Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the M+C organization must disenroll an individual who moves out of a plan's service area if the M+C organization establishes, on the basis of a written statement from the individual, or other evidence acceptable to HCFA, that the individual has moved out of a plan's service area for over 12 months.

(ii) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that

meets the requirements set forth in paragraph (c) of this section.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, HCFA notifies the M+C organization that the disenrollment is effective the first day of the calendar month following the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) If the plan terminates or is terminated or the service area or continuation area are reduced with respect to all M+C enrollees in the area in which they reside, the M+C organization must give each Medicare enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction.

(e) *Consequences of disenrollment—*
(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B.* An individual who is disenrolled under paragraph (b)(1)(i), (b)(1)(ii), (b)(1)(iii), or paragraph (b)(2)(i) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

§ 422.80 Approval of marketing materials and election forms.

(a) *HCFA review of marketing materials.* An M+C organization may not distribute any marketing materials (as defined in paragraph (b)), or election forms, or make such materials or forms available to individuals eligible to elect an M+C plan, unless—

(1) At least 45 days before the date of distribution the M+C organization has submitted the material or form to HCFA for review under the guidelines in paragraph (c); and

(2) HCFA has not disapproved the distribution of the material or form.

(b) *Definition of marketing materials.* Marketing materials include any

informational materials targeted to Medicare beneficiaries which:

(1) Promote the M+C organization, or any M+C plan offered by the M+C organization;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an M+C plan offered by the M+C organization;

(3) Explain the benefits of enrollment in an M+C plan, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under an M+C plan, including conditions that apply to such coverage;

(5) Examples of marketing materials include, but are not limited to:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (e.g., physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks, and newsletters.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities (e.g., materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

(c) *Guidelines for HCFA Review.* In reviewing marketing material or election forms under paragraph (a) of this section, HCFA determines that the marketing materials:

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by HCFA, the following information to Medicare beneficiaries interested in enrolling:

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written description of any supplemental benefits and services.

(iii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iv) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its service and continuation area.

(3) Include in the written materials notice that the organization is authorized by law to refuse to renew its contract with HCFA, that HCFA also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(4) Contain no statements that are inaccurate or misleading or otherwise make misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(d) *Deemed approval (one-stop shopping).* If HCFA has not disapproved the distribution of marketing material or forms submitted by an M+C organization with respect to an M+C plan in an area, HCFA is deemed not to have disapproved the distribution in all other areas covered by the M+C plan and organization except with regard to any portion of the material or form that is specific to the particular area.

(e) *Standards for M+C organization marketing.*

(1) In conducting marketing activities, M+C organizations may not:

(i) Provide for cash or other monetary rebates as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the M+C plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services.

(ii) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit door-to-door for Medicare beneficiaries.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the M+C organization, the M+C organization may not claim that it is recommended or endorsed by HCFA or Medicare or that HCFA or Medicare recommends that the beneficiary enroll in the M+C plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day

period, the M+C organization receives from HCFA written notice of disapproval because it is inaccurate or misleading, or misrepresents the M+C organization, its marketing representatives, or HCFA.

(2) In its marketing, the M+C organization must:

(i) Demonstrate the HCFA's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact, enrolled in the M+C plan, and understand the rules applicable under the plan.

(f) *Employer group retiree Marketing.* HCFA may permit M+C organizations to develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and to furnish these materials only to such group members. While such materials must be submitted for approval under paragraph (a) of this section, HCFA will only review portions of these materials that related to M+C plan benefits.

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Subpart C—Benefits and Beneficiary Protections

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an M+C organization offering an M+C plan must provide enrollees in that plan with coverage of the basic benefits described in § 422.101 (and, to the extent applicable, the benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. HCFA reviews these benefits subject to the requirements of § 422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An M+C organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the M+C organization to provide services covered by the M+C plan:

(i) Emergency services as defined in § 422.2.

(ii) Urgently needed services as defined § 422.2.

(iii) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(iv) Post-stabilization care services that were—

(A) Pre-approved by the organization; or

(B) Were not pre-approved by the organization because the organization did not respond to the provider of post-stabilization care services' request for pre-approval within 1 hour after being requested to approve such care, or could not be contacted for pre-approval.

(v) Services for which coverage has been denied by the M+C organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the M+C organization.

(2) An M+C plan (other than an M+C MSA plan) offered by an M+C organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that M+C plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An M+C plan may include two types of benefits:

(1) Basic benefits as defined in § 422.2.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits as defined in § 422.2; and

(ii) Optional supplemental benefits as defined in § 422.2.

(d) *Availability and structure of plans.* An M+C organization offering an M+C plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the M+C plan;

(2) At a uniform premium; and

(3) With a uniform level of cost-sharing, as defined in § 422.2.

(e) *Terms of M+C plans.* Terms of M+C plans described in instructions to beneficiaries, as required by § 422.111, will include basic and supplemental benefits and terms of coverage for those benefits.

(f) *Multiple plans in one service area.* An M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations set forth in this subpart for each M+C plan.

(g) *HCFA review and approval of M+C plans.* HCFA reviews and approves each M+C plan to ensure that the plan does not—

(1) Promote discrimination;

(2) Discourage enrollment;

(3) Steer specific subsets of Medicare beneficiaries to particular M+C plans; or

(4) Inhibit access to services.

(h) *Benefits affecting screening mammography, influenza vaccine, and pneumococcal vaccine.* (1) Enrollees of

M+C organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) M+C organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine.

(i) *Requirements relating to Medicare conditions of participation.* Basic benefits must be provided through providers meeting the requirements in § 422.204(a)(3).

(j) *Choice of practitioners.* Consistent with the requirements of § 422.204 relating to the prohibition of discrimination against providers, if more than one type of practitioner is qualified to furnish a particular service, the M+C organization may select the type of practitioner to be used.

§ 422.101 Requirements relating to basic benefits.

Except as specified in § 422.264 (for entitlement that begins or ends during a hospital stay) and § 422.266 (with respect to hospice care), each M+C organization must—

(a) Provide coverage of, through the provision of or payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the geographic area in which services are covered under the M+C plan (or to Part A and Part B services obtained outside the geographic area if it is common practice to refer patients to sources outside that geographic area); and

(b) Comply with—

(1) HCFA's national coverage decisions; and

(2) Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C plan.

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to HCFA's approval, an M+C organization may require Medicare enrollees of an M+C plan other than an MSA plan to accept and pay for services in addition to those included in the basic benefits described in § 422.101.

(2) If the M+C organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the M+C plan.

(3) HCFA approves mandatory supplemental benefits if it determines that imposition of the mandatory benefits will not substantially discourage Medicare beneficiaries from enrolling in the M+C plan.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the

case of MSA plans, each M+C organization may offer (for election by the enrollee and without regard to health status) services that are in addition to those included in the basic benefits described in § 422.101 and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits must be offered to all Medicare beneficiaries enrolled in the M+C plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for directly by (or on behalf of) the enrollee of the M+C plan.

§ 422.103 Benefits under an M+C MSA plan.

(a) *General rule.* An M+C organization offering an M+C MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described under in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

(b) *Countable expenses.* An M+C organization offering an M+C MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an M+C organization offering an M+C MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an M+C MSA plan—

(1) For contract year 1999, may not exceed \$6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under § 422.252(b).

§ 422.104 Special rules on supplemental benefits for M+C MSA plans.

(a) An M+C organization offering an M+C MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in § 422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that HCFA may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for point of service option.

(a) A POS benefit is an option that an M+C organization may offer in an M+C coordinated care plan or network M+C MSA plan to provide enrollees with additional choice in obtaining specified health care services from individuals or entities that do not have a contract with the M+C organization to provide service through the M+C coordinated care plan or network M+C MSA plan offering the POS option. The plan may offer a POS option—

(1) Under a coordinated care plan only as an additional benefit as described in § 422.312;

(2) Under a coordinated care plan only as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan or network MSA plan as an optional supplemental benefit as described in § 422.102(b).

(b) *Approval required.* An M+C organization may not implement a POS benefit until it has been approved by HCFA.

(c) *Ensuring availability and continuity of care.* An M+C network plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* M+C organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The M+C organization must provide to beneficiaries enrolling in a plan with a POS benefit an "evidence of coverage" document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS Related Data.* An M+C organization that offers a POS benefit must report data on the POS benefit in the form and manner prescribed by HCFA.

§ 422.106 Special arrangements with employer groups.

An M+C organization may negotiate with an employer group to provide benefits to members of the employer group who are enrolled in an M+C plan offered by the organization. While these negotiated employer group benefits may be designed to complement the benefits available to Medicare beneficiaries enrolled in the M+C plan, they are offered by the employer group independently as the product of private negotiation. Examples of such employer-benefits include the following:

(a) Reductions in the portion of the premium that the M+C organization charges to the beneficiary.

(b) Reductions in portion of other cost sharing amounts the M+C organization charges to the beneficiary.

(c) The addition of benefits that may require additional premium and cost sharing. The addition of benefits and the charges for those benefits are not subject to HCFA review or approval.

§ 422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* HCFA does not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(b) *Responsibilities of the M+C organization.* The M+C organization must, for each M+C plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Determine the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

(c) *Charges to other entities.* The M+C organization may charge, or authorize a provider to charge, other individuals or entities for covered Medicare services

for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Charge to other insurers or the enrollee.* If a Medicare enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may charge, or authorize a provider to charge any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Charge to group health plans (GHPs) and large group health plans (LGHPs).* An M+C organization may charge a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

§ 422.109 Effect of national coverage determinations (NCDs).

(a) If HCFA determines and announces that an NCD meets the criteria for "significant cost" described in paragraph (c) of this section, an M+C organization is not required to assume risk for the costs of that service until the contract year for which the annual M+C capitation rate is determined on a basis that includes the cost of the NCD service.

(b) The M+C organization must furnish, arrange or pay for an NCD "significant cost" service prior to the adjustment of the annual M+C capitation rate. The following rules apply to such services:

(1) Medicare payment for the service is:

(i) In addition to the capitation payment to the M+C organization; and

(ii) Made directly by the fiscal intermediary and carrier to the M+C organization in accordance with original Medicare payment rules, methods, and requirements.

(2) NCD costs for which HCFA intermediaries and carriers will not make payment and are the responsibility of the M+C organization are—

(i) Services necessary to diagnose a condition covered by the NCD;

(ii) Most services furnished as follow-up care to the NCD service;

(iii) Any service that is already a Medicare-covered service and included in the annual M+C capitation rate; and

(iv) Any service, including the costs of the NCD service itself, to the extent the M+C organization is already obligated to cover it as an additional benefit under § 422.312 or supplemental benefit under § 422.102.

(3) NCD costs for which HCFA intermediaries and carriers make payment are—

(i) Costs relating directly to the provision of services related to the NCD that were noncovered services prior to the issuance of the NCD; and

(ii) A service that is not included in the M+C per capita payment rate.

(4) If the M+C organization does not provide or arrange for the service consistent with HCFA's NCD, enrollees may obtain the services through qualified providers not under contract to the M+C organization, and the organization will pay for the services consistent with § 422.109(c).

(5) Beneficiaries are liable for Part A deductible and any applicable coinsurance amounts.

(c) The term "significant cost" as it relates to a particular NCD means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is \$100,000;

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in § 422.254(b).

(2) The estimated cost of all of Medicare services furnished nationwide as a result of a particular NCD represents at least 0.1 percent of the national standardized annual capitation rate (see § 422.254(f)), multiplied by the total number of Medicare beneficiaries nationwide for the applicable calendar year.

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an M+C organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an M+C plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception.* An M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular M+C organization may not be disenrolled for that reason. An individual who is an enrollee of a particular M+C organization, and resides in the M+C plan service area at the time he or she first becomes M+C eligible, is considered to be "enrolled" in the M+C organization for purposes of the preceding sentence.

(c) Plans are required to observe the provisions of the Civil Rights Act, Age Discrimination Act, and Americans with Disabilities Act (see § 422.501(h)).

§ 422.111 Disclosure requirements.

(a) *Detailed description of plan provisions.* An M+C organization must disclose the information specified in § 422.64 and in paragraph (b) of this section—

(1) To each enrollee electing an M+C plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description.* The description must include the following information:

(1) *Service area.* The M+C plan's service area and any enrollment continuation area.

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

(i) The benefits offered under original Medicare, including the content specified in § 422.64(c);

(ii) For an M+C MSA plan, the benefits under other types of M+C plans; and

(iii) The availability of the Medicare hospice option and any approved hospices in the service area, including those the M+C organization owns, controls, or has a financial interest in.

(3) *Access.* The number, mix, and distribution (addresses) 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 M+C organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

(4) *Out-of-area coverage.* Out-of-area coverage provided by the plan.

(5) *Emergency coverage.* Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.2;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

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

(iv) 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 M+C plan.

(6) *Supplemental benefits.* Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules.* Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The M+C 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 M+C organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality assurance program.* A description of the quality assurance program required under § 422.152.

(10) *Disenrollment rights and responsibilities.*

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an M+C plan, an M+C organization must provide to the individual the following information:

(1) The information required under § 422.64(c).

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) 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

(i) Grievances according to § 422.564; and

(ii) Appeals according to § 422.578 et seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the M+C organization, including the most recently audited information regarding, at least, a description of the financial condition of the M+C organization offering the plan.

(d) *Changes in rules.* If an M+C organization intends to change its rules for an M+C plan, it must—

(1) Submit the changes for HCFA review under the procedures of § 422.80; and

(2) Give notice to all enrollees 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider within 15 working days of receipt or issuance of a notice of termination, as described in § 422.204(c)(4), to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must also be notified.

§ 422.112 Access to services.

(a) *Rules for coordinated care plans and network M+C MSA plans.* An M+C organization that offers an M+C coordinated care plan or network M+C MSA plan may specify the networks of providers from whom enrollees may obtain services if the following conditions are met:

(1) The M+C organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To do this, the M+C organization must do the following:

(i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically utilized in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) Select the panel of PCPs from which the enrollee selects a PCP.

(iii) Provide or arrange for necessary specialty care, and in particular—

(A) Women enrollees may choose direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits

(as defined in § 422.2) while the plan maintains a PCP or some other means for continuity of care; and

(B) Plans must have procedures approved by HCFA for—

(1) Identification of individuals with complex or serious medical conditions;

(2) Assessment of those conditions, including medical procedures to diagnose and monitor them on an ongoing basis; and

(3) Establishment and implementation of a treatment plan appropriate to those conditions, with an adequate number of direct access visits to specialists to accommodate the treatment plan.

Treatment plans must be time-specific and updated periodically by the PCP.

(2) In the case of involuntary termination of an M+C plan or specialist(s) for a reason other than for cause, the M+C organization must do the following:

(i) Inform beneficiaries, at the time of termination, of their right to maintain access to specialists.

(ii) Provide the names of other M+C plans in the area that contract with specialists of the beneficiary's choice, as well as an explanation of the process the beneficiary would need to follow should he or she decide to return to original Medicare.

(iii) If seeking a service area expansion for an M+C plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(iv) Demonstrate to HCFA that its providers in an M+C plan are credentialed through the process set forth at § 422.204(a).

(v) Establish written standards for—

(A) Timeliness of access to care and member services that meet or exceed standards established by HCFA. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the M+C organization must take corrective action as necessary;

(B) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations; and

(C) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(vi) Ensure that the hours of operation of its M+C plan providers are convenient to the population served by the plan and do not discriminate against Medicare enrollees.

(vii) Ensure services are provided in a culturally competent manner to all enrollees, including those with limited

English proficiency or reading skills, diverse cultural and ethnic backgrounds, and physical or mental disabilities.

(viii) Make plan services available 24 hours a day, 7 days a week, when medically necessary.

(ix) Provide coverage for emergency and urgent care services in accordance with paragraph (b) of this section.

(3) The M+C organization must ensure continuity of care and integration of services through arrangements that include, but are not limited to—

(i) Use of a practitioner who is specifically designated as having primary responsibility for coordinating the enrollee's overall health care;

(ii) Policies that specify whether services are coordinated by the enrollee's primary care practitioner or through some other means;

(iii) An ongoing source of primary care, regardless of the mechanism adopted for coordination of services;

(iv) Programs for coordination of care that coordinate services with community and social services generally available through contracting or noncontracting providers in the area served by the M+C plan, including nursing home and community-based services;

(v) Procedures to ensure that the M+C organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that—

(A) An initial assessment of each enrollee's health care needs is completed within 90 days of the effective date of enrollment.

(B) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the M+C organization, taking into account professional standards; and

(C) Appropriate and confidential exchange of information among provider network components;

(vi) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(vii) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

(b) *Special rules for all M+C organizations for emergency and urgently needed services.* (1) The M+C organization covers emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the organization; and

(ii) Without required prior authorization.

(2) The M+C organization may not deny payment for a condition that—

(i) Is an emergency medical condition as defined in § 422.2; or

(ii) A plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan.

(3) The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the M+C organization.

(4) For emergency services obtained outside the M+C plan's provider network, the organization may not charge the enrollee more than \$50 or what it would charge the enrollee if he or she obtained the services through the organization, whichever is less.

§ 422.114 Access to services under an M+C private fee-for-service plan.

(a) *Sufficient access.* (1) An M+C organization that offers an M+C private fee-for-service plan must demonstrate to HCFA that it has sufficient number and range of providers willing to furnish services under the plan.

(2) HCFA finds that an M+C organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the M+C organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the M+C private fee-for-service plan; or

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(b) *Freedom of choice.* M+C fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish procedures to do the following:

(a) Safeguard the privacy of any information that identifies a particular enrollee. Information from, or copies of, records may be released only to

authorized individuals, and the M+C organization must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released only in accordance with Federal or State laws, court orders, or subpoenas.

(b) Maintain the records and information in an accurate and timely manner.

(c) Ensure timely access by enrollees to the records and information that pertain to them.

(d) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, other health information, and enrollee information.

§ 422.128 Information on advance directives.

(a) Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An M+C organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the M+C organization.

(1) An M+C organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The M+C organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the M+C organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the M+C organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An M+C organization must be able to document its community education efforts.

(2) The M+C organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of M+C organizations are entitled to the protections specified in § 422.502(g).

Subpart D—Quality Assurance

§ 422.152 Quality assessment and performance improvement program.

(a) *General rule.* Each M+C organization that offers one or more M+C plans must have, for each of those plans, an ongoing quality assessment and performance improvement program that meets the applicable requirements of this section for the services it furnishes to its M+C enrollees.

(b) *Requirements for M+C coordinated care plans and network M+C MSA plans.* An organization offering an M+C coordinated care plan or M+C network MSA plan must do the following:

(1) Meet the requirements in paragraph (c)(1) of this section concerning performance measurement and reporting. With respect to an M+C coordinated care plan, an organization must also meet the requirements of paragraph (c)(2) of this section concerning the achievement of minimum performance levels. The requirements of paragraph (c)(2) of this section do not apply with respect to an M+C MSA plan.

(2) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

(3) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(4) Have in effect mechanisms to detect both underutilization and overutilization of services.

(5) Make available to HCFA information on quality and outcomes

measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(c) *Performance measurement and reporting.* The organization offering the plan must do the following:

(1) Measure performance under the plan, using standard measures required by HCFA, and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA, and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Achieve any minimum performance levels that HCFA establishes locally, regionally, or nationally with respect to the standard measures.

(i) In establishing minimum performance levels, HCFA considers historical plan and original Medicare performance data and trends.

(ii) HCFA establishes the minimum performance levels prospectively upon contract initiation and renewal.

(iii) The organization must meet the minimum performance levels by the end of the contract year.

(iv) In accordance with § 422.506, HCFA may decline to renew the organization's contract in the year that HCFA determines that it did not meet the minimum performance levels.

(d) *Performance improvement projects.* (1) Performance improvement projects are organization initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic follow-up on the effect of the interventions.

(2) Each project must address the entire population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) HCFA establishes M+C organization and M+C plan-specific obligations for the number and distribution of projects among the required clinical and nonclinical areas, in accordance with paragraphs (d)(4) and (d)(5) of this section, to ensure that the projects are representative of the entire spectrum of clinical and nonclinical care areas associated with a plan.

(4) The required clinical areas include:

- (i) Prevention and care of acute and chronic conditions.
- (ii) High-volume services.
- (iii) High-risk services.
- (iv) Continuity and coordination of care.

(5) The required nonclinical areas include:

- (i) Appeals, grievances, and other complaints.
- (ii) Access to, and availability of, services.

(6) In addition to requiring that the organization initiate its own performance improvement projects, HCFA may require that the organization—

- (i) Conduct particular performance improvement projects that are specific to the organization; and
- (ii) Participate in national or statewide performance improvement projects.

(7) For each project, the organization must assess performance under the plan using quality indicators that are—

- (i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and
- (ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Interventions must achieve improvement that is significant and sustained over time.

(10) The organization must report the status and results of each project to HCFA as requested.

(e) *Requirements for non-network M+C MSA plans and M+C private fee-for-service plans.* An organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan must do the following:

- (1) Measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to—
 - (i) Prevention and care of acute and chronic conditions;
 - (ii) High-volume services;
 - (iii) High-risk services; and
 - (iv) Enrollee satisfaction.
- (2) Evaluate the continuity and coordination of care furnished to enrollees.

(3) If the organization uses written protocols for utilization review, the organization must—

- (i) Base those protocols on current standards of medical practice; and
- (ii) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans—(1) Health information.* For all types of plans that it offers, an organization must—

- (i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;
- (ii) Ensure that the information it receives from providers of services is reliable and complete; and
- (iii) Make all collected information available to HCFA.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

§ 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

- (1) Require that the organization—
 - (i) Allocate adequate space for use of the review organization whenever it is conducting review activities; and
 - (ii) Provide all pertinent data, including patient care data, at the time the review organization needs the data to carry out the reviews and make its determinations.

(2) Except in the case of complaints about quality, exclude review activities that HCFA determines would duplicate review activities conducted as part of an accreditation process or as part of HCFA monitoring.

(c) *Exceptions.* The requirement of paragraph (a) of this section does not apply for an M+C private fee-for-service plan or a non-network M+C MSA plan if the organization does not carry out utilization review with respect to the plan.

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization may be deemed to meet any of the requirements of paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by HCFA; and

(2) The accreditation organization used the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deeming requirements.* The following requirements are deemable:

(1) The quality assessment and performance improvement requirements of § 422.152.

(2) The confidentiality and accuracy of enrollee records requirements of § 422.118.

(c) *Effective date of deemed status.*

The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by HCFA.

(2) The date the M+C organization is accredited by the accreditation organization.

(d) *Obligations of deemed M+C organizations.* An M+C organization deemed to meet Medicare requirements must—

(1) Submit to surveys by HCFA to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to HCFA a copy of its most recent accreditation survey, together with any survey-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements).

(e) *Removal of deemed status.* HCFA removes part or all of an M+C organization's deemed status for any of the following reasons:

(1) HCFA determines, on the basis of its own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted.

(2) HCFA withdraws its approval of the accreditation organization that accredited the M+C organization.

(3) The M+C organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* HCFA retains the authority to initiate enforcement action against any M+C

organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* HCFA may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting M+C organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It is not controlled, as defined in § 413.17 of this chapter, by the entities it accredits.

(b) *Notice and comment—(1) Proposed notice.* HCFA publishes a proposed notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Specifies the basis for granting approval;

(ii) Describes how the accreditation organization's accreditation program meets or exceeds all of the Medicare requirements for which HCFA would deem compliance on the basis of the organization's accreditation; and

(iii) Provides opportunity for public comment.

(2) *Final notice.* (i) After reviewing public comments, HCFA publishes a final **Federal Register** notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If HCFA grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by HCFA must undertake the following activities on an ongoing basis:

(1) Provide to HCFA in written form and on a monthly basis all of the following:

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

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed M+C organizations.

(iv) Information about any M+C organization against which the accrediting organization has taken

remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without HCFA approval, HCFA may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in HCFA requirements, submit to HCFA—

(i) An acknowledgment of HCFA's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to HCFA's new requirements, within the time-frames specified in the notification of change it receives from HCFA.

(3) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited M+C organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give HCFA written notice of the deficiency.

(5) Within 10 days of HCFA's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* HCFA compares the accreditation organization's standards and its application and enforcement of those standards to the comparable HCFA requirements and processes when—

(i) HCFA imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* HCFA or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, HCFA identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by HCFA or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by HCFA or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or HCFA's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, HCFA gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* HCFA may withdraw its approval of an accreditation organization at any time if HCFA determines that—

(i) Deeming based on accreditation no longer guarantees that the M+C organization meets the M+C requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw HCFA approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.

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

(1) The types of M+C plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

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

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

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

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and

investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if HCFA approves the accreditation organization.

(9) A list of all currently accredited M+C organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by HCFA.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish HCFA with electronic data in HCFA compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If HCFA determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* HCFA may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of

documents, and interviews with the organization's staff.

(e) *Notice of determination.* HCFA gives the accreditation organization a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the M+C organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of HCFA's denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E—Relationships with Providers.

422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the M+C organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under M+C private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An M+C organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual health care professionals, and the management and members of groups of health care professionals, through reasonable procedures that include the following:

(1) Written notice of rules of participation such as terms for payment, utilization review, quality improvement programs, credentialing, data reporting, confidentiality, guidelines or criteria for the furnishing of particular services, and other rules related to administrative policy.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to health care professionals.

(4) A process for appealing adverse decisions, including the right of physicians and other health care professionals to present information and their views on the decision. In the case of a termination of a provider contract by the M+C organization, this process must conform to the rules in § 422.204(c).

(b) *Consultation.* The M+C organization must consult with the physicians, and other health care professionals who have agreed to provide services under an M+C plan offered by the organization, regarding the organization's medical policy, quality assurance program, and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting health care professionals; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) An M+C organization that operates an M+C plan through subcontracted physician groups or other subcontracted networks of health care professionals must provide that the participation procedures in this section apply equally

to physicians and other health care professionals within those subcontracted groups.

§ 422.204 Provider credentialing and provider rights.

(a) *Basic requirements.* An M+C organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure and other information from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 2 years that updates information obtained during initial credentialing and considers performance indicators such as those collected through quality assurance programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for receiving advice from contracting health care professionals with respect to criteria for credentialing and recredentialing; and

(iv) Requiring that, to the extent applicable, the requirements in paragraphs (a)(2)(i) and (a)(2)(iii) of this section are satisfied; and

(3)(i) Specify that basic benefits must be provided through, or payments must be made to, providers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of "provider of services" in section 1861(u), basic benefits may only be provided through such providers if they have a provider agreement with HCFA

permitting them to provide services under original Medicare.

(ii) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

(b) *Discrimination prohibited—(1) General rule.* An M+C organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification.

(2) *Construction.* The prohibition in paragraph (b)(1) of this section does not preclude any of the following by the M+C organization:

(i) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for M+C private-fee-for-service plans, which may not refuse to contract on this basis).

(ii) Use of different reimbursement amounts for different specialties.

(iii) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

(c) *Denial, suspension, or termination of contract.* The requirements in this paragraph (c) apply to an M+C organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers.

(1) *Notice to health care professional.* An M+C organization that denies, suspends, or terminates an agreement under which the health care professional provides services to M+C plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action.

(ii) The standards and the profiling data the organization used to evaluate the health care professional.

(iii) The numbers and mix of health care professionals the organization needs.

(iv) The affected health care professional's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The M+C organization must ensure that the majority of the hearing panel members are peers of the affected health care professional.

(3) *Notice to licensing or disciplinary bodies.* An M+C organization that suspends or terminates a contract with a health care professional because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An M+C organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an M+C plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the M+C plan to cover, furnish, or pay for a particular counseling or referral service if the M+C organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To HCFA, with its application for a Medicare contract, or within 10 days of submitting its ACR proposal, as appropriate.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the

exception provided in paragraph (a)(1) of this section if it provides notice within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An M+C organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability.* The requirements in this section apply to an M+C organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements.* Any physician incentive plan operated by an M+C organization must meet the following requirements:

(1) The M+C organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the M+C organization provides aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section, and conducts periodic surveys in accordance with paragraph (g) of this section.

(3) For all physician incentive plans, the M+C organization provides to HCFA the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis.* Substantial financial risk occurs when risk is based on the use or costs of referral services,

and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold.* The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk.* The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than

25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—Withhold % = -0.75 (Bonus %) +25%.

(v) Capitation arrangements, if—
(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) An M+C fee-for-service plan may not operate a physician incentive plan.

(f) Stop-loss protection requirements.

(1) *Basic rule.* The M+C organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient

stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1-1,000	\$6,000	\$10,000	\$3,000
1,001-5,000	30,000	40,000	10,000
5,001-8,000	40,000	60,000	15,000
8,001-10,000	75,000	100,000	20,000
10,001-25,000	150,000	200,000	25,000
>25,000	(1)	(1)	(1)

¹ None.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several M+C organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Periodic surveys of current and former enrollees.* An M+C organization must conduct periodic surveys of current and former enrollees where substantial financial risk exists. These periodic surveys must—

(1) Include either a sample of, or all, current Medicare/Medicaid enrollees in the M+C organization and individuals disenrolled in the past 12 months for reasons other than—

(i) The loss of Medicare or Medicaid eligibility;

(ii) Relocation outside the M+C organization's service area;

(iii) For failure to pay premiums or other charges;

(iv) For abusive behavior; and

(v) Retroactive disenrollment.

(2) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(3) Measure the degree of enrollees'/ disenrollees' satisfaction with the quality of the services provided and the degree to which the enrollees'/ disenrollees have or had access to the services provided under the M+C organization; and

(4) Be conducted no later than 1 year after the effective date of the M+C organization's contract and at least annually thereafter.

(i) *Sanctions.* An M+C organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

§ 422.210 Disclosure of physician incentive plans

(a) *Disclosure to HCFA—(1) Basic requirement.* Each M+C organization must provide to HCFA descriptive information about its physician incentive plan in sufficient detail to enable HCFA to determine whether that plan complies with the requirements of § 422.208. Reporting should be on the HCFA PIP Disclosure Form (OMB No. 0938-0700).

(2) *Content.* The information must include at least the following:

(i) Whether services not furnished by the physician or physician group are covered by the incentive plan.

(ii) The type or types of incentive arrangements, such as, withholds, bonus, capitation.

(iii) The percent of any withhold or bonus the plan uses.

(iv) Assurance that the physicians or physician group has adequate stop-loss protection, and the amount and type of stop-loss protection.

(v) The patient panel size and, if the plan uses pooling, the pooling method.

(vi) If the M+C organization is required to conduct enrollee surveys, a summary of the survey results.

(3) *When disclosure must be made to HCFA.* An M+C organization must disclose annually to HCFA the physician incentive arrangements that are effective at the start of each year. In addition, HCFA does not approve an M+C organization's application for a contract unless the M+C organization discloses the physician incentive arrangements effective for that contract.

(b) *Disclosure to Medicare beneficiaries—Basic requirement.* An M+C organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the M+C organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

(4) If the M+C organization was required to conduct a survey, a summary of the survey results.

§ 422.212 Limitations on provider indemnification.

An M+C organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the M+C organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished to enrollees of coordinated care plans by providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an M+C plan also apply to the payment described in paragraph (a)(1) of this section.

(b) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.86(d)) that it could collect if the beneficiary were enrolled in original Medicare.

§ 422.216 Special rules for M+C private fee-for-service plans.

(a) *Payment to providers—(1) Payment rate.* (i) The M+C organization must establish uniform payment rates for items and services that apply to all contracting providers, regardless of whether the contract is signed or deemed under paragraph (f) of this section.

(ii) Contracting providers must be reimbursed on a fee-for-service basis.

(iii) The M+C organization must make information on its payment rates available to providers that furnish services that may be covered under the M+C private fee-for-service plan.

(2) *Payment to contract providers.* For each service, the M+C organization pays a contract provider (including one deemed to have a contract) an amount that is equal to the payment rate under paragraph (a)(1) of this section minus any applicable cost-sharing.

(3) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.109(g) and 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees—(1) Contract providers.* (i) Contract providers and "deemed" contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these

amounts must be the same for "deemed" contract providers as for those that have signed contracts in effect.

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The M+C organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for "deemed" contract providers as for those that have signed contracts in effect.

(iv) The M+C organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the M+C private fee-for-service plan as specified in § 422.308(b).

(c) *Enforcement of limit—(1) Contract providers.* An M+C organization that offers an M+C fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA.

(d) *Information on enrollee liability—*

(1) *General information.* An M+C organization that offers an M+C fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the M+C organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than \$500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The M+C organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

- (i) To an enrollee of an M+C fee-for-service plan; and
- (ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the M+C organization.

(2) Before furnishing the services, the provider—

- (i) Was informed of the individual's enrollment in the plan; and
- (ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in § 422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.*

Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from HCFA, a Medicare intermediary or carrier, or the M+C organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The M+C organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

- (i) The provider.
- (ii) The employer or billing agent of the provider.
- (iii) A partnership of which the provider is a member.
- (iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The M+C organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

- (A) Billing procedures.
- (B) The amount the organization will pay towards the service.
- (C) The amount the provider is permitted to collect from the enrollee.
- (D) The information described in § 422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credentialing requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in § 422.204(a)(1) and (a)(1)(iii).

§ 422.220 Exclusion of services furnished under a private contract.

An M+C organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An M+C organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Subpart F—Payments to Medicare+Choice Organizations

§ 422.249 Terminology.

In this subpart—

(a) The terms “per capita rate” and “capitation rate” (see § 422.252) are used interchangeably; and

(b) In the term “area-specific,” “area” refers to any of the payment areas described in § 422.250(c).

§ 422.250 General provisions.

(a) *Monthly payments—(1) General rule.* Except as provided in paragraph (a)(2) of this section, HCFA makes advance monthly payments equal to $\frac{1}{12}$ th of the annual M+C capitation rate for the payment area described in paragraph (c) of this section adjusted for such demographic risk factors as an individual's age, disability status, sex, institutional status, and other such factors as it determines to be appropriate to ensure actuarial equivalence. Effective January 1, 2000, HCFA adjusts for health status as provided in § 422.256(c). When the new risk adjustment is implemented, $\frac{1}{12}$ th of the annual capitation rate for the payment area described in paragraph (c) of this section will be adjusted by the risk adjustment methodology under § 422.256(d).

(2) *Special rules.* (i) *Enrollees with end-stage renal disease.* (A) For enrollees determined to have end-stage renal disease (ESRD), HCFA establishes special rates that are determined under an actuarially equivalent approach to that used in establishing the rates under original Medicare.

(B) HCFA reduces the payment rate by the equivalent of 50 cents per renal dialysis treatment. These funds will be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(ii) *MSA enrollees.* For MSA enrollees, HCFA makes advanced monthly payments as described in paragraph (a)(1) less the amount (if any) identified in § 422.262(c)(1)(ii) to be deposited in the M+C MSA. In addition, HCFA deposits in the M+C MSA the lump sum amounts (if any) determined in accordance with § 422.262(c).

(iii) *RFB plan enrollees.* For RFB plan enrollees, HCFA adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. Such adjustment can be made on an individual or organization basis.

(b) *Adjustment of payments to reflect number of Medicare enrollees—General rule.* HCFA adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which HCFA based an advance monthly payment.

(c) *Payment areas—(1) General rule.* Except as provided in paragraph (e) of this section, the M+C payment area is a county or an equivalent geographic area specified by HCFA.

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the M+C payment

area is a State or other geographic area specified by HCFA.

(d) *Terminology.* As used in paragraph (e) of this section, "metropolitan statistical area," "consolidated metropolitan statistical area," and "primary metropolitan statistical area" mean any areas so designated by the Secretary of Commerce.

(e) *Geographic adjustment of payment areas.* For contract years beginning after 1999—

(1) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1) of this section:

(i) A single Statewide M+C payment area.

(ii) A metropolitan-based system in which all nonmetropolitan areas within the State constitute a single payment area and any of the following constitutes a separate M+C payment area:

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(A) All portions of each single metropolitan statistical area within the State.

(B) All portions of each primary metropolitan statistical area within each consolidated metropolitan statistical area within the State.

(iii) A consolidation of noncontiguous counties.

(2) *HCFA response.* In response to the request, HCFA makes the payment adjustment requested by the chief executive.

(3) *Budget neutrality adjustment for geographically adjusted payment areas.* If HCFA adjusts a State's payment areas in accordance with paragraph (e)(2) of this section, HCFA at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payment areas, absent the geographic adjustment.

(f) *Determination and applicability of payment rates.* (1) All payment rates are annual rates, determined and promulgated no later than March 1st, for the following calendar year.

(2) For purposes of paragraphs (b) and (c) of § 422.252, except as provided in § 422.254(e)(4), the "capitation payment rate for 1997" is the rate determined under section 1876(a)(1)(c) of the Act.

§ 422.252 Annual capitation rates.

Subject to the adjustments specified in this subpart, the annual capitation

rate for a particular payment area is equal to the largest of the following:

(a) *Blended capitation rate.* The blended capitation rate is the sum of—

(1) The area-specific percentage (specified in § 422.254(a)) for the year multiplied by the annual area-specific capitation rate for the payment area as determined under § 422.254(e) for the year, and

(2) The national percentage (specified in § 422.254(a)) for the year multiplied by the national input-price-adjusted capitation rate for the payment area as determined under § 422.254(g) for the year.

(3) Multiplied by the budget neutrality adjustment factor determined under § 422.254(d).

(b) *Minimum amount rate.* (1) For 1998—

(i) For the 50 States and the District of Columbia, the minimum amount rate is 12 times \$367.

(ii) For all other jurisdictions the minimum amount rate is the lesser of the rate described in (b)(1)(i) or 150 percent of the capitation payment rate for 1997.

(2) For each succeeding year, the minimum amount rate is the minimum amount rate for the preceding year, increased by the national per capita growth percentage (specified in § 422.254(b)) for the year.

(c) *Minimum percentage increase rate.*

(1) For 1998, the minimum percentage increase rate is 102 percent of the annual capitation rate for 1997.

(2) For each succeeding year, the minimum percentage increase rate is 102 percent of the annual capitation rate for the preceding year.

§ 422.254 Calculation and adjustment factors.

The following are the factors used in calculating the per capita payment rates:

(a) *Area-specific and national percentages.* For purposes of § 422.252(a)(1), the area-specific percentage and the national percentage, for each year, are as follows:

	Area-specific	National
For 1998	90	10
For 1999	82	18
For 2000	74	26
For 2001	66	34
For 2002	58	42
For years after 2002	50	50

(b) *National per capita growth percentage.* For purposes of § 422.252(a)(2),

(1) The national per capita growth percentage for a year is HCFA's estimate

of the rate of growth in per capita expenditures, reduced by the percentage points specified in paragraph (b)(2) of this section for the year. HCFA may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(2) The percentage points that HCFA uses to reduce its estimates are as follows:

(i) For 1998, 0.8 percentage points.

(ii) For years 1999–2002, 0.5

percentage points.

(iii) For years after 2002, 0 percentage points.

(c) *Medical education payment adjustments.* For purposes of paragraph (e)(2) the medical education payment adjustments are amounts that HCFA estimates were payable to teaching hospitals during 1997 for—

(1) the indirect costs of medical education under section 1886(d)(5)(B) of the Act; and

(2) The direct costs of graduate medical education under section 1886(h) of the Act.

(d) *General budget neutrality factor.*

For each year, HCFA applies a budget neutrality factor to the blended capitation rates under § 422.252(a) so that the estimated aggregate payments made under this part equal the estimated aggregate payments that would have been made if based entirely on area-specific capitation rates.

(e) *Annual Area-specific capitation rate (1) Basic rule.* Subject to the provisions of paragraphs (e)(2) and (e)(3) of this section, the annual area-specific capitation rate for a particular payment area is—

(i) For 1998, subject to paragraph (e)(4) of this section, the per capita rate determined for that area for 1997 under section 1876(a)(1)(c) of the Act, increased by the national per capita growth percentage for 1998; and

(ii) For a subsequent year, the area-specific capitation rate determined for the previous year, increased by the national per capita growth percentage for the year.

(2) *Exclusion of medical education costs.* In calculating the area-specific capitation rates, the following percentages of the amounts estimated by HCFA under § 422.254(c) as medical education payment adjustments to hospitals, are excluded:

For 1998 20 percent.

For 1999 40 percent.

For 2000 60 percent.

For 2001 80 percent.

For years after 2001 100 percent.

(3) *Payments under the State hospital reimbursement system.* To the extent that HCFA estimates that a 1997 per

capita rate reflects payments to hospitals under section 1814(b)(3) of the Act, HCFA makes a payment adjustment that is comparable to the adjustment that would have been made under paragraph (e)(2) of this section if the hospitals had not been reimbursed under section 1814(b)(3) of the Act.

(4) *Areas with highly variable per capita rates.* With respect to a payment area for which the per capita rate for 1997 varies by more than 20 percent from the per capita rate for 1996, HCFA may substitute for the 1997 rate a rate that is more representative of the costs of the enrollees in the area.

(f) *National standardized annual capitation rate.* The national standardized annual capitation rate is equal to—

(1) The sum, for all payment areas, of the products of—

(i) The annual area-specific capitation rate and

(ii) The average number of Medicare beneficiaries residing in the area multiplied by the average of the risk-factor weights used to adjust payments under § 422.256(c);

(2) Divided by the sum, for all payment areas, of the products specified in paragraph (f)(1)(ii) of this section for all payment areas.

(g) *The input-price-adjusted annual national capitation rate—(1) General rule.* The input-price-adjusted annual national capitation rate for a M+C payment area for a year is equal to the sum, for all the types of Medicare services (as classified by HCFA), of the product (for each service) of—

(i) The national standardized annual M+C capitation rate (determined under paragraph (f) of this section) for the year;

(ii) The proportion of such rates for the year which is attributable to such type of services; and

(iii) An index that reflects (for that year and that type of services) the relative input price of such services in the area compared to the national average input price for such services.

(2) HCFA may, subject to the special rules for 1988, use indices that are used in applying or updating national payment rates for particular areas and localities.

(3) *Special rules for 1988.* In applying this paragraph for 1998—

(i) Medicare services are classified as Part A and Part B services;

(ii) The proportion attributable to Part A services is the ratio (expressed as a percentage) of the national average per capita rate of payment for Part A services for 1997 to the national average per capita rate of payment for Part A and Part B services for that year;

(iii) The proportion attributed to part B services is 100 percent minus the ratio described in paragraph (g)(3)(ii) of this section;

(iv) For Part A services, 70 percent of the payments attributable to those services are adjusted by the index used under section 1886(d)(3)(E) of the Act to adjust payment rates for relative hospital wage levels for hospitals located in the particular payment area; and

(v) For part B services—

(A) 66 percent of payments attributable to those services are adjusted by the index of the geographic area factors under section 1848(e) of the Act used to adjust payment rates for physician services in the particular payment area; and

(B) Of the remaining 34 percent, 40 percent is adjusted by the index specified in paragraph (g)(3)(iv) of this section.

§ 422.256 Adjustments to capitation rates and aggregate payments.

(a) *Adjustment for over or under projection of national per capita growth percentages.* (1) Beginning with rates for 1999, HCFA adjusts all area-specific and national capitation rates for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for such years.

(2) Beginning with rates for 2000, HCFA also adjusts the minimum amount rate (calculated under § 422.252(b)) in the same manner.

(b) *Adjustment for national coverage determination (NCD) services.* If HCFA determines that the cost of furnishing an NCD service is “significant,” HCFA adjusts capitation rates for the next calendar year to take account of the cost of that service. Until the new capitation rates are in effect, the M+C organization is paid for the “significant cost” service on a fee-for-service basis as provided under section 422.105(b).

(c) *Risk adjustment: General rule.* Capitation payments are adjusted for age, gender, institutional status, and other appropriate factors, including health status.

(d) *Risk adjustment: Health status—(1) Data collection.* To adjust for health status, HCFA applies a risk factor based on data obtained in accordance with § 422.257.

(2) *Initial implementation.* HCFA applies this adjustment factor to payments beginning January 1, 2000.

(3) *Uniform application.* Except as provided for M+C RFB plans under § 422.250(a)(2)(iii), HCFA applies this adjustment factor to all types of plans.

§ 422.257 Encounter data.

(a) *Data collection: Basic rule.* Each M+C organization must submit to HCFA (in accordance with HCFA instructions) all data necessary to characterize the context and purposes of each encounter between a Medicare enrollee and a provider, supplier, physician, or other practitioner.

(b) *Types of service and timing of submittal.* M+C organizations must submit data as follows:

(1) Beginning on a date determined by HCFA, inpatient hospital care data for all discharges that occur on or after July 1, 1997.

(2) HCFA will provide advance notice to M+C organizations to collect and submit data for services that occur on or after July 1, 1998, as follow:

(i) Physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and

(ii) All other data HCFA deems necessary beginning no earlier than October 1, 2000.

(c) *Sources and extent of data.* (1) To the extent required by HCFA, the data must account for services covered under the original Medicare program, for Medicare covered services for which Medicare is not the primary payor, or for other additional or supplemental benefits that the M+C organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the Medicare fee-for-service program, even if they participate jointly in the same encounter.

(d) *Other data requirements.* The data must—

(1) Conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards; and

(2) Be submitted electronically to the appropriate HCFA contractor.

(e) *Validation of data.* M+C organizations and their providers and practitioners will be required to submit medical records for the validation of encounter data, as prescribed by HCFA.

(f) *Use of data.* HCFA uses the data obtained under this section to determine the risk adjustment factor that it applies to annual capitation rates under § 422.256(c). HCFA may also use the data for other purposes.

§ 422.258 Announcement of annual capitation rates and methodology changes.

(a) *Capitation rates.* (1) No later than March 1 of each year, HCFA announces to M+C organizations and other interested parties the capitation rates for the following calendar year.

(2) HCFA includes in the announcement a description of the risk and other factors and explains the methodology in sufficient detail to enable M+C organizations to compute monthly adjusted capitation rates for individuals in each of its payment areas.

(b) *Advance notice of changes in methodology.* (1) No later than January 15 of each year, HCFA notifies M+C organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The M+C organizations have 15 days to comment on the proposed changes.

§ 422.262 Special rules for beneficiaries enrolled in M+C MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an M+C MSA plan—

(1) Must establish an M+C MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one M+C MSA, designate the particular account to which payments under the M+C MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an M+C MSA must—

(1) Register with HCFA;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the M+C MSA provisions of section 138 of the IRS Code of 1986; and

(4) Provide any other information that HCFA may require.

(c) *Deposit in the M+C MSA.* (1) The payment is calculated as follows:

(i) The monthly M+C MSA premium is compared with $\frac{1}{12}$ of the annual capitation rate for the area determined under § 422.252.

(ii) If the monthly M+C MSA premium is less than $\frac{1}{12}$ of the annual capitation rate, the difference is the amount to be deposited in the M+C MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) HCFA deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which M+C MSA coverage begins.

(3) If the beneficiary's coverage under the M+C MSA plan ends before the end of the calendar year, HCFA recovers the amount that corresponds to the remaining months of that year.

§ 422.264 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability.* This section applies to inpatient services in a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act.

(b) *Coverage that begins during an inpatient hospital stay.* If coverage under an M+C plan offered by an M+C organization begins while the beneficiary is an inpatient in a subsection (d) hospital—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous M+C organization or original Medicare, as appropriate.

(2) The M+C organization offering the newly-elected M+C plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The M+C organization offering the newly-elected M+C plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient hospital stay.* If coverage under an M+C plan offered by an M+C organization ends while the beneficiary is an inpatient in a subsection (d) hospital—

(1) The M+C organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding M+C organization offering a newly-elected M+C plan; and

(3) The M+C organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.266 Special rules for hospice care.

(a) *Information.* An M+C organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to elect hospice care under section 1812(d)(1) of the Act about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment Status.* Unless the enrollee disenrolls from the M+C plan, a beneficiary electing hospice continues his or her enrollment in the M+C plan and is entitled to receive, through the

M+C plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment.* During the time the hospice election is in effect, HCFA's monthly capitation payment to the M+C organization is reduced to an amount equal to the adjusted excess amount determined under § 422.312. In addition, HCFA pays through the original Medicare program (subject to the usual rules of payment)—

(1) The hospice program for hospice care furnished to the Medicare enrollee; and

(2) The M+C organization, provider or supplier for other Medicare-covered services furnished to the enrollee.

§ 422.268 Source of payment and effect of election of the M+C plan election on payment.

(a) *Source of payments.* Payments under this subpart, to M+C organizations or M+C MSAs, are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. HCFA determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(b) *Payments to the M+C organization.* Subject to §§ 412.105(g) and 413.86(d) of this chapter and §§ 422.105, 422.264, and 422.266, HCFA's payments under a contract with an M+C organization (described in § 422.250) with respect to an individual electing an M+C plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the M+C organization entitled to payment.* Subject to § 422.262, 422.264, 422.266, and 422.520 of this part and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the M+C organization is entitled to receive payment from HCFA under title XVIII of the Act for items and services furnished to the individual.

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Subpart G—Premiums and Cost-Sharing

§ 422.300 Basis and scope.

(a) *General.* This subpart is based on section 1854 of the Act. It sets forth the requirements and limitations for payments by and on behalf of Medicare beneficiaries who elect an M+C plan.

(b) *Transition period.* For contract periods beginning before January 1,

2002, HCFA applies the following special rules.

(1) M+C organizations may, with HCFA's agreement, modify an M+C plan offered prior to January 1, 2002 by—

- (i) Adding benefits at no additional cost to the M+C plan enrollee; and
- (ii) Lowering the premiums approved through the ACR process;
- (iii) Lowering other cost-sharing amounts approved through the ACR process.

(2) For contracts beginning on a date other than January 1 (according to § 422.504(d)), M+C organizations may submit ACRs on a date other than May 1 approved by HCFA.

§ 422.302 Terminology.

As used in this subpart, unless specified otherwise—

Additional revenues are revenues collected or expected to be collected from charges for M+C plans offered by an M+C organization in excess of costs actually incurred or expected to be incurred. Additional revenues would include such things as revenues in excess of expenses of an M+C plan, profits, contribution to surplus, risk margins, contributions to risk reserves, assessments by a related entity that do not represent a direct medical or related administrative cost, and any other premium component not reflected in direct medical care costs and administrative costs.

APR stands for the M+C plan's average per capita rates of payment. The APR is the average amount the M+C organization estimates HCFA will pay (without any needed offsets or reductions, such as, those required by § 422.250(a)(2)(ii) for M+C MSA plan enrollees) for the period covered by the ACR for all of the Medicare beneficiaries electing the M+C plan.

M+C monthly basic beneficiary premium means, with respect to an M+C coordinated care plan, the amount authorized to be charged under § 422.308(a)(1) for the plan, or, with respect to a M+C private fee-for-service plan, the amount filed under § 422.306(d)(1).

M+C monthly supplemental beneficiary premium means, with respect to an M+C coordinated care plan, the amount authorized to be charged under § 422.308(a)(2) for the M+C plan, or, with respect to an MSA or an M+C private fee-for-service plan, the amount filed under § 422.306(c)(2) or § 422.306(d)(2).

M+C monthly MSA premium means, with respect to an M+C plan, the amount of such premium filed under § 422.306(c)(1).

§ 422.304 Rules governing premiums and cost-sharing.

(a) *Monthly premiums.* The monthly premium charged to the beneficiary is—

- (1) For an individual enrolled in an M+C plan (other than an M+C MSA plan) offered by an M+C organization, the sum of the M+C monthly basic beneficiary premium plus the M+C monthly supplemental beneficiary premium (if any); or
- (2) For an individual enrolled in an M+C MSA plan offered by an M+C organization, the M+C monthly supplemental beneficiary premium (if any).

(b) *Uniformity.* The M+C monthly basic beneficiary premium, the M+C monthly supplemental beneficiary premiums, and the M+C monthly MSA premium of an M+C organization may not vary among individuals enrolled in the M+C plan. In addition, the M+C organization may not vary the level of copayments, coinsurance, or deductibles charged for basic benefits or supplemental benefits (if any), among individuals enrolled in the M+C plan.

(c) *Timing of payments.* The M+C organization must permit payments of M+C monthly basic and supplemental beneficiary premium on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b)(1).

(d) *Monetary inducements prohibited.* An M+C organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

§ 422.306 Submission of proposed premiums and related information.

(a) *General rule.* (1) Not later than May 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to HCFA, in the manner and form prescribed by HCFA, for each M+C plan it intends to offer in the following year—

- (i) The information specified in paragraph (b), (c), or paragraph (d) of this section for the type of M+C plan involved; and
- (ii) The service area and enrollment capacity (if any).

(2) If the submission is not complete, timely, or accurate, HCFA has the authority to impose sanctions under Subpart O of this part or may choose not to renew the contract.

(b) *Information required for coordinated care plans—*(1) *Basic benefits.* For basic benefits, the following information is required:

- (i) The ACR as specified in § 422.310.
- (ii) The M+C monthly basic beneficiary premium.

(iii) A description of cost-sharing to be imposed under the plan, and its actuarial value.

(iv) A description of any additional benefits to be provided pursuant to § 422.312 and the actuarial value determined for those benefits.

(v) Amounts collected in the previous contract period for basic benefits.

(2) *Supplemental benefits.* For supplemental benefits, the following information is required:

- (i) The ACR.
- (ii) The M+C monthly supplemental beneficiary premium.
- (iii) A description of supplemental benefits being offered, the cost sharing to be imposed, and their actuarial value.
- (iv) Amounts collected in the previous contract period for supplemental benefits.

(c) *Information required for MSA plans.* (1) The monthly MSA premium for basic benefits.

(2) The M+C monthly supplementary beneficiary premium for supplemental benefits.

(3) A description of all benefits offered under the M+C MSA plan.

(4) The amount of the deductible imposed under the plan.

(5) Amounts collected in the previous contract period for supplemental benefits.

(d) *Information required for M+C private fee-for-service plans.* (1) The information specified under paragraph (b)(1) of this section.

(2) The amount of the M+C monthly supplemental beneficiary premium.

(3) A description of all benefits offered under the plan.

(4) Amounts collected in the previous contract period for basic and supplemental benefits.

(e) *HCFA review—*(1) *Basic rule.* Except as specified in paragraph (e)(2) of this section, HCFA reviews and approves or disapproves the information submitted under this section.

(2) *Exception.* HCFA does not review or approve or disapprove the following information:

- (i) Any amounts submitted with respect to M+C MSA plans.
- (ii) The M+C monthly basic and supplementary beneficiary premiums for M+C private fee-for-service plans.

§ 422.308 Limits on premiums and cost sharing amounts.

(a) *Rules for coordinated care plans—*

- (1) For basic benefits, the M+C monthly basic beneficiary premium (multiplied by 12) charged, plus the actuarial value of the cost-sharing applicable, on average, to beneficiaries enrolled under this part may not exceed the annual actuarial value of the deductibles and

coinsurance that would be applicable, on average, to beneficiaries entitled to Medicare Part A and enrolled in Medicare Part B if they were not enrollees of an M+C organization as determined in the ACR under § 422.310. For those M+C plan enrollees that are enrolled in Medicare Part B only, the M+C monthly basic beneficiary premium (multiplied by 12) charged, plus the actuarial value of the deductibles, coinsurance and copayments applicable, on average, to those beneficiaries enrolled under this part may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable, on average, to beneficiaries enrolled in Medicare Part B if they were not enrollees of an M+C organization as determined in the ACR under § 422.310.

(2) *For supplemental benefits*, the M+C monthly supplemental beneficiary premium (multiplied by 12) charged, plus the actuarial value of its cost-sharing, may not exceed the amounts approved in the ACR for those benefits, as determined under § 422.310 on an annual basis.

(3) *Coverage of Part A services for Part B-only Medicare enrollees*. If an M+C organization furnishes coverage of Medicare Part A-type services to a Medicare enrollee entitled to Part B only, the M+C plan's premium plus the actuarial value of its cost-sharing for these services may not exceed the lesser of—

(i) The APR that is payable for these services for those beneficiaries entitled to Part A plus the actuarial value of Medicare deductibles and Coinsurance for the services;

(ii) or the ACR for such services.

(b) *Rule for M+C private fee-for-service plans*. The average actuarial value of the cost-sharing for basic benefits may not exceed the actuarial value of the cost-sharing that would apply, on average, to beneficiaries entitled to Medicare Part A and enrolled in Medicare Part B if they were not enrolled in an M+C plan as determined in the ACR under § 422.310.

(c) *Special rules for determination of actuarial value*. If HCFA determines that adequate data are not available to determine actuarial value under paragraph (a) or (b) of this section, HCFA may make the determination with respect to all M+C eligible individuals in the same geographic area or State or in the United States, or on the basis of other appropriate data.

§ 422.309 Incorrect collections of premiums and cost-sharing.

(a) *Definitions*. As used in this section—

(1) *Amounts incorrectly collected*

(i) Means amounts that:

(A) Exceed the limits imposed by § 422.308;

(B) In the case of a M+C private fee-for-service plan, exceed the M+C monthly basic beneficiary premium or the M+C monthly supplemental premium submitted under § 422.306; and

(C) In the case of a M+C MSA plan, exceed the M+C monthly supplemental premium submitted under § 422.306 and the deductible for basic benefits; and

(ii) Includes amounts collected from an enrollee who was believed not entitled to Medicare benefits but was later found to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the M+C plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the M+C organization.

(b) *Basic commitments*. An M+C organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment*. The M+C organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the M+C organization is going out of business or terminating its M+C contract for an M+C plan(s).

(2) *Premium adjustment or lump-sum payment, or both*. If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the M+C organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located*. If an enrollee has died or cannot be located after reasonable effort, the M+C organization must make the refund in accordance with State law.

(d) *Reduction by HCFA*. If the M+C organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, HCFA reduces the premium the M+C organization is allowed to charge an

M+C plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the M+C organization would be subject to sanction under Subpart O for failure to refund amounts incorrectly collected from M+C plan enrollees.

§ 422.310 Adjusted community rate (ACR) approval process.

(a) *General rule*. (1) Except with respect to M+C MSA plans, each M+C organization must compute a separate ACR for each M+C coordinated care or private fee-for-service plan offered to Medicare beneficiaries. In computing the ACR, the M+C organization calculates an initial rate (for years after 1999, using the methods described in paragraph (b), for 1999, under § 417.594(b)) that represents the "commercial premium" the M+C organization would charge its general non-Medicare eligible enrollment population for the basic benefits, and any mandatory supplemental benefits covered under the M+C plan. The M+C organization should also calculate a separate initial rate (using the same approach) for each optional supplemental benefit package it offers under an M+C plan. For years after 1999 the M+C organization then either adjusts that rate by the factors specified in paragraph (c) of this section or requests that HCFA adjust the rate in accordance with the procedures specified in paragraph (c)(6) of this section. For 1999, adjustments are made under section 417.594(c). All data submitted as part of the ACR process is subject to audit by HCFA or any person or organization designated by HCFA.

(2) To calculate the adjusted excess described in section 422.312, the M+C organization or HCFA further reduces the rate for Medicare-covered services by the actuarial value of applicable Medicare coinsurance and deductibles.

(3) Separate ACRs must be calculated for Part A and Part B enrollees and Part B-only enrollees for each M+C plan offered, and for each optional supplemental benefit option.

(4) In calculating its initial rate, the M+C organization must identify and take into account anticipated revenue collectible from other payers for those services for which Medicare is not the primary payer as described in § 422.108.

(5) Except as provided in paragraph (a)(6) of this section, the M+C organization must have an adequate accounting system that is accrual based and uses generally-accepted accounting principles to develop its ACR.

(6) For M+C organizations that are part of a government entity that uses a cash basis of accounting, ACR cost data

developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the asset, is acceptable.

(b) *Initial rate calculation for years after 1999.* (1) The M+C organization's initial rate for each M+C plan is calculated on a 12-month basis for non-Medicare enrollees, using either, at the M+C organization's election—

(i) A community rating system (as defined in section 1308(8) of the PHS Act, other than subparagraph (C)); or

(ii) A system, approved by HCFA, under which the M+C organization develops an aggregate premium for each M+C plan for all enrollees of that M+C plan that is weighted by the size of the various enrolled groups and individuals that compose the M+C organization's enrollment in that M+C plan. For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers (including individual subscribers) that enroll in the M+C plan on a premium basis.

(2) Regardless of which method the M+C organization uses to calculate its initial rate, the initial rate must be equal to the premium the M+C organization would charge its non-Medicare enrollees on a yearly basis for services included in the M+C plan.

(3) Except as provided in paragraph (b)(4) of this section, the M+C organization must identify in its initial rate calculation for an M+C plan, the following components whose rates must be consistent with rates used by the M+C organization in calculating premiums for non-Medicare enrollees:

- (i) Direct medical care.
- (ii) Administration.
- (iii) Additional Revenues.
- (iv) Enrollee cost sharing (for example, deductibles, coinsurance, or copayments) for Medicare-covered services and for additional and supplemental benefits.

(4) An M+C organization that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the M+C organization provides HCFA with the documentation necessary to support any adjustments the M+C organization makes to the initial rate in accordance with paragraph (c)(5) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the M+C organization during prior contract periods. The M+C organization must submit supporting documentation to assure HCFA that ACR values do not include past losses but only premiums for covered services, additional services, and supplemental

benefits for the upcoming 12-month period.

(c) *Adjustment factors for years after 1999.* Adjustment factors are designed to adjust on a component basis the initial rate calculated under paragraph (b) of this section to reflect differences in utilization characteristics of the M+C organization's Medicare enrollees electing an M+C plan using a relative cost ratio. Adjustment factors are as follows:

(1) *Direct medical care.* The relative cost ratio for direct medical care for an M+C plan is determined by comparing the direct medical care costs actually incurred on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees that elected the M+C plan to the direct medical care costs of non-Medicare enrollees incurred over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation.

(2) *Administration.* The relative cost ratio for Administration for an M+C plan is determined by comparing the administrative costs actually incurred on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees that elected the M+C plan to the administrative costs of non-Medicare enrollees incurred over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation.

(3) *Additional revenues.* The relative cost ratio for additional revenues for an M+C plan is determined by comparing the additional revenues collected on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees that elected the M+C plan to the additional revenues of non-Medicare enrollees collected over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation.

(4) *Additional adjustments.* Additional adjustments may be necessary if the M+C organization, with agreement of HCFA, determines that the adjustment of the initial rate by the relative cost ratios does not represent an accurate ACR value of the initial rate component. Adjustments will be allowed that are designed to reduce ACR values to equal the actuarial value of the M+C plan charge structure.

(5) *Supporting documentation.* All adjustments made by the M+C

organization must be accompanied by adequate supporting data. If an M+C organization does not have sufficient enrollment experience to develop this data, it may, during its initial contract period use reasonable estimates acceptable to HCFA to establish its ACR values.

(6) *Adjustment by HCFA.* If it is determined that the M+C organization does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of Medicare enrollees, HCFA adjusts the initial rate. HCFA adjusts the rate on the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other M+C plans; or

(ii) Medicare beneficiaries in the M+C organization's area, State, or the United States who are eligible to elect an M+C plan and other individuals in that same area, State, or the United States.

(d) *Special rules for certain organizations.* An M+C organization that does not have non-Medicare enrollees or sufficient Medicare enrollment experience to adequately calculate ACR values may calculate its ACR using estimates described in paragraphs (a)(1) and (a)(2) of this section as an additional adjustment described in paragraph (c)(4) of this section.

(1) The M+C organization may use an estimate of the ACR value for the direct medical and administrative components of a service or services offered using generally-accepted accounting principles.

(2) The M+C organization may use an estimate of the ACR value for the additional revenue component of a service or services offered based on the lesser of (if the information is available)—

(i) The average of additional revenues received through risk payments for health services contracted to be furnished to an enrolled population of other organizations;

(ii) The average of additional revenues received for health services furnished; or

(iii) A reasonable estimate of additional revenues of other M+C organizations in the general marketplace.

(e) *Adjustment by HCFA.* If HCFA finds that there is insufficient enrollment experience to determine the APR or ACR for a M+C plan at the beginning of a contract period, HCFA may—

(1) Determine the APR based on the enrollment experience of other M+C organizations;

(2) Determine ACR using data in the general commercial marketplace; or

(3) Determine either or both rates using the best available information, which may include enrollment experience of other M+C organizations and section 1876 risk contractors.

(f) *HCFA review.* (1) The M+C organization's methodology and computation of its ACR are subject to review and approval by HCFA. When the M+C organization submits the ACR computation, it must include adequate supporting data. Except as provided in § 422.306(e)(2), HCFA authorizes the M+C organization to collect premiums and other cost sharing amounts described in § 422.306 that are equal to the amounts calculated in the ACR.

(2) If the M+C organization is dissatisfied with an HCFA determination that the M+C organization's computation is not acceptable, the M+C organization may within 2 weeks after the date of receipt of notification of this determination, file a request for a hearing with HCFA. The request must state why the M+C organization believes the determination is incorrect and must be accompanied by any supporting evidence the M+C organization wishes to submit. The hearing is conducted by a hearing officer designated by HCFA under the hearing procedures described in subpart N.

§ 422.312 Requirement for additional benefits.

(a) *Definitions.* As used in this section—

(1) *Excess amount* is the amount by which the APR exceeds the actuarial value of the Medicare covered services required under § 422.101(a), as determined on the basis of the ACR determined under § 422.310, as reduced for the actuarial value of the cost-sharing under Medicare Parts A and B. A separate excess amount must be determined for Part B-only enrollees.

(2) *Adjusted excess amount* is the excess amount minus any amount withheld and reserved for the organization in a stabilization fund, as provided in paragraph (c) of this section.

(b) *Requirement for additional benefits.* If there is an adjusted excess amount for the plan it offers, the M+C organization must—

(1) Provide additional benefits with an actuarial value (less the actuarial value of any copayment or coinsurance associated with the benefit) which HCFA determines is at least equal to the adjusted excess amount; and

(2) Provide those benefits uniformly for all Medicare enrollees electing the plan.

(c) *Stabilization fund.* (1) An M+C organization may request for part of an excess amount to be withheld and reserved, for a specified number of contract periods, in the Federal Hospital Insurance Trust Fund, or the Federal Supplementary Insurance Trust Fund in the proportions that HCFA determines to be appropriate.

(2) The reserved funds are to be used to stabilize and prevent undue fluctuations in the additional benefits that are required under this section and are provided during subsequent contract periods.

(3) Any amounts not provided as additional benefits during the period specified by the M+C organization for which the stabilization fund is established, reverts for the use of the trust funds.

(4) *Establishment of a stabilization fund.* An M+C organization's request to have monies withheld in a stabilization fund for a specific M+C plan must be made when the M+C organization notifies HCFA under § 422.306 of its proposed premiums, other cost-sharing amounts, and related information in preparation for its next contract period.

(i) *Limit per contract period.* Except as provided in paragraph (c)(4)(iii) of this section, HCFA does not withhold in a stabilization fund more than 15 percent of the excess amount for a given contract period.

(ii) *Cumulative limit.* If HCFA has established a stabilization fund for an M+C plan, it does not approve a request for withholding made by that M+C organization for a subsequent contract period that would cause the total value of the stabilization fund to exceed 25 percent of the excess amount applicable to the M+C plan for that subsequent contract period.

(iii) *Exception.* HCFA may grant an exception to the limit described in paragraph (c)(3)(i) of this section if the M+C organization can demonstrate to HCFA's satisfaction that the value of the additional benefits it provides to its Medicare enrollees electing this M+C plan fluctuates substantially in excess of 15 percent from one contract period to another.

(iv) *Interest.* The amounts withheld in a stabilization fund are accounted for by HCFA in accounts for which interest does not accrue to the M+C organization.

(5) *Withdrawal from a stabilization fund.* An M+C organization's request to make a withdrawal from the stabilization fund established for an M+C plan to be used during a contract

period must be made when the M+C organization notifies HCFA under § 422.306 of its proposed premiums, cost-sharing amounts, and related information in preparation for its next contract period.

(i) *Notification requirements.* An M+C organization must—

(A) Indicate how it intends to use the withdrawn amounts;

(B) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(C) Document the M+C plan's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(D) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the M+C organization will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(ii) *Criteria for HCFA approval.* HCFA approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(A) The average of the APR for the M+C plan's next contract period of the M+C plan is less than that of the previous contract period;

(B) The M+C plan's ACR for the next contract period is significantly higher than that of the previous contract period;

(C) The M+C plan's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period; or

(D) The ACR for the next contract period results in additional benefits that are significantly less in total value than that of the previous contract period.

(iii) *Basis for denial.* HCFA does not approve a request for a withdrawal from a stabilization fund if the withdrawal would allow the M+C organization to refinance prior contract period losses or to avoid losses in the upcoming contract period.

(iv) *Form of payment.* Payment of monies withdrawn from a stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the M+C organization for Medicare beneficiaries electing the M+C plan during the period of the contract.

(d) *Construction.* Nothing in this section may be construed as preventing an M+C organization from providing supplemental benefits in addition to those required under this section and

from imposing a premium for those supplemental benefits.

Subpart H—Provider-Sponsored Organizations

3. *Nomenclature change.* Throughout subpart H, “Medicare+Choice”, wherever it appears, is revised to read “M+C”.

4. *Nomenclature change.* Throughout subpart H, “items and services”, wherever it appears, is revised to read “services”.

§ 422.350 [Amended]

5. In § 422.350, the following changes are made:

a. In paragraph (a)(1), “hereinafter referred to as PSOs” is revised to read “(PSOs)”.

b. The definition of “capitated basis” is removed and a definition of “capitation payment” is added in its place, to read as set forth below.

c. In the definition of “cash equivalent”, “accounts receivables, which” is revised to read “accounts receivable that”.

d. The definition of “health care provider” and the statement for “M+C” are removed.

e. In the definition of “insolvency”, “where” is revised to read “in which”.

f. The definition of “provider-sponsored organization is revised to read as set forth below.

§ 422.350 Basis, scope, and definitions.

* * * * *

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to the type, cost, or frequency of services furnished.

* * * * *

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a health care provider or group of affiliated health care providers;

(2) Provides a substantial proportion (as defined in § 422.352) of the health care services under the M+C contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under § 422.356, for the provision of services that are the obligation of the PSO under the M+C contract; and

(ii) Have at least a majority financial interest in the PSO.

§ 422.352 [Amended]

6. In § 422.352, the following changes are made:

a. In paragraph (a)(1) “such licensure” is revised to read “State licensure”, and “section 1855(a)(2) of the Act” is revised to read “§ 422.370”.

b. In paragraph (b)(2), “as defined in § 422.354” is removed.

c. Paragraph (c) is revised to read as follows:

§ 422.352 Basic requirements.

* * * * *

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must—

(1) Demonstrate to HCFA that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

§ 422.354 [Amended]

7. In § 422.354, the following changes are made:

a. In the introductory text, “of by two or more” is revised to read “of two or more”.

b. In paragraphs (a)(1), (a)(2), and (c), the parenthetical phrases are removed.

c. Paragraph (b) is revised to read as follows:

§ 422.354 Requirements for affiliated providers.

* * * * *

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

* * * * *

§ 422.356 [Amended]

8. In § 422.356, in paragraph (a)(3)(ii), “Agreement by the affiliated provider” is revised to read “Affiliated providers agree”.

§ 422.370 [Amended]

9. In § 422.370 the following changes are made:

a. In the introductory text, the word “as” is revised to read “to offer”.

b. Paragraphs (1) and (2) are redesignated as paragraphs (a) and (b).

10. § 422.372 is revised to read as follows:

§ 422.372 Basis for waiver of State licensure.

(a) *General rule.* Subject to this section and to paragraphs (a) and (e) of § 422.374, HCFA may waive the State licensure requirement if the

organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an M+C plan.

(b) *Basis for waiver of State licensure.* Any of the following may constitute a basis for HCFA’s waiver of State licensure.

(1) *Failure to act timely on application.* The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an M+C plan.

(3) *Denial of application based on different solvency requirements.* (i) The State has denied the application, in whole or in part, on the basis of the organization’s failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) HCFA determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by HCFA to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

11. In § 422.374, paragraph (b) is revised to read as follows:

§ 422.374 Waiver request and approval process.

* * * * *

(b) HCFA gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

* * * * *

12. In § 422.384, paragraph (b)(3) is revised to read as follows:

§ 422.384 Financial plan requirement.

* * * * *

(b) * * *

(3) Cash-flow statements;

* * * * *

13. *Nomenclature change:*

Throughout subpart H, the phrase "health care provider", wherever it appears, is revised to read "provider".

14. Subpart I is added as follows:

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

Sec.

422.400 State licensure requirement.

422.402 Federal preemption of State law.

422.404 State premium taxes prohibited.

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each M+C organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more M+C plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an M+C organization; and

(c) Demonstrate to HCFA that—

(1) The scope of its license or authority allows the organization to offer the type of M+C plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

(a) *General preemption.* Except as provided in paragraph (b) of this section, the rules, contract requirements, and standards established under this part supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C organizations and their M+C plans only to the extent that such State laws are inconsistent with the standards established under this part. This preemption of State laws and other standards applies only to coverage pursuant to an M+C contract, and does not extend to benefits outside of such contract or to individuals who are not M+C enrollees of an organization with an M+C contract.

(b) *Specific preemption.* As they might otherwise apply to the M+C plans of an M+C organization in a State, State laws and regulations pertaining to the following areas are specifically preempted by this part:

(1) Benefit requirements, such as mandating the inclusion in an M+C plan of a particular service, or specifying the scope or duration of a service (for example, length of hospital stay, number of home health visits). State cost-sharing standards with respect to any benefits are preempted only if they are inconsistent with this part, as provided for in paragraph (a) of this section.

(2) Requirements relating to inclusion or treatment of providers and suppliers.

(3) Coverage determinations (including related appeal and grievance processes for all benefits included under an M+C contract). Determinations on issues other than whether a service is covered under an M+C contract, and the extent of enrollee liability under the M+C plan for such a service, are not considered coverage determinations for purposes of this paragraph.

(c) Except as provided in paragraphs (a) and (b) of this section, nothing in this section may be construed to affect or modify the provisions of any other law or regulation that imposes or preempts a specific State authority.

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivision or other governmental authorities with respect to any payment HCFA makes on behalf of M+C enrollees under subpart F of this part.

(b) *Construction.* Nothing in this section shall be construed to exempt any M+C organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J [Reserved]

15. Subpart J is reserved.

16. Subpart K is added as follows:

Subpart K—Contracts With Medicare+Choice Organizations

Sec.

422.500 Definitions.

422.501 General provisions.

422.502 Contract provisions.

422.504 Effective date and term of contract.

422.506 Nonrenewal of contract.

422.508 Modification or termination of contract by mutual consent.

422.510 Termination of contract by HCFA.

422.512 Termination of contract by the M+C organization.

422.514 Minimum enrollment requirements.

422.516 Reporting requirements.

422.520 Prompt payment by M+C organization.

422.524 Special rules for RFB societies.

Subpart K—Contracts With Medicare+Choice Organizations

§ 422.500 Definitions.

For purposes of this subpart, the following definitions apply:

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.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the M+C organization's enrollees by hospitals and other providers, and by M+C organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean Claim means a claim that has no defect, impropriety, lack of any required substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an M+C 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 M+C 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:

(i) Is an officer, director, or partner; or

(ii) 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 M+C organization.

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

Related entity means any entity that is related to the M+C organization by common ownership or control and—

(1) Performs some of the M+C 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 M+C organization at a cost of more than \$2,500 during a contract period.

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 M+C organization, have a total value that exceeds \$25,000 or 5 percent of the M+C organization's total operating expenses, whichever is less.

§ 422.501 General provisions.

(a) *Basic rule.* In order to qualify as an M+C organization, enroll beneficiaries in any M+C plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an M+C organization must enter into a contract with HCFA.

(b) *Conditions necessary to contract as an M+C organization.* Any entity seeking to contract as an M+C organization must:

(1) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an M+C plan as defined in § 422.2.

(2) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(3) Have administrative and management arrangements satisfactory to HCFA, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the M+C organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the M+C organization to organize, plan, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the M+C organization, in an amount fixed by its policymaking 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 M+C organization.

(v) Insurance policies or other arrangements, secured and maintained by the M+C organization and approved by HCFA to insure the M+C organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Provision for internal monitoring and auditing.

(G) Ensures prompt response to detected offenses and development of corrective action initiatives.

(H) An adhered-to process for reporting to HCFA and/or the OIG credible information of violations of law by the M+C organization, plan, subcontractors or enrollees for a determination as to whether criminal, civil, or administrative action may be appropriate. With respect to enrollees, this reporting requirement shall be restricted to credible information on violations of law with respect to enrollment in the plan, or the provision of, or payment for, health services.

(4) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an M+C plan.

(5) The M+C organization's contract must not have been terminated by HCFA under § 422.510 within the past 5 years.

(c) *Contracting authority.* Under the authority of section 1857(c)(5) of the Act, HCFA may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if HCFA determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) HCFA annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the ACR) of at least one-third of the M+C organizations offering M+C plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that HCFA, or any person or organization designated by HCFA has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the M+C contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to—

(A) The ability of the organization to bear the risk of potential financial losses, or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon HCFA's request—

(1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by HCFA; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

§ 422.502 Contract provisions.

The contract between the M+C organization and HCFA must contain the following provisions:

(a) *Agreement to comply with regulations and instructions.* The M+C organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An M+C organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The M+C organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in § 422.108 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under § 422.100 and, to the extent applicable, supplemental benefits under § 422.101; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by HCFA as required under § 422.110;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.257 for submitting encounter data to HCFA;

(9) That it will be paid under the contract in accordance with the payment rules in subpart F of this part;

(10) To develop its annual ACR, and submit all required information on premiums, benefits, and cost-sharing by May 1, as provided in subpart G of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply will all requirements that are specific to a particular type of M+C plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) An M+C organization's compliance with paragraphs (a)(1) through (a)(13) and (c) of this section is material to performance of the contract.

(b) *Communication with HCFA.* The M+C organization must have the capacity to communicate with HCFA electronically.

(c) *Prompt payment.* The M+C organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by HCFA,

as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The M+C organization agrees to maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the ACR) of M+C organizations.

(ii) Enable HCFA to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable HCFA to audit and inspect any books and records of the M+C organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the ACR proposal.

(v) Establish component rates of the ACR for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the M+C organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and six prior periods.

(iii) Federal income tax or informational returns for the current contract period and six prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the M+C organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The M+C organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the M+C organization; and

(iii) The enrollment and disenrollment records for the current contract period and six prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the M+C organization, 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 contract.

(3) The M+C organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that HCFA may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the final date of the contract period or completion of audit, whichever is later unless—

(i) HCFA determines there is a special need to retain a particular record or group of records for a longer period and notifies the M+C organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or fraud or similar fault by the M+C organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) HCFA determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the M+C organization at any time.

(f) *Disclosure of information.* The M+C organization agrees to submit—

(1) To HCFA, certified financial information that must include the following:

(i) Such information as HCFA may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as HCFA may require pertaining to the disclosure of ownership and control of the M+C organization.

(2) To HCFA, all information that is necessary for HCFA 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:

- (i) The benefits covered under an M+C plan;
 - (ii) The M+C monthly basic beneficiary premium and M+C monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the M+C monthly MSA premium.
 - (iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;
 - (iv) Plan quality and performance indicators for the benefits under the plan including —
 - (A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;
 - (B) Information on Medicare enrollee satisfaction;
 - (C) Information on health outcomes;
 - (D) The recent record regarding compliance of the plan with requirements of this part, as determined by HCFA; and
 - (E) Other information determined by HCFA to be necessary to assist beneficiaries in making an informed choice among M+C plans and traditional Medicare;
 - (v) Information about beneficiary appeals and their disposition;
 - (vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;
 - (vii) For M+C organizations offering an MSA plan, information specified by HCFA for HCFA's use in preparing its report to the Congress on the MSA demonstration, including data specified by HCFA in the areas of selection, use of preventative care, and access to services.
 - (viii) To HCFA, any other information deemed necessary by HCFA for the administration or evaluation of the Medicare program.
- (3) To its enrollees all informational requirements under § 422.64 and, upon an enrollee's, request the financial disclosure information required under § 422.516.
- (g) *Beneficiary Financial Protection.* The M+C organization agrees to comply with the following requirements:
- (1) Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability for payment of any fee that are the legal obligation of the M+C organization. To meet this requirement the M+C organization must—

- (i) 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
 - (ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the M+C organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the M+C organization, to provide services to the organization's beneficiary enrollees.
- (2) The M+C organization must provide for continuation of enrollee health care benefits—
- (i) For all enrollees, for the duration of the contract period for which HCFA payments have been made; and
 - (ii) For enrollees who are hospitalized on the date its contract with HCFA terminates, or, in the event of an insolvency, through discharge.
- (3) In meeting the requirements of this paragraph (g), other than the provider contract requirements specified in paragraph (g)(1) of this section, the M+C organization may use—
- (i) Contractual arrangements;
 - (ii) Insurance acceptable to HCFA;
 - (iii) Financial reserves acceptable to HCFA; or
 - (iv) Any other arrangement acceptable to HCFA.
- (h) *Requirements of other laws and regulations.* (1) The M+C organization agrees to comply with—
- (i) Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84;
 - (ii) The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91;
 - (iii) The Americans With Disabilities Act; and
 - (iv) Other laws applicable to recipients of Federal funds; and
 - (v) All other applicable laws and rules.
- (2) M+C organizations receiving Federal payments under M+C contracts, and related entities, contractors, and subcontractors paid by an M+C organization to fulfill its obligations under its M+C contract are subject to certain laws that are applicable to individuals and entities receiving Federal funds. M+C organizations must inform all related entities, contractors and subcontractors that payments that they receive are, in whole or in part, from Federal funds.
- (i) *M+C organization relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the M+C organization may have with related entities, contractors, or subcontractors, the M+C organization maintains

ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with HCFA.

- (2) The M+C organization agrees to require all related entities, contractors, or subcontractors to agree that—
- (i) HHS, 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) involving transactions related to the M+C contract; and
 - (ii) HHS', 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 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.
- (3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, or subcontractors must contain the following:
- (i) Enrollee protection provisions that provide—
 - (A) Consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C Organization; and
 - (B) Consistent with paragraph (g)(2) of this section, provision for the continuation of benefits.
 - (ii) Accountability provisions that indicate that—
 - (A) The M+C organization oversees and is accountable to HCFA for any functions or responsibilities that are described in these standards; and
 - (B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.
 - (iii) A provision requiring that any services or other activity performed by a related entity, contractor or subcontractor in accordance with a contract or written agreement will be consistent and comply with the M+C organization's contractual obligations.
- (4) If any of the M+C organizations' activities or responsibilities under its contract with HCFA are delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:
- (i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where HCFA or the M+C organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the M+C organization on an ongoing basis.

(iv) Written arrangements must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the M+C organization; or

(B) The credentialing process will be reviewed and approved by the M+C organization and the M+C organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and HCFA instructions.

(5) If the M+C organization delegates selection of the providers, contractors, or subcontractor to another organization, the M+C organization's written arrangements with that organization must state that the HCFA-contracting M+C organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The M+C organization agrees to include in the contract such other terms and conditions as HCFA may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon HCFA's request—

(1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by HCFA; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO) or chief financial officer (CFO) must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of relevant data that HCFA requests. Such data include specified enrollment information, encounter data, and other information that HCFA may specify.

(1) The CEO or CFO must certify that each enrollee for whom the organization is requesting payment is validly

enrolled in an M+C plan offered by the organization and the information relied upon by HCFA in determining payment is accurate.

(2) The CEO or CFO must certify that the encounter data it submits under § 422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data.

(m) *Certification of accuracy of ACR.* The M+C organization agrees, as a condition for retaining (and not providing additional benefits with) payment amounts below the amount of its ACR, that the information in its ACR submission is accurate and fully conforms to the requirements in § 422.310.

§ 422.504 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the M+C organization and HCFA and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Except as provided in paragraph (d) of this section, each contract is for a period of 12 months beginning on January 1 and ending on December 31.

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if—

(1) HCFA informs the M+C organization that it authorizes a renewal; and

(2) The M+C organization has not provided HCFA with a notice of intention not to renew.

(d) *Exception.* Prior to January 1, 2002, at HCFA's discretion, a contract may be for a term longer than 12 months and may begin on a date specified by HCFA other than January 1.

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an M+C organization.* (1) An M+C organization may elect not to renew its contract with HCFA as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an M+C organization does not intend to renew its contract, it must notify—

(i) HCFA in writing, by May 1 of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the

nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative M+C plans, Medigap options, and original Medicare and must receive HCFA approval.

(iii) 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 M+C organization's service area.

(3) HCFA may accept a nonrenewal notice submitted after May 1 if—

(i) The M+C organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(2)(ii) and (a)(2)(iii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an M+C organization does not renew a contract under this paragraph (a), HCFA will not enter into a contract with the organization for 5 years unless there are special circumstances that warrant special consideration, as determined by HCFA.

(b) *HCFA decision not to renew.* (1) HCFA may elect not to authorize renewal of a contract for any of the following reasons:

(i) The M+C organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in § 422.152(d).

(ii) The M+C organization's level of enrollment or growth in enrollment is determined by HCFA to threaten the viability of the organization under the M+C program and or be an indicator of beneficiary dissatisfaction with the M+C plan(s) offered by the organization.

(iii) For any of the reasons listed in § 422.510(a), which would also permit HCFA to terminate the contract.

(iv) The M+C organization has committed any of the acts in § 422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(2) *Notice.* HCFA provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the M+C organization by May 1 of the contract year.

(ii) If HCFA decides not to authorize a renewal of the contract, to the M+C organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If HCFA decides not to authorize a renewal of the contract, to 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 or county located in the M+C organization's service area.

(3) *Notice of appeal rights.* HCFA gives the M+C organization written notice of its right to appeal the decision not to renew in accordance with § 422.644.

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the M+C organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the M+C organization must notify its Medicare enrollees of any changes that HCFA determines are appropriate for notification within timeframes specified by HCFA.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new M+C contract, the M+C organization is not required to provide the notice specified in paragraph (a)(1) of this section.

§ 422.510 Termination of contract by HCFA.

(a) *Termination by HCFA.* HCFA may terminate a contract for any of the following reasons:

(1) The M+C organization has failed substantially to carry out the terms of its contract with HCFA.

(2) The M+C organization is carrying out its contract with HCFA in a manner that is inconsistent with the effective and efficient implementation of this part.

(3) HCFA determines that the M+C organization no longer meets the requirements of this part for being a contracting organization.

(4) The M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program, including submission of fraudulent data.

(5) The M+C 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.

(6) The M+C organization substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(7) The M+C organization fails to provide HCFA with valid encounter data as required under § 422.257.

(8) The M+C organization fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(9) The M+C organization substantially fails to comply with the prompt payment requirements in § 422.520.

(10) The M+C organization substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(11) The M+C organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(b) *Notice.* If HCFA decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), it gives notice of the termination as follows:

(1) *Termination of contract by HCFA.*

(i) HCFA notifies the M+C organization in writing 90 days before the intended date of the termination.

(ii) The M+C organization notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The M+C organization notifies 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 M+C organization's service area.

(2) *Immediate termination of contract by HCFA.* (i) For terminations based on violations prescribed in § 422.510(a)(5), HCFA notifies the M+C organization in writing that its contract has been terminated effective the date of the termination decision by HCFA. If termination is effective in the middle of a month, HCFA has the right to recover the prorated share of the capitation payments made to the M+C organization covering the period of the month following the contract termination.

(ii) HCFA notifies the M+C organization's Medicare enrollees in writing of HCFA's decision to terminate the M+C organization's contract. This notice occurs no later than 30 days after HCFA notifies the plan of its decision to terminate the M+C contract. HCFA simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative M+C organizations in a similar geographic area and original Medicare.

(iii) HCFA notifies the general public of the termination no later than 30 days

after notifying the plan of HCFA's decision to terminate the M+C contract. This notice is published in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

(c) *Corrective action plan—(1) General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, HCFA provides the M+C organization with reasonable opportunity, not to exceed timeframes specified at subpart N of this part, to develop and receive HCFA approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under § 422.510(a)(5), the M+C organization will not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If HCFA decides to terminate a contract, it sends written notice to the M+C organization informing it of its termination appeal rights in accordance with subpart N of this part.

§ 422.512 Termination of contract by the M+C organization.

(a) *Cause for termination.* The M+C organization may terminate the M+C contract if HCFA fails to substantially carry out the terms of the contract.

(b) *Notice.* The M+C organization must give advance notice as follows:

(1) To HCFA, at least 90 days before the intended date of termination. This notice must specify the reasons why the M+C organization is requesting contract termination.

(2) 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 M+C plans, Medigap options, original Medicare and must receive HCFA approval.

(3) To the general public at least 60 days before the termination effective date by publishing an HCFA-approved notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by HCFA and is at least 90 days after the date HCFA receives the M+C organization's notice of intent to terminate.

(d) *HCFA's liability.* HCFA's liability for payment to the M+C organization ends as of the first day of the month

after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* HCFA does not enter into an agreement with an organization that has terminated its contract within the preceding 5 years unless there are circumstances that warrant special consideration, as determined by HCFA.

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, HCFA does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) 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

(2) 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 § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an M+C organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum Enrollment Waiver.* (1) For an organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of such contract, HCFA may waive the minimum enrollment requirement as provided for below. To receive a waiver, an organization must demonstrate to HCFA's satisfaction that it is capable to administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that HCFA will take into consideration in making this evaluation include the extent to which—

(i) 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 as described in paragraph (a) of this section, or

(ii) The organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, HCFA considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this

section and stop-loss insurance that is adequate and acceptable to HCFA; and,

(iii) The organization is able to establish a marketing and enrollment process that will allow it to meet the applicable enrollment requirement specified in paragraph (a) of this section prior to completion of the third contract year.

(2) If an M+C organization fails to meet the enrollment requirement in the first year, HCFA may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an M+C contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an M+C organization fails to meet the enrollment requirement in the second year, HCFA may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. HCFA may elect not to renew its contract with an M+C organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

§ 422.516 Reporting requirements.

(a) *Required information.* Each M+C organization must have an effective procedure to develop, compile, evaluate, and report to HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the M+C organization has a fiscally sound operation.

(6) Other matters that HCFA may require.

(b) *Significant business transactions.* Each M+C organization must report to

HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in § 422.500) between the M+C organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the M+C organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the M+C organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the M+C organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the M+C organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an M+C organization showing good cause, HCFA may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an M+C organization in its offerings, the M+C organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The M+C organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify HCFA of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information.* Each M+C organization must make the information reported to HCFA under § 422.502(f)(1) available to its enrollees upon reasonable request.

§ 422.520 Prompt payment by M+C organization.

(a) *Contract between HCFA and the M+C organization.*

(1) The contract between HCFA and the M+C organization must provide that the M+C 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 M+C private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The M+C organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims must be approved or denied within 60 calendar days from the date of the request.

(b) *Contracts between M+C organizations and providers and suppliers.* Contracts or other written agreements between M+C organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the M+C organization and the relevant provider.

(c) *Failure to comply.* If HCFA determines, after giving notice and opportunity for hearing, that an M+C organization has failed to make payments in accordance with paragraph (a) of this section, HCFA may provide—

(1) For direct payment of the sums owed to providers, or M+C private fee-for-service plan enrollees; and

(2) 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.

§ 422.524 Special rules for RFB societies.

In order to participate as an M+C organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the M+C 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.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

17. *Nomenclature change.* Throughout newly designated subpart L, "HMO or CMP" is revised to read "M+C organization" wherever it appears.

18. *Nomenclature change.* Throughout newly designated subpart L, "HMO's or CMP's" are revised to read "M+C organization" and "M+C organization's" respectively.

§ 422.550 [Amended]

19. In § 422.550, the following changes are made:

a. In paragraph (b), the following sentence is added at the end: "The M+C organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization."

b. In paragraphs (c)(2) and (e), "§ 417.522" is revised to read "§ 422.552".

c. In paragraph (d)(2), "subpart L" is revised to read "subpart K".

§ 422.552 [Amended]

20. In § 422.552, in paragraph (a)(1), the following sentence is added at the end: "The M+C organization also provides HCFA with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization."

§ 422.553 [Amended]

21. In § 422.553, "subpart J" is revised to read "subpart K".

22. Subparts M through O are added to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

Sec.

422.560 Basis and scope.
422.561 Definitions.
422.562 General provisions.
422.564 Grievance procedures.
422.566 Organization determinations.
422.568 Standard timeframes and notice requirements for organization determinations.

422.570 Expediting certain organization determinations.

422.572 Timeframes and notice requirements for expedited organization determinations.

422.574 Parties to the organization determination.

422.576 Effect of an organization determination.

422.578 Right to a reconsideration.

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422.582 Request for a standard reconsideration.

422.584 Expediting certain reconsiderations.

422.586 Opportunity to submit evidence.
422.590 Timeframes and responsibility for reconsiderations.
422.592 Reconsideration by an independent entity.
422.594 Notice of reconsidered determination by the independent entity.
422.596 Effect of a reconsidered determination.
422.600 Right to a hearing.
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422.608 Departmental Appeals Board review.
422.612 Judicial review.
422.616 Reopening and revising determinations and decisions.
422.618 How an M+C organization must effectuate reconsidered determinations or decisions.
422.620 How M+C organizations must notify enrollees of noncoverage of inpatient hospital care.
422.622 Requesting immediate PRO review of noncoverage of inpatient hospital care.

Subpart N—Medicare Contract Appeals

422.641 Contract determinations.
422.644 Notice of contract determination.
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Subpart O—Intermediate Sanctions

422.750 Kinds of sanctions.
422.752 Basis for imposing sanctions.
422.756 Procedures for imposing sanctions.
422.758 Maximum amount of civil money penalties imposed by HCFA.
422.760 Other applicable provisions.

Subpart M—Grievances, Organization Determinations and Appeals**§ 422.560 Basis and scope.**

(a) *Statutory basis.* (1) Section 1852(f) of the Act provides that an M+C organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an M+C organization must meet concerning organization determinations and appeals.

(b) *Scope.* This subpart sets forth—

(1) Requirements for M+C organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of M+C enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an M+C enrollee requests immediate PRO review of a determination that he or she no longer needs inpatient hospital care.

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services an enrollee is entitled to receive or any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.

Authorized representative means an individual authorized by an enrollee to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in this subpart.

Enrollee means an M+C eligible individual who has elected an M+C plan offered by an M+C organization, or his or her authorized representative.

Grievance means any complaint or dispute other than one involving an organization determination, as defined in § 422.566(b).

Physician has the meaning given the term in section 1861(r) of the Act.

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that

do not involve organization determinations;

(ii) A procedure for making timely organization determinations; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An M+C organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the M+C organization; and

(ii) Complaint process available to the enrollee under the PRO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the M+C organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of M+C enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the M+C organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the M+C organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an M+C organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by HCFA, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is \$100 or more, as provided in § 422.600.

(v) The right to request DAB review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is \$1000 or more, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate PRO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the M+C organization; and

(ii) The PRO review decision is subject only to the appeal procedures set forth in part 473 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an M+C organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in 20 CFR, part 404, subparts J and R (covering, respectively, the administrative review and hearing process and representation of parties under title II of the Act), apply under this subpart to the extent they are appropriate.

§ 422.564 Grievance procedures.

(a) *General rules.* (1) Each M+C organization must provide meaningful procedures for timely hearing and resolution of grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any M+C plan it offers.

(2) Grievance procedures must meet any guidelines established by HCFA.

(b) *Distinguished from organization determinations and appeals.* Grievance procedures are separate and distinct from organization determinations and appeal procedures, which address organization determinations.

(c) *Distinguished from the PRO complaint process.* Under section 1154(a)(14) of the Act, the PRO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program; this process is separate and distinct from the grievance procedures of the M+C organization.

§ 422.566 Organization determinations.

(a) *Responsibilities of the M+C organization.* Each M+C organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an M+C plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The M+C organization must have a

standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization when the enrollee has not received the services outside the M+C organization.

(4) Discontinuation of a service, if the enrollee disagrees with the determination that the service is no longer medically necessary.

(c) *Who can request an organization determination.* Any of the parties listed in § 422.574 can request an organization determination, with the exception that only the parties listed in § 422.570(a) can request an expedited determination.

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health

condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in § 422.520.

(c) *Written notification for denials.* If an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(d) *Content of the notice.* The notice of any denial under paragraph (c) of this section must—

(1) State the specific reasons for the denial in understandable language;

(2) Inform the enrollee of his or her right to a reconsideration;

(3) Describe both the standard and expedited reconsideration processes, including the enrollee's right to and conditions for obtaining an expedited reconsideration for service requests, and the rest of the appeal process; and

(4) Comply with any other requirements specified by HCFA.

(e) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the determination, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the M+C organization must process requests.* The M+C organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The M+C organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the M+C organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the M+C organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether

adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 2 working days of the oral notification.

(d) *How information from noncontract providers affects timeframes for expedited determinations.* If an M+C organization must receive medical information from noncontract providers, the 72-hour period begins when the organization receives that information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

- (i) Inform the enrollee of his or her right to a reconsideration;
- (ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and
- (iii) Comply with any other requirements specified by HCFA.

(f) *Effect of failure to provide a timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or HCFA obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by filing a written request with—

- (1) The M+C organization that made the organization determination;
- (2) An SSA office; or
- (3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for a reconsideration within 60 calendar days from the date of the notice of the organization determination. If the SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The timeframe within which the organization must conduct its review begins when it receives the request.

(c) *Extending the time for filing a request.*

(1) *General rule.* If a party shows good cause, the M+C organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for reconsideration with the M+C organization, SSA, or an RRB office. If SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

- (i) Be in writing; and
- (ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the M+C organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.) A physician that requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the M+C organization must process requests.* The M+C organization must establish and maintain the

following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The M+C organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the M+C organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the M+C organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an M+C organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590(d).

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

§ 422.586 Opportunity to submit evidence.

The M+C organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the M+C organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.*

(1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue its reconsidered determination to the enrollee (and effectuate it in

accordance with § 422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the M+C organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the M+C organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the M+C organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration—(1) Timeframe.* Except as provided in paragraph (d)(2) of this section, an M+C organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee orally of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 2 working days.

(4) *How information from noncontract providers affects timeframes for expedited reconsiderations.* If the M+C organization must receive medical information from noncontract providers, the 72-hour period begins when the

organization receives the information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity, the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue.

§ 422.592 Reconsideration by an independent entity.

(a) When the M+C organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with HCFA.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same

parties listed in § 422.582(d) who qualified during the M+C organization's reconsideration, with the addition of the M+C organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to HCFA.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the M+C organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is \$100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by HCFA.

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy is \$100 or more, any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ. The M+C organization does not have the right to request a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.817 of this chapter for Part B services.

(c) If the basis for the appeal is the M+C organization's refusal to provide services, HCFA uses the projected value of those services to compute the amount remaining in controversy.

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing at one of the places listed in § 422.582(a) or with the independent, outside entity. The organizations listed in § 422.582(a) forward the request to the independent, outside entity, which

is responsible for transferring the case to the appropriate ALJ hearing office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in 20 CFR 404.933(c), a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the M+C organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *When the amount in controversy is less than \$100.* (1) If a request for a hearing clearly shows that the amount in controversy is less than \$100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than \$100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 422.608 Departmental Appeals Board (DAB) review.

Any party to the hearing, including the M+C organization, who is dissatisfied with the ALJ hearing decision, may request that the DAB review the ALJ's decision or dismissal. Regulations located at 20 CFR 404.967 through 404.984 regarding SSA Appeals Council Review apply to DAB review for matters addressed by this subpart.

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The DAB denied the party's request for review; and

(2) The amount in controversy is \$1,000 or more.

(b) *Review of DAB decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the DAB decision if—

(1) It is the final decision of HCFA; and

(2) The amount in controversy is \$1,000 or more.

(c) *How to request judicial review.* A party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an M+C

organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the DAB that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in § 405.750 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the M+C organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

§ 422.618 How an M+C organization must effectuate reconsidered determinations or decisions.

(a) *Reversals by the M+C organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the M+C organization receives the request for reconsideration.

(b) *Reversals other than by the M+C organization.* If the M+C organization's organization determination is reversed in whole or in part by the independent outside entity or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the organization determination. The M+C organization must also inform the independent, outside entity that the organization has effectuated the decision.

§ 422.620 How M+C organizations must notify enrollees of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of

an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the enrollee remains entitled to inpatient hospital care until he or she receives notice of noncoverage of that care.

(b) *Physician concurrence required.* Before the M+C organization gives notice of noncoverage as described in paragraph (c) of this section, the physician who is responsible for the enrollee's hospital care must concur.

(c) *Notice to the enrollee.* The M+C organization must give the enrollee written notice that includes the following:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Comply with any other requirements specified by HCFA.

(d) *Physician concurrence when a hospital determines if care is necessary.* If the M+C organization allows the hospital to determine whether inpatient care is necessary, the hospital obtains the concurrence of the contracting physician responsible for the enrollee's hospital care or of another physician as authorized by the M+C organization, and notifies the enrollee, following the procedures set forth in § 412.42(c)(3) of this chapter.

§ 422.622 Requesting immediate PRO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an M+C organization or hospital that inpatient care is no longer necessary must request immediate PRO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate PRO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate PRO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the M+C organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate PRO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the PRO that has an agreement with the hospital under § 466.78 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the M+C organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the PRO must notify the M+C organization that the enrollee has filed a request for immediate review.

(3) The M+C organization must supply any information that the PRO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the M+C organization, the hospital must submit medical records and other pertinent information to the PRO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The PRO must solicit the views of the enrollee who requested the immediate PRO review.

(6) The PRO must make a determination and notify the enrollee, the hospital, and the M+C organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the M+C organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if the M+C organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. If coverage of the hospital admission was never approved by the M+C organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the M+C organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the M+C plan.

(ii) The hospital may not charge the M+C organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate PRO review; and

(B) The PRO upholds the noncoverage determination made by the M+C organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the PRO notifies the enrollee of its review determination.

Subpart N—Medicare Contract Determinations and Appeals

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with HCFA under Part C of title XVIII of the Act.

(b) A determination to terminate a contract with an M+C organization in accordance with § 422.510(a).

(c) A determination not to authorize a renewal of a contract with an M+C organization in accordance with § 422.506(b).

§ 422.644 Notice of contract determination.

(a) When HCFA makes a contract determination, it gives the M+C organization written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The M+C organization's right to request reconsideration.

(c) For HCFA-initiated terminations, HCFA mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 422.510(a)(5), HCFA immediately notifies the M+C organization of its decision to terminate the organization's M+C contract.

(d) When HCFA determines that it will not authorize a contract renewal, HCFA mails the notice to the M+C organization by May 1 of the current contract year.

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with §§ 422.648 through 422.658;

(b) A timely request for a hearing is filed under § 422.662; or

(c) The reconsideration decision is revised as a result of a reopening under § 422.696.

§ 422.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 422.641.

(b) HCFA reconsiders the specified determinations if the M+C organization files a written request in accordance with § 422.650.

§ 422.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any HCFA office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the entity or M+C organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The M+C organization or M+C contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with HCFA.

§ 422.652 Opportunity to submit evidence.

HCFA provides the M+C organization or M+C contract applicant and the HCFA official or officials who made the contract determination reasonable opportunity to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 422.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the M+C organization subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 422.656 Notice of reconsidered determination.

(a) HCFA gives the M+C organization or M+C contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the M+C organization's qualifications to

enter into or remain under a contract with HCFA pursuant to Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the M+C organization or M+C contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 422.658 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 422.662 or it is revised in accordance with § 422.696.

§ 422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) An applicant entity that has been determined in a reconsidered determination to be unqualified to enter into a contract with HCFA under Part C of the Act.

(b) An M+C organization whose contract with HCFA has been terminated or has not been renewed as a result of a contract determination as provided in § 422.641.

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the applicant entity or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the notice of contract or reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) HCFA.

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.

(a) HCFA postpones the proposed effective date of the contract determination to terminate a contract with an M+C organization until a hearing decision is reached and affirmed by the Administrator following review under § 422.692 in instances where an M+C organization requests review by the Administrator; and

(b) HCFA extends the current contract at the end of the contract period (in the

case of a determination not to renew) only—

(1) If HCFA finds that an extension of the contract will be consistent with the purpose of this part; and

(2) For such period as HCFA and the M+C organization agree.

(c) Exception: A contract terminated in accordance with § 422.510(a)(5) will be immediately terminated and will not be postponed if a hearing is requested.

§ 422.666 Designation of hearing officer.

HCFA designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, HCFA designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to HCFA.

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§ 422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 422.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 422.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by HCFA in implementing the Act.

§ 422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for Review by Administrator.* An M+C organization that has received a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 422.690(b).

(b) *Review by the Administrator.* The Administrator shall review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the M+C organization, whether the termination decision should be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the M+C organization requesting review.

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* HCFA may reopen and revise an initial or reconsidered determination upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is

unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by HCFA may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 422.698 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662.

Subpart O—Intermediate Sanctions

§ 422.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from \$10,000 to \$100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the M+C organization for Medicare beneficiaries who enroll.

(4) Require the M+C organization to suspend all marketing activities to Medicare beneficiaries for the M+C plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until HCFA is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, HCFA may impose any of the sanctions specified in § 422.750 on any M+C organization that has a contract in effect. The M+C organization may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to an M+C enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to an M+C enrollee, and that

failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on M+C enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and Subpart G of this part.

(3) Expels or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To HCFA; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of § 422.204, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with § 422.216, which requires the organization to enforce the limit on balance billing under a private fee-for-service plan.

(8) Employs or contracts with an individual who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an individual) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If HCFA makes a determination under § 422.510(a), HCFA may impose the intermediate sanctions in § 422.756(c)(1) and (c)(3).

§ 422.756 Procedures for imposing sanctions.

(a) *Notice of Sanction and opportunity to respond*—(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section HCFA—

(i) Sends a written notice to the M+C organization stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* HCFA allows the M+C organization 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 422.752, as applicable. HCFA may allow a 15-day addition to the original 15 days upon receipt of a written request from the

M+C organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by HCFA before the end of the 15-day period following the date of receipt of the sanction notice. HCFA does not grant an extension if it determines that the M+C organization's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section the M+C organization submits a timely response to HCFA's notice of sanction, HCFA conducts an informal reconsideration that:

(1) Consists of a review of the evidence by an HCFA official who did not participate in the initial decision to impose a sanction; and

(2) Gives the M+C organization a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If HCFA determines that an M+C organization has acted or failed to act as specified in § 422.752 and affirms this determination in accordance with paragraph (b) of this section, HCFA may—

(1) Require the M+C organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned M+C plan during the sanction period;

(2) In the case of a violation under § 422.752(a), suspend payments to the M+C organization for Medicare beneficiaries enrolled in the sanctioned M+C plan during the sanction period; and

(3) Require the M+C organization to suspend all marketing activities for the sanctioned M+C plan to Medicare enrollees.

(d) *Effective date and duration of sanctions*—(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the M+C organization timely seeks reconsideration under paragraph (b) of this section, on the date specified in the notice of HCFA's reconsidered determination.

(2) *Exception.* If HCFA determines that the M+C organization's conduct poses a serious threat to an enrollee's health and safety, HCFA may make the sanction effective on a date before issuance of HCFA's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until HCFA notifies the M+C organization that HCFA is satisfied that the basis for imposing the

sanction has been corrected and is not likely to recur.

(e) *Termination by HCFA.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, HCFA may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3), or terminate the contract in accordance with § 422.510.

(f) *Civil Money Penalties.* (1) If HCFA determines that an M+C organization has committed an act or failed to comply with a requirement described in § 422.752, HCFA notifies the OIG of this determination, and also notifies OIG when HCFA reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of 42 CFR parts 1003 and 1005, the OIG may impose civil money penalties on the M+C organization in accordance with parts 1003 and 1005 of this title in addition to, or in place of,

the sanctions that HCFA may impose under paragraph (c) of this section.

(3) In the case of a determination under paragraph (b) of § 422.752 other than a determination based upon a violation under § 422.510(a)(4), in accordance with the provisions of 42 CFR parts 1003 and 1005, HCFA may impose civil money penalties on the M+C organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that HCFA may impose under paragraph (c) of this section.

§ 422.758 Maximum amount of civil money penalties imposed by HCFA.

If HCFA makes a determination under § 422.752(b), based on any determination under § 422.510(a) except a determination under § 422.510(a)(4), HCFA may impose civil money penalties in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more M+C enrollees—\$25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the M+C organization receives HCFA's notice of the determination—\$10,000.

§ 422.760 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 17, 1998.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Dated: June 18, 1998.

Donna E. Shalala,
Secretary.

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