DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 403, 410, 411, 417, and 422

[HCFA–1030–IFC]

RIN 0938–AI29

Medicare Program; Establishment of the Medicare+Choice Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: The Balanced Budget Act of 1997 (BBA) establishes a new Medicare+Choice (M+C) program that significantly expands the health care options available to Medicare beneficiaries. Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original Medicare program or the plans now available through managed care organizations under section 1876 of the Social Security Act. Among the alternatives that will be available to Medicare beneficiaries are M+C coordinated care plans (including plans offered by health maintenance organizations, preferred provider organizations, and provider-sponsored organizations), M+C ''MSA'' plans, that is, a combination of a high deductible M+C health insurance plan and a contribution to an M+C medical savings account (MSA), and M+C private fee-for-service plans.

The introduction of the M+C program will have a profound effect on Medicare beneficiaries and on the health plans and providers that furnish care. The new provisions of the Medicare statute, set forth as Part C of title XVIII of the Social Security Act, address a wide range of areas, including eligibility and enrollment, benefits and beneficiary protections, quality assurance, participating providers, payments to M+C organizations, premiums, appeals and grievances, and contracting rules. This interim final rule explains and implements these provisions.

In addition, we are soliciting letters of intent from organizations that intend to offer M+C MSA plans to Medicare beneficiaries and/or to serve as M+C MSA trustees.

DATES: *Effective date:* This interim final rule is effective July 27, 1998.

Comment period: Comments will be considered if received at the appropriate address, as provided below, no later than September 24, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1030–IFC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1027–IFC Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:

Provider Sponsored Organizations, Aaron Brown, 410–786–1033.

M+C Private Fee-For Service Plans, Anita Heygster, 410–786–4486.

M+C MSA Plans, Cindy Mason, 410–786–6680.

Applications, Robert King, 410–786–7623.

Quality Assurance, Brian Agnew, 410–786–5964.

Payment/ACRs, Al D'Alberto, 410–786–1100.

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Federal/State, Rebecca Cardozo, 410–786–0300.

Beneficiary Appeals, Valerie Hart, 410–786–6690.

Enrollment, Debe McKeldin, 410–786–9159.

Information Campaign, Jan Drass, 410–786–1354.

Contracts, Chris Eisenberg, 410–786–5509.

General Issues, Tony Hausner, 410–786–8290.

General Issues, Dorothea Musgrave, 410–786–8290.

SUPPLEMENTARY INFORMATION:

I. Background

A. Balanced Budget Act of 1997

Health care benefits covered under the Medicare program are divided into two parts: hospital insurance, also known as ''Part A,'' and supplementary medical insurance, also known as ''Part B.'' Health care services covered under Part A include: inpatient hospital care, skilled nursing facility care, home health agency care, and hospice care. Part B coverage is optional and requires payment of a monthly premium. Part B covers physician services (in both hospital and nonhospital settings) and services furnished by certain nonphysician practitioners. It also covers certain other services, including: clinical laboratory tests, durable medical equipment, medical supplies, diagnostic tests, ambulance services, prescription drugs that cannot be self-administered, certain self-administered anti-cancer drugs, some other therapy services, certain other health services, and blood not covered under Part A.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the ''Medicare+Choice Program.'' Note that hereinafter, unless otherwise indicated references to the statute are references to the Act. (The existing Part C of the statute, which included provisions in section 1876 governing existing Medicare health maintenance organization (HMO) contracts, has been redesignated as Part D.) Under section 1851(a)(1), every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end-stage renal disease, may elect to receive benefits through either the existing Medicare fee-for-service program or a Part C M+C plan.

The introduction of the M+C program represents what is arguably the most significant change in the Medicare program since its inception in 1965. As its name implies, the primary goal of the M+C program is to provide Medicare beneficiaries with a wider range of health plan choices to complement the Original Medicare option. Alternatives available to beneficiaries under the M+C program include both the traditional managed care plans (such as HMOs) that have participated in Medicare on a capitated payment basis under section 1876 , as well as a broader range of plans comparable to those now available through private insurance. Specifically, effective January 1, 1999, section 1851(a)(2) provides for three types of M+C plans:

- M+C coordinated care plans, including HMO plans (with or without point of service options), provider-sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.

• M+C medical savings account (MSA) plans (that is, combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).

• M+C private fee-for-service plans.

In addition to expanding the types of available health plans, the M+C program introduces several other fundamental changes to the private health plan sector of the Medicare program. These changes include:

• Establishment of an expanded array of quality assurance standards and other consumer protection requirements.

• Introduction of an annual coordinated election period. This election period, to be conducted in November for a January effective date, will feature a phased in lock-in of enrollees to the plan they have elected during this coordinated election period. In addition, the annual coordinated election period will include the distribution by HCFA of uniform, comprehensive information about participating plans that is needed to promote informed choices by beneficiaries.

• Revisions in the way we calculate payment rates to the plans that will narrow the amount of payment variation across the country and increase incentives for plans to operate in diverse geographic areas.

• Establishment of requirements concerning participation procedures for physicians and other health care professionals in M+C plans, including prohibitions on interference with advice to enrollees.

These requirements will bring about changes for beneficiaries, for physicians and other health care providers, for managed care organizations that now contract with Medicare as well as those that will be able to contract with Medicare for the first time, and for HCFA and the States. The specific areas addressed by the different sections of the statute are as follows:

• Section 1851—Eligibility, election and enrollment

• Section 1852—Benefits and beneficiary protections

• Section 1853—Payments to M+C organizations

• Section 1854—Premiums

• Section 1855—Organizational and financial requirements for M+C organizations

• Section 1856—Establishment of standards

• Section 1857—Contracts with M+C organizations

• Section 1859—Definitions and miscellaneous provisions

As provided for in section 1856(b)(1), this interim final rule (1) incorporates the new M+C provisions into the Medicare regulations, (2) interprets the new statutory provisions in Part C, and (3) establishes by regulation new standards under the M+C program. Other provisions of the BBA addressed in this interim final rule include:

• Section 4002—Transitional rules for current HMO Medicare program.

• Section 4003—Conforming changes in the Medigap program.

• Section 4006—M+C MSAs.

We note that in February, 1998, the President issued an Executive Order directing the Secretary to comply to the extent possible through administrative activities with the standards contained in the Consumer Bill of Rights and Responsibilities. Therefore, as discussed in several sections of this preamble, we have taken these standards into consideration in developing the regulations contained in this interim final rule. We have also incorporated conforming provisions consistent with other parts of the Medicare statute, such as exempting services under M+C coordinated care plans from the anti-referral provisions in section 1877.

In several places in this preamble, we indicate that HCFA intends to develop additional policy guidance or instructions. In doing so, we will use a formal rulemaking process and allow for review by the Office of Management and Budget pursuant to the requirements of the Paperwork Reduction Act of 1995, wherever it is appropriate to do so.

B. Codification of Regulations

The regulations text set forth in this interim final rule is codified in 42 CFR Part 422—Medicare+Choice Program. (Note that new part 422 was established in our April 14, 1998 interim final rule on PSOs (63 FR 18124).) The current Medicare regulations for managed care organizations that contract with HCFA under section 1876, or for health care prepayment plans (HCPPs) that are paid under section 1833(a)(1)(A), will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Although the part 422 provisions will eventually supersede the regulations in part 417 for contracts with risk-bearing HMOs and competitive medical plans (CMPs), there are some purposes for which the part 417 provisions will continue in effect for a transitional period. Also, various provisions of section 4002 of the BBA provide for the continuation of cost-based contracts under section 1876 and of agreements with HCPPs under section 1833(a). Thus, the part 422 regulations cannot entirely replace the part 417 regulations at this time. (Both transitional provisions and those relating to cost-based contracts and HMOs are discussed in detail below in the appropriate sections of this interim final rule.)

For the convenience of organizations that contract with HCFA only under the M+C program, we are including in part 422 both new requirements that implement newly enacted provisions in Part C and existing requirements from part 417 that also will be imposed under Part C. For transitional requirements, which could logically appear in both parts, we are setting forth the full requirements in part 422 and referencing them in part 417. Requirements that apply to organizations that contract with HCFA, or are paid by HCFA, only under section 1876 or 1833(a) will remain in part 417. Regulations implementing the provisions of section 1310 of the Public Health Service Act concerning Federally-qualified HMOs also remain in part 417.

C. Organizational Overview of Part 422

The major subjects covered in each subpart of part 422 are as follows:

• Subpart A—Definitions, including definition of types of plans, application process, and user fees.

• Subpart B—Requirements concerning beneficiary eligibility, election, enrollment and disenrollment procedures, and plan information and marketing materials.

• Subpart C—Requirements concerning benefits, point of service options, disclosure of information, access to services, confidentiality of enrollee records, advance directives, and beneficiary protection against liability.

• Subpart D—Quality assurance standards, external review, and deeming of accredited organizations.

• Subpart E—Organizational relationships with participating entities including the prohibition against interference with health care professionals' advice to enrollees, physician incentive requirements, and special rules for M+C private fee-for-service plans and private contracts with health care professionals.

• Subpart F—Payment methodology for M+C organizations, coverage that begins or ends during inpatient hospital stays, hospice care, and encounter data requirements.

• Subpart G—Requirements concerning terms and conditions for receiving capitated payments, limits on premiums and cost sharing, determination of adjusted community rate, and prohibition of State-imposed premium taxes.

- Subpart H—Requirements concerning provider-sponsored organizations (PSOs).
- Subpart I—Organization compliance with State law and preemption by Federal law.
- Subpart K—General contract and enrollment requirements, administration and management, and procedures for nonrenewal or termination of contracts.
- Subpart L—Effect of change of ownership or leasing of facilities during term of contract.
- Subpart M—Requirements concerning beneficiary grievances and organization determinations and appeals.
- Subpart N—Requirements and procedures for contractor appeals of nonrenewals or terminations of contracts.
- Subpart O—Procedures for imposing intermediate sanctions.

Each of these subparts is discussed below in section II of this preamble. Sections III and IV consist of separate discussions of provisions of the part 422 regulations that specifically concern M+C MSA plans and M+C private fee-for-service plans, respectively.

II. Provisions of the Interim Final Rule

A. General Provisions—Subpart A

1. Overview

Subpart A begins with a brief section (§ 422.1) that specifies the general statutory authority for the ensuing regulations and indicates that the scope of part 422 is to establish standards applicable to the M+C program. Under § 422.2, we then set forth definitions for terms used in part 422 that we believe need clarification. These definitions provide the generally applied meaning for terms that are used throughout part 422. Where necessary, we have included in specific subparts of part 422 definitions for terms used primarily in those subparts. In § 422.4, we define the three different types of M+C plans, consistent with section 1851(a)(2)—M+C coordinated care plans, M+C MSA plans and M+C private fee-for-service plans.

Sections 422.6 and 422.8 then detail the application process for an entity seeking an M+C contract and HCFA's application evaluation procedures.

Section 422.10 adopts, for purposes of the M+C program, the user fee provisions now set forth at § 417.472(h).

2. Definitions (§ 422.2)

For the most part, the definitions presented here are taken directly from the statute or are essentially self-explanatory. Below, we discuss some notable exceptions to this, including cases where we have clarified the exact meaning and context of certain terms. Please keep in mind that the definitions set forth in subpart A reflect general meanings for the terms as they are used in part 422 unless otherwise indicated; the definitions apply strictly for purposes of part 422. For example, the term ''provider'' has a more inclusive meaning under part 422 than it does for other Medicare purposes, as discussed below. Similarly, when we define a term anywhere in part 422 other than in subpart A, it can be assumed that the definition of the term is limited to a specified purpose in the relevant subpart or section. Thus, as specified in the relevant sections of the regulations, the term ''substantial financial risk'' has a different meaning for purposes of the physician incentive provisions under § 422.208 than it does in the PSO provisions under § 422.356.

Benefits and Benefit Categories

In § 422.2, we have defined both the term ''benefits'' as well the different categories under which benefits are provided: basic benefits, additional benefits, mandatory supplemental benefits, and optional supplemental benefits. ''Benefits'' consist of the health care services delivered or covered by an M+C organization. (Note that ''services,'' under the long-standing Medicare definition at § 400.202, encompass medical care, services, and items.) The definition of benefits is relevant both for purposes of the process of determining adjusted community rates (ACRs) for M+C plans and for purposes of a new provision in Part C that ''pre-empts'' State laws relating to ''benefits.''

When we refer to one of the categories under which benefits are provided, however, we generally are referring not only to the actual health services that a beneficiary receives or is eligible to receive, but also to the pricing structure applied to these benefits. For example, the definition of ''additional benefits'' includes both the health care services covered under a plan that are in addition to regularly covered Medicare services, as well as any reductions in premiums or cost-sharing for Medicare covered services. Thus, the amount of deductibles or copayments that an M+C plan enrollee must expend to receive services would fall within the scope of the term ''additional benefits.''

We wish to note that we have defined ''basic benefits'' in this regulation to include *both* the Medicare-covered benefits required under section 1852(a)(1)(A) *and* required ''additional benefits'' under section 1852(a)(1)(B). Both Medicare benefits and required additional benefits are: (1) Coupled together in section 1852(a)(1), in the first paragraph under subsection (a), titled ''Basic Benefits''; (2) benefits that an M+C has an obligation to provide (in contrast to supplemental benefits, which may be provided totally at the M+C organization's discretion); (3) benefits paid for with Medicare trust fund money; and (4) benefits that are covered by the basic premium, if any, that counts towards the limit based on the actuarial value of original Medicare coinsurance and deductible amounts.

For all of these reasons, we have decided to divide benefits into the two categories of the ''basic benefits'' including all required benefits, and ''supplemental benefits,'' including both mandatory and optional supplemental benefits provided at the discretion of the M+C organization. We note that while Congress did not include a ''definition'' of ''basic benefits'' in Part C, it appears to use the term ''basic'' to refer only to the Medicare-covered service package. (See, for example, section 1851(b)(1)(B) or section 1854(e)(1).) Although Congress did not actually include additional benefits in the term ''basic benefits,'' in almost all cases, it coupled these benefits together, and treated them the same. (See sections 1852(a)(1), and 1854(a)(2)(A), (3)(A), (4)(A), and (e)(1).) We accordingly believe that it is appropriate in this regulation to include these two categories together in the definition of ''basic benefits'' that applies for purposes of part 422. We note, however, that where a statutory provision refers only to the Medicare benefit component of our part 422 definition of ''basic benefits,'' we will similarly limit the regulation implementing that provision.

M+C Organization and M+C Plan

The definitions of ''M+C organization'' and ''M+C plan'' set forth in § 422.2 are based on the BBA's use of these terms, which is not always compatible with the way the terms ''organization'' and ''plan'' have been used in the past. In previous HCFA documents, the term ''managed care organization'' frequently has been used interchangeably with the term ''managed care plan'' or ''health plan.'' Section 422.2 addresses this area of potential confusion by clarifying the distinction between an M+C organization and an M+C plan. Succinctly stated, an M+C ''organization'' is an entity that contracts with HCFA to offer an M+C plan; the ''plan'' consists of the specific health benefits, terms of coverage, and pricing structure.

Section 1857(a) specifically states that HCFA contracts with an M+C organization. Thus, for requirements that we would normally think of as contractual requirements, we use the term ''M+C organization.'' In § 422.2 then, an M+C organization is defined as a public or private entity organized and licensed under State law as a risk-bearing entity (with the exceptions of PSOs receiving waivers) that is certified by HCFA as meeting the M+C contract requirements. Under various BBA provisions, the requirements M+C organizations are responsible for meeting include: processing the enrollment and disenrollment of beneficiaries within a plan; transmitting information such as enrollment information and encounter data to HCFA; submitting marketing materials; providing all Medicare-covered benefits and other benefits covered under the contract in a manner consistent with specified access standards; performing quality assurance; creating and carrying out all plan procedures for grievances, organization determinations, and appeals; maintaining necessary records; providing advance directives; establishing procedures related to provider participation; setting medical policies; notifying beneficiaries of any ''Conscience Protection'' exceptions; disclosing physician incentive plans; receiving payment; reporting financial information; paying user fees; making prompt payments to providers; receiving any sanctions invoked by HCFA on any of the organization's plans; and fulfilling other contract requirements as specified in regulation.

Again, in contrast, an M+C plan is merely the health benefits coverage and pricing structure that the organization offers to beneficiaries. An M+C plan may include the basic benefits only (basic benefits include Medicare-covered benefits and additional benefits) or basic benefits combined with mandatory and/or optional supplemental benefits.

An M+C organization may select which providers furnish services under the plan, as long as the benefit package meets all the requirements for access within the area, and outside of the area for specific services. As discussed in detail below, service areas and benefit packages generally are associated with individual plans; uniform premium requirements and the need for an ACR proposal also apply at the plan level.

Service Area

The service area designation of an M+C plan is an important element of the structure and design of a particular plan. A plan's service area—

- Determines the payment rate to the organization for enrollees of the plan, based on the counties included in the service area;
- Affects what benefits will be provided, since benefits and premiums must be uniform under an M+C plan, throughout that plan's defined service area;
- Determines which beneficiaries are able to elect the plan, because organizations are obligated to enroll any eligible resident of the service area who elects the plan; and
- For network plans, is the area in which the plan is required to make covered services available and accessible; and determines the boundaries beyond which the plan assumes liability for urgently needed care and may offer enrollment continuation options.

As explained below, we will exercise discretion in reviewing and approving service areas requested by M+C plans. For network plans, we will use our knowledge of how service areas have been designated in the past in the Medicare managed care program and in the Federally-qualified HMO program, which we have administered since 1986, to ensure availability and accessibility of services. We will attempt to ensure that service areas of M+C network plans are consistent with community patterns of care and/or rating practices—that is, service area designations are not artificially delineated in such a way that usual sources of care, in terms of geographic location, are not available to beneficiaries; or in such a way that the service area designation allows ''gaming'' of the community rate that forms the basis of M+C premiums and benefits, to the disadvantage of Medicare beneficiaries. A nondiscrimination standard will also apply to both network and non-network plans. To the extent possible, we will attempt to ensure a ''level playing field'' among plans operating in the same geographic area (for example, if one plan in an area is subject to the county integrity rule discussed below, a new plan may also be subject to the same standard in determining a new service area). These standards will also be applied in evaluating requests for M+C service area expansions and service area reductions. Consistent with the goals of the new M+C program, we will attempt to maximize the number of choices available to Medicare beneficiaries and maximize the availability of low-cost plans offering additional benefits.

The regulations at § 422.2 provide that an M+C organization may propose a specified service area for each M+C plan, and HCFA will determine whether the proposed area can be approved. The regulatory definition of service area is slightly different from the current service area definition at § 417.401. The latter regulation defines the term geographic area (which we used interchangeably with service area with respect to section 1876 contracts) as ''the area found by the Secretary to be the area in which an HMO is able to deliver the full range of services,'' a definition that was essentially common to both the Medicare program and the Federally qualified HMO program (§ 417.1, ''service area''). The earlier definition emphasizes the role of the Secretary (HCFA) in the designation of service areas, and incorporates one of the standards applicable to network plans (which continue to apply to such plans in these regulations). Statutory references to a service area or geographic area under Medicare, including references in the BBA, do not offer a definition of the term or an indication of how the area is to be determined.

We have modified the wording of the earlier regulatory definition of ''service area'' to recognize that organizations will propose specific areas for M+C plans. Pursuant to section 1856(b)(1), which provides for establishing M+C standards by regulation, and section 1856(b)(2), which provides for basing the standards on standards under section 1876, we have retained our authority to approve or deny service area configurations that organizations propose. This reflects what has been the actual past practice of the agency in administering the Medicare HMO/CMP program and the Federally-qualified HMO program. The new definition also recognizes that service areas designated by organizations for non-network plans are designated for the purpose of determining who is eligible to enroll in the plan.

Consistent with current and past regulatory and statutory standards, we will evaluate proposed service areas of network plans to determine whether covered services are available and accessible, under the standards of § 422.112, to any resident of the area eligible to elect enrollment in the plan. We will also examine the proposed service area of any plan, including non-network plans, to ensure that the delineation of the area does not result in discrimination against beneficiaries through ''gerrymandering'' or ''red-lining'' to deliberately avoid particular areas (e.g., to prevent the enrollment of poorer Medicare beneficiaries, or those known to be in poorer health). An example of such a practice would be an

urban area network plan's exclusion of poorer inner-city areas, leaving obvious ''holes'' in the service area where residents would not have any problem gaining access to care through the plan's providers had the area been included in the proposed service area. Although we would not ordinarily dictate the inclusion of particular areas in the service area of a plan—for example, a multi-county commercial plan could include only some of its counties in a Medicare contract—we would seek to prevent clear cases of discrimination against, or disadvantaging of, particular groups or populations.

Prior to the BBA, contracting HMOs and CMPs (virtually without exception) all had existing, defined service areas prior to entering into a Medicare contract. These were areas in which the entities offered comprehensive health care services to non-Medicare enrollees of the specified geographic area. As noted above, Medicare's statutory language did not clearly define the terms service area or geographic area, but it was assumed that each organization would have a specific service area in which it operated and provided coverage to any enrollee from the community (including any Medicare enrollee). The Medicare premiums and benefits are a function of the community rate of the plan, the rate applicable to any covered group within the community covered by the plan. Hence, until the mid-1980s, we required that the service area for Medicare be the same as the service area for the non-Medicare population. Subsequently, we changed our policy to permit HMOs and CMPs to limit the Medicare service area to a subset of the non-Medicare (commercial) area, breaking the link between commercial service areas and Medicare service areas (though the Medicare premiums and benefits continue to be based on the community rate for the entire non-Medicare community). We applied a ''county integrity'' standard in determining how HMOs could reduce their service areas for Medicare; whole counties could be excluded, but partial counties could only be excluded if the organization operated (for commercial purposes) only in a portion of the county.

Because the BBA provisions on waiver of minimum enrollment and composition of enrollment requirements permit organizations to have M+C plans with no prior enrollment, there will be plans that do not have designated service areas and do not have a commercial service area that can be used as a reference point for the designation of a Medicare service area. In the case of network plans, we would work with such organizations to determine an appropriate service area for the plan's provider network, taking into consideration the patterns of medical care in the community (e.g., where people obtain care, the types of providers available in the community, reasonable travel times to obtain care). We would also use our knowledge of how plan service areas generally have been determined and approved in the past, as well as how other organizations in the same area, or a similar area, have established their service areas. There could be concerns both with a proposed area that is too wide, offering limited availability of services for outlying areas, and with a proposed area that is too small, which would limit choices available to beneficiaries or might raise the concerns discussed above regarding discrimination.

We believe that basing our decisions on community patterns of care and the practices of other organizations in the same area, or in similar areas, is consistent with our past approach to the issue of service area designations, and consistent with the BBA. The BBA requires a similar approach in developing elements of the adjusted community rate for new plans (e.g., 1854(f)(4), referring to ''enrollment experience of other contracts entered into under this part and * * * data in the general commercial marketplace'').

With respect to another issue related to service areas, our policy that permitted HMOs and CMPs under 1876 to vary premium and benefit offerings by county within a service area (the ''flexible benefits'' policy) will no longer apply under M+C. The flexible benefits policy permitted organizations to use non-Medicare revenue to offer extra benefits or reduced premiums (''free benefits'') to residents of a particular county or counties rather than in the entire service area, as long as all Medicare beneficiaries in the entire service received at least the level of benefits required under the statute as determined through the adjusted community rate process. With the requirement that premiums and benefits be uniform throughout an M+C service area, it is not possible to continue the flexible benefits policy. However, an organization may be able to offer multiple plans and propose different service areas for the plans in order to achieve a similar result as the flexible benefits policy. This presents us with an issue of how to deal with the proposals for service areas, or the carving up of existing non-Medicare service areas, when it is done in order to have different premiums and benefits in different counties. In the case of network plans, a carving up of an existing service area, and the offering of multiple plans across what may be a single service area for the non-Medicare population, is only possible if each of the plans with different service areas is able to ''stand alone'' in terms of meeting all the requirements applicable to plans. The designation of multiple service areas in such cases should also be consistent with community practices in patterns of care, and/or consistent with rating practices, and service are designations, for other purchasers.

Except in the case of non-network MSA plans, as discussed below, the fact that Medicare pays different capitation rates by county is not a sufficient reason to establish service areas consisting of individual counties. For example, a staff-model HMO operating in a multi-county area, that has a service delivery network consisting of only one hospital and a group of physicians employed by the organization, cannot designate each county as a separate service area. Although services are accessible and available in each county, we do not believe there is a valid reason to charge different premiums by county, for example, when all Medicare beneficiaries enrolled in the organization will be using the same providers.

On the other hand, some organizations that operate with very large service areas may be justified in breaking up larger service areas for Medicare contracting purposes. This would be similar to what Federally-qualified HMOs do in designating distinct service areas as ''regional components,'' which are sub-areas with an autonomous provider network and with different community rating for the regional component. Some HMOs, although they do not identify distinct service areas, require enrollees to obtain services from a particular subset of providers within the broader network (as Federally-qualified HMOs are permitted to do (see 45 FR 28655 (April 29, 1980)). Some HMOs offer large employers a statewide service area consisting of different provider networks in geographically distinct areas in which there is no crossing of boundaries, or very little crossing of boundaries, to receive services. The large employer may be offered one rate for all areas, but the same HMO may have smaller designated service areas for smaller regional employers, in which different rates apply.

In evaluating proposals requesting approval of multiple service areas in a contiguous geographic area, we would consider the patterns of care in the community; and the rating and service

area practices of the individual organization, of other organizations in the area, and of other organizations in similar areas. The commercial service area will continue to be a reference point in that we would be likely to approve a proposal if what is proposed for Medicare contracting is similar to what is done in the commercial marketplace. Similarly, we would take into consideration any determination, or approval, of service areas by State regulatory bodies.

At a minimum, each proposed M+C service area must be an area in which the full range of covered services are available and accessible to all Medicare enrollees primarily through providers located in the service area. We would also evaluate proposals on the basis of the criteria we discuss above relating to discrimination against, or disadvantaging of, particular beneficiaries in the community. These criteria would also be used in evaluating the proposed service areas of non-network plans. Using the inner-city example, an entity could request an area consisting only of the poorer inner-city area, where residents would be required to pay a relatively high premium, while other areas were charged a much lower premium. We would view this practice as discouraging enrollment within a particular area. Although the statute does not expressly provide for evaluation of service area designations to determine whether they are discriminatory, we believe that it is consistent with statutory requirements relating to discrimination and discouraging enrollment (at 1852(a)(3), with respect to the pricing of mandatory supplemental premiums, and 1852(b), with respect to limiting enrollment based on a health status factor, including claims experience or insurability). We have included the above criteria for service area approval in the definition of ''service area'' in § 422.2.

As noted above, we are providing for a special exception for service areas for non-network MSA plans. In the case of M+C MSA plans, differences in payment rates for a given county affect not just the amount the M+C organization offering the MSA plan is paid, but the amount that is deposited in MSA accounts. (See section III of this preamble.) We have decided that in the case of M+C non-network MSA plans, under which enrollees are not limited to receiving services in a defined area, we will permit M+C organizations to offer a different M+C plan in each county in which they wish to enroll beneficiaries. This would mean that a uniform amount would be deposited in the M+C MSA account of every enrollee in the M+C MSA plan, and the M+C organization could file a separate premium amount for each county to ensure that the proper amount is deposited in accounts in that county.

Emergency and Urgently Needed Services

The definitions of emergency services and urgently needed services in § 422.2 are based on section 1852(d) and thus differ from those in existing § 417.401. In accordance with section 1852(d)(3) of the statute, we are codifying the concept that an ''emergency medical condition'' exists if a ''prudent layperson'' could reasonably expect the absence of immediate medical attention to result in serious jeopardy or harm to the individual. In addition, the new definition of ''emergency services'' includes emergency services provided both within and outside of the plan, while the definition of ''urgently needed services'' continues to encompass only services provided outside of the plan's service area (or continuation area, if applicable), except in extraordinary circumstances such as those discussed below.

Under section 1852(d)(1)(C)(i), M+C organizations are required to pay for nonemergency services provided other than through the organization where the services are immediately required because of unforseen illness, injury or condition, and it is not reasonable given the circumstances to obtain the services through the organization. We believe that except in the rarest and most extraordinary of circumstances, the only situation in which it would not be reasonable to receive nonemergency services through the organization would be when the enrollee is absent from the service area of the M+C plan in which he or she is enrolled. It is possible, however, albeit extremely unlikely, that there might be other situations in which this standard would be met by an enrollee who is in the plan service area.

For example, there could be some temporary disruption of access to the M+C plan's provider network, such as a strike, or possibly some temporary physical impediment to traveling to M+C plan providers that are otherwise readily accessible. Under such circumstances, an individual might not need emergency services, but still may warrant immediate attention. Because we do not believe that we can say that the statutory standard could *never* be met by an individual who is in the plan service area, we believe it is appropriate to provide for an exception in the definition of urgently needed services to the rule that the enrollee be out of area. We are thus providing for such an exception in extraordinary cases in which the network is unavailable or inaccessible due to an unusual event.

Other Definitions

In our April 14, 1998 interim final rule setting forth the definition of a PSO and related requirements, we established under § 422.350(b) a definition for ''health care provider'' that is based on the PSO requirements in section 1855(d)(5). In this interim final rule, we are adopting the identical definition for general purposes of the M+C program. Under this definition, as discussed in greater detail in our April 14 interim final rule (63 FR 18126), the term ''provider'' applies both to individuals licensed or certified by a State to engage in the delivery health care services (such as physicians, nurse practitioners, clinical social workers), as well as to entities engaged in the delivery of health care services (such as hospitals, nursing homes, home health agencies).

Another clarification contained in this subpart involves the definition of ''copayment.'' We have defined copayment as a fixed amount that can be charged for a service. This is to distinguish copayment from ''coinsurance,'' which is a fixed percentage of the total cost of a service that can be charged. Copayments, coinsurance, and deductibles represent the three forms of cost-sharing under a plan.

Finally, we have included a general definition of the term ''balance billing,'' indicating that balance billing 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. We note that there is significant variation within both original Medicare and the M+C program regarding the extent to which balance billing is permissible. For example, under original Medicare, no balance billing is permitted for providers of services (such as hospitals and home health agencies), while for nonparticipating physicians, balance billing is permissible only up to the difference between the Medicare allowed amount and the Medicare limiting charge. Different rules apply under original Medicare for other nonparticipating suppliers (such as ambulance or durable medical equipment suppliers, for which there are currently no limits on balance

billing). Similarly, under the M+C program, different balance billing restrictions apply depending on the type of M+C plan and the contracting status of the provider. These restrictions are discussed in detail in the appropriate sections of this preamble, particularly in section IV regarding M+C private fee-for-service plans.

3. Types of M+C Plans (§ 422.4)

The creation of the M+C program allows beneficiaries access to a much wider array of private health plan choices than the existing alternatives to the original Medicare program. Moreover, this new program will enable Medicare to use innovations from the commercial sector that have helped the private market contain costs and expand health care delivery options.

The BBA provides for several different types of M+C plans to be available for beneficiaries. As noted above, these various M+C plans can be classified into three general categories: M+C coordinated care plans, M+C MSA plans (that is, a combination of a high deductible M+C health insurance plan and a contribution to an M+C MSA), and M+C private fee-for-service plans. Within each of these three categories, M+C organizations may offer a variety of plans to Medicare beneficiaries.

Since these are the only legally significant categories of plans under the M+C program, we do not believe it is necessary to define all of the different entities that accept prepaid, capitated payment for delivering health services. Thus, examples of these entities, such as PPOs, HMOs, or health insurance organizations, are not defined for purposes of this regulation. Essentially, all entities that apply to offer an M+C plan must conform to the requirements for either an M+C coordinated care plan, an M+C MSA plan, or an M+C private fee-for-service plan.

M+C Coordinated Care Plans (§ 422.4(a)(1))

Under the M+C program, beneficiaries may choose from among a variety of coordinated care plans. Coordinated care plans include, but are not limited to, HMO plans (with or without point of service options) (HMOs), plans offered by PSOs (as defined in section 1855(d) and in our April 14, 1998 interim final rule), and PPO plans. In addition, certain beneficiaries may be able to choose another type of coordinated care plan, the Religious Fraternal Benefit Society plan, which is defined in section 1859(e).

Except in the case of a PSO granted a waiver under subpart H of part 422, all organizations offering M+C coordinated care plans must meet the State licensure requirements in section 1855 (and § 422.400). Thus, an M+C coordinated care plan must be offered by an entity that is (1) appropriately licensed by the State to bear risk and (2) eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan.

In addition, an M+C coordinated care plan must meet the definition of a coordinated care plan set forth in § 422.4. That is, an M+C coordinated care plan is a type of plan offered by an M+C organization that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by HCFA. The network must be approved by HCFA to ensure that all applicable requirements are met including access and availability standards, service area requirements, and quality standards. A coordinated care plan may include mechanisms to control utilization, such as referrals from a gatekeeper to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

Except for PSOs that have obtained a waiver of the State licensure requirement, and thus are subject to the additional requirements set forth in subpart H of part 422, distinctions among HMOs, PSOs, PPOs, and other coordinated care plans are not relevant for the purpose of applying to offer an M+C plan. The distinctions among the various types of coordinated care plans may be relevant for purposes of State licensure. However, for the purpose of an M+C application, we are not concerned with what type of coordinated care plan an applicant intends to offer. In fact, an entity may offer an M+C coordinated care plan even though it is not specifically licensed as an HMO, PSO, or PPO. As long as the entity is licensed as a risk-bearing entity in accordance with section 1855 of the statute and the plan being offered meets the definition of a coordinated care plan under § 422.4, the entity does not need to be licensed specifically as an HMO, PSO, or PPO to offer an M+C coordinated care plan.

For example, like an HMO or a PSO, a PPO may offer an M+C plan. Any organization that is licensed as a risk-bearing entity in a State may offer an M+C plan that is structured in the form of a PPO. We are not requiring that an organization applying to offer an M+C PPO plan be operating as a PPO in the non-Medicare marketplace. In that sense, the BBA imposes a distinct change from prior law, because it does not require that organizations with Medicare prepaid health plan contracts meet certain conditions imposed on their structure and their commercial business. Under section 1876, a PPO generally could not obtain a Medicare risk contract because most PPOs have members that are enrollees of an indemnity insurance product, and would not meet the requirements under section 1876 to be an ''eligible organization'' entitled to contract under that section. The BBA only requires that an organization be providing health benefits and insurance to enrollees (regardless of whether on an indemnity or prepaid, capitated status) and that it be licensed by the State as a risk-bearing entity.

The majority of the PPOs that are currently operating are plans being offered by State-licensed indemnity carriers or State-licensed HMOs. However, where the State does license the PPO as a risk-bearing entity, the PPO may be eligible to become an M+C organization in and of itself. Conversely, where the State does not allow the PPO to bear risk, the PPOs in those States would not be eligible to become an M+C organization on their own. These PPOs that are not allowed to bear risk may partner with a licensed risk-bearing entity or contract with a licensed risk-bearing entity to ''rent out'' their PPO network of providers. Consistent with our policy of deferring to the State as to which entities constitute licensed risk-bearing entities eligible for the M+C program, HCFA will defer to the State in terms of whether the PPOs can accept partial capitation from the licensed indemnity carrier or licensed HMO.

An entity offering a PPO plan must still comply with the requirements in 1854(e), which limit enrollee financial liability under a PPO plan in the same manner that liability is limited under an HMO plan or any other type of M+C coordinated care plan. That is, the sum of the premium for basic benefits and the actuarial value of all out-of-pocket expenses for such benefits (including the actuarial value of all cost-sharing for non-participating providers in a PPO) cannot exceed the actuarial value of the deductibles and coinsurance in original fee-for-service Medicare. Therefore, if a PPO expects a high level of utilization of non-participating providers, it must have a very low premium or it must have a significantly reduced level of cost-sharing for such services.

Religious Fraternal Benefit Society Plans

One specific type of coordinated care plan authorized by the BBA is a religious fraternal benefit society plan

(RFB plan), which is defined in section 1859(e). An RFB plan is an entirely new type of plan that may be offered under the M+C program.

As with the other types of coordinated care plans, an entity offering an RFB plan must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan. Essentially, an RFB society must meet the state licensing requirements outlined in section 1855. As discussed above, the States define the criteria for licensure, including any fiscal solvency standards that apply.

Also, an organization offering an RFB plan under the M+C program must do more than merely pay health care claims on behalf of their beneficiaries. Rather, RFB plans that constitute M+C coordinated care plans must meet the definition of a coordinated care plan included in this regulation. That is, they must have a network of health professionals and meet the applicable access, availability, service area, and quality assurance requirements.

Section 1859(e) defines and describes the requirements for RFB plans. Section 1859(e)(2) describes an M+C RFB plan as a coordinated care plan that: (A) Is offered by a religious fraternal benefit society only to members of the church, convention, or affiliated group; and (B) permits all members to enroll without regard to health status-related factors. Section 1859(e)(3) states that the RFB plan must be offered by a religious fraternal benefit society that: (A) is described under section 501(c)(8) of the Internal Revenue Code and is exempt from taxation under section 501(a) of that Act; (B) 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; (C) offers, in addition to an M+C religious fraternal benefit society plan, at least the same level of health coverage to individuals not entitled to Medicare benefits who are members of such church, convention, or group; and (D) does not impose any limitation on membership in the society based on any health status-related factor.

Section 501(c) of the Internal Revenue Code generally describes the rules applicable to those organizations which are not subject to Federal income tax under section 501(a) of the code. Section 501(c)(8) describes one type—fraternal beneficiary societies, orders or associations that (a) operate under the lodge system for the exclusive benefit of a Fraternity itself operating under the lodge system; (b) provide for the payment of life, sick or accident or other benefits for the members of such society or association or their dependents.

RFB Plans have two distinguishing factors from other types of M+C coordinated care plans. The first is that RFB plans are allowed to limit their enrollment to members of the church. Section 1859(e)(1) indicates that a religious fraternal benefit society offering an M+C plan may restrict the enrollment of individuals in the plan to individuals who are members of the church, convention, or group with which the society is affiliated.

In addition to this ability to limit enrollment strictly to members of the church, RFB plans are distinct from other M+C coordinated care plans in that RFB plans may be subject to possible payment adjustments to ensure an ''appropriate payment level.'' Specifically, section 1859(e)(4) indicates that the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1854 as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

M+C MSA Plans (§ 422.4(a)(2))

The definition of an M+C MSA plan, as well as other requirements that apply solely or in a different manner to M+C MSA plans, are discussed in full in section III. of this preamble. Note that in section III.K. of this preamble, we solicit letters of intent from organizations that intend to offer M+C MSA plans to Medicare beneficiaries and/or to serve as M+C MSA trustees.

M+C Private Fee-For-Service Plans (§ 422.4(a)(3))

The definition of an M+C private fee-for-service plan, as well as other requirements that apply solely or in a different manner to M+C private fee-for-service plans, are discussed in full in section IV of this preamble.

Multiple Plans (§ 422.4(b))

Section 422.4(b) establishes that an M+C organization may offer multiple plans, including plans of different types, under a single contract with HCFA, provided that the organization is licensed or approved under State law to offer the applicable types of plans. We believe that this policy should prove to be less administratively burdensome for both prospective M+C organizations and for HCFA than other alternatives, such as requiring separate contracts between HCFA and an M+C organization for each plan, or type of plan, being offered by the organization. We also specify under this section that if an M+C organization has received a waiver of the licensing requirement to offer a PSO plan, the waiver does not apply to the licensing requirement for other types of plans. Other issues associated with the ability of an M+C organization to offer multiple plans under a single contract with HCFA are discussed below, in the section of the preamble that deals with the contract requirements contained in subpart K of part 422.

4. Applications (§§ 422.6 and 422.8)

Sections 422.6 and 422.8 set forth the application requirements for entities seeking to contract with HCFA to offer M+C plans, as well as HCFA's application evaluation procedures. For the most part we have retained the contracting requirements from §§ 417.143 and 417.144 as authorized by section 1856(b)(2). This section of the law allows HCFA to use past contracting standards applied to contracts under section 1876 or to create new standards as needed to implement the M+C program. The application requirements and evaluation procedures are almost identical to the current application procedures.

The primary change to our previous process is the additional requirement that organizations wishing to contract with HCFA must submit documentation of their appropriate State licensure, or submit documentation of State certification that the entity is, in fact, able to offer health insurance or health benefits coverage meeting State fiscal solvency standards and authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health care services. (Entities meeting the definition of a PSO can be exempted from this requirement if they meet conditions for a waiver, which can be granted by HCFA—see subpart H of part 422.) This requirement is necessitated by the fact that HCFA will no longer have primary responsibility for determining the fiscal solvency of new contractors. We intend to rely for the most part on State certification to insure that the entities that we contract with are indeed fiscally solvent and have the ability to handle and afford risk payments for health care coverage, although we will if necessary ''look behind'' State certifications for validation purposes.

In one addition to existing rules, § 422.8(b) specifies that HCFA may deny an entity's application to offer an M+C plan if the entity has failed to complete a corrective action plan during the term of its previous contract with HCFA, regardless of whether the contract was under the section 1833, 1876, or the new Part C provisions of the law. We

believe that this provision explicitly ensures that the proven performance problems of entities that apply to contract with HCFA under the M+C program are taken into consideration in the application evaluation process.

5. User Fees (§ 422.10)

The last section of subpart A contains regulations implementing the user fees provided for in section 1857(e)(2). Section 1857(e)(2) directs the Secretary to collect user fees from M+C organizations, with each paying its pro rata share, for the purpose of paying for costs associated with enrollment and information activities under section 1851 and subpart B, and counseling and assistance programs under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 103–66).

Under section 1876(k)(4)(D), the user fees provided for in section 1857(e)(2) apply in 1998 to HMOs and CMPs with risk contracts under section 1876. On December 2, 1997, we published regulations in § 417.472(h) implementing the user fee authority in section 1857(e)(2), and setting forth a methodology for determining an organization's ''pro rata share'' of these fees. (62 FR 63669).

In this interim final rule, we are simply adopting at § 422.10, for purposes of the M+C program, the user fee provisions now set forth at § 417.472(h). Our reasons for adopting the methodology reflected in these regulations are set forth in the preamble to the December 2, 1997 rule. We intend to respond to comments received on the December 2 interim final rule, as well as comments on this rule, in a future rulemaking document.

B. Eligibility, Election, and Enrollment

1. Eligibility to Elect an M+C Plan (§ 422.50)

Section 1876 background: The provisions that have in the past applied to managed care entities (and continue to apply until these entities become M+C organizations) are in section 1876 and part 417 of this chapter. Section 1876(d) provides that Medicare beneficiaries who are entitled to benefits under Part A and enrolled in Part B, or enrolled under Part B only, except those with ESRD, residing in the service area of the plan are eligible to receive all their Medicare benefits through an HMO or CMP that has a contract with HCFA. Regulations at § 417.423(b) excluded beneficiaries who elect hospice care from enrolling in an HMOs or CMPs as long as the hospice election remains in effect. Existing regulations at § 417.460(f) require that HMO or CMP disenroll individuals who move out of their geographic areas, except that § 417.460(f)(2) allows enrollees to remain enrolled in an HMO or CMP under the following circumstances: (1) During a temporary move from the service area for up to 90 days, or (2) during a move to a new area for as long as 1 year if the HMO or CMP has elected to offer this option under § 417.460(f)(2).

a. Eligibility. The BBA established a new section 1851(a) that includes the eligibility criteria an individual must meet in order to enroll in an M+C plan, as defined in § 422.4. Accordingly, except as discussed below at section B.1.b. regarding the transition of Part B only individuals, § 422.50 states that individuals who are entitled to Part A and enrolled in Part B are eligible to enroll in an M+C plan. These individuals are referred to as ''M+C eligible individuals.''

Individuals with end stage renal disease (ESRD) are not permitted to be new enrollees of an M+C organization offering an M+C plan. Section 1851(a)(3)(B) excludes individuals with ESRD from enrolling in an M+C plan generally, but provides that an individual who develops ESRD while an enrollee in an M+C plan may ''continue to be enrolled'' in that plan. For purposes of this provision only we are considering individuals who are enrolled in a private health plan offered by the M+C organization to have been enrollees of the M+C plan when they developed ESRD. In section 422.50(a)(2), therefore, we provide that an individual who develops end-stage renal disease while enrolled in an M+C plan, or in a private health plan offered by the M+C organization offering an M+C plan, may continue to be enrolled in the M+C organization as an M+C plan enrollee.

We take this position because we believe that Congress intended in section 1851(a)(3)(B) to permit individuals with ESRD who are enrolled with an M+C organization to remain enrolled with that organization. If an individual develops ESRD as an enrollee of the organization *after* becoming Medicare eligible, he or she clearly would be permitted under section 1851(a)(3)(B) to remain enrolled with the organization. We do not believe that enrollees of an M+C organization should be penalized because they develop ESRD prior to becoming Medicare eligible rather than after. This position is consistent with our existing policy implementing a similar ESRD exclusion under section 1876, and therefore is supported by section 1856(b)(2), which provides for the retention of ''standards established under section 1876 to carry out analogous provisions of such section.''

We are not continuing the § 417.423(b) exclusion policy on hospice; individuals who elect hospice coverage may elect an M+C plan. Unlike ESRD patients, individuals who elect hospice care are not specifically excluded from participating in the M+C program. In fact, section 1853(h) contains special rules for M+C organizations that enroll hospice patients.

Section 1851(b) states that, except as the Secretary may otherwise provide, individuals must live in the geographic area served by the M+C plan in order to enroll in that plan. We have exercised the discretion provided in this provision to provide that those individuals converting from health plans in which they were enrolled prior to Medicare entitlement who reside out of the plan's service area may also continue enrollment in the M+C organization if they reside in the continuation area of the plan.

An M+C organization must disenroll beneficiaries who permanently move from the service area, unless the plan has chosen to provide a continuation of enrollment option in the area to which the enrollee moved, as allowed in section 1851(b)(1)(B) and the enrollee chooses to remain with the plan. We discuss continuation of enrollment in detail in section b.2., ''Continuation of Enrollment.'' Section 4002 enrollment transition for 1876 risk contracts.

Section 1876 risk contracts cannot be renewed for a contract year beginning on or after January 1, 1999. Current risk contractors that remain in compliance with current standards and that demonstrate compliance with new requirements established by this regulation will be able to transition into the M+C program by entering into an M+C contract, as an M+C organization, with a contract effective date of January 1, 1999.

Section 4002(c) of the BBA provided for a seamless transition of enrolled membership. An individual who is enrolled on December 31, 1998 with an eligible organization under section 1876 shall be considered to be enrolled with that organization on January 1, 1999 under the M+C program if that organization has a contract under Part C of title XVIII for providing services on January 1, 1999, unless the individual has disenrolled effective on that date.

In addition, section 4002(b) provides that an individual who is enrolled in Part B only and is enrolled in an eligible organization with a risk-sharing contract under section 1876 on December 31, 1998, may continue to be enrolled in the

organization in accordance with our regulations. This means that on January 1 there will be a small population of ''grandfathered Part B only'' enrollees retained in organizations formerly with risk contracts that now hold contracts under the M+C program. However, this is a one time opportunity, and an individual who is enrolled in Part B and not entitled to Part A and who disenrolls from the M+C organization is not eligible to elect a plan offered by another M+C organization.

In summary, we are interpreting the statute to allow an individual to transition enrollment from the 1876 program without regard to location of residence or whether the individual has end-stage renal disease and to choose to enroll in any plan offered by the M+C organization into which they are transitioning.

2. Continuation of Enrollment (§ 422.54)

As stated previously, section 1851(b)(1)(B) allows M+C organizations to offer enrollees the option of continued enrollment in the M+C plan when enrollees leave the plan's service area to reside elsewhere, we have to interpieted this to mean on a permanent basis.

M+C organizations that choose the continuation of enrollment option must explain it in marketing materials and make it available to all enrollees in the service area. Enrollees may choose to exercise this option when they move or they may choose to disenroll.

Before an M+C organization may offer a continuation of enrollment option to Medicare beneficiaries, the organization must obtain HCFA approval of the continuation area, its marketing materials, and the organization's assurances that it will meet access requirements. Under section 1851(b)(1)(B), the organization must provide enrollees with reasonable access within the continuation area to the Medicare covered benefits described in section 1852(a)(1)(A).

The payment rate at which the M+C organization will receive payment from HCFA will be based on the rate and adjustment factors that correspond to the beneficiary's permanent residence. The M+C organization must, at a minimum, provide or arrange for the provision of Medicare covered benefits in the continuation area as described in the first sentence of § 422.100(b)(1), and the plan must meet access and cost-sharing requirements for all basic benefits.

Because the rate that we pay to M+C organizations includes amounts that ordinarily must be used to provide additional benefits (see preamble for subpart G), we believe that M+C organizations should be required to provide additional benefits in the continuation area. As noted above, however, section 1851(b)(1)(B) requires only that Medicare benefits be provided to continuation enrollees. We accordingly are considering a legislative proosial to require M+C organizations to provide all services in section 1852(a)(1), including required additional benefits under section 1852(a)(1)(B).

Section 1851(b)(1)(B) requires that ''reasonable access'' be provided in the continuation area, and that enrollees be subject to ''reasonable cost-sharing.'' We are requiring that M+C organizations satisfy the access requirements in § 422.112, and provide services either through written agreements with providers or by making payments that satisfy the requirements in § 422.100(b)(2).

We are defining ''reasonable cost-sharing'' in the continuation area to be limited to (1) 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; (2) the cost-sharing amounts required by the continuation area plan if provided through agreements with another M+C plan; or (3) the amount for which a beneficiary would be liable under original Medicare if noncontracting providers furnish the services.

We have included two items in these regulations that reflect our prior experience with similar situations. They are: (1) that plans may require prior notification from members of their intention to use the continuation of enrollment option, but this requirement must be in their marketing materials, and (2) appeals and grievances in the continuation area must be handled in the same timely fashion as in the service area, but the ultimate responsibility for the appropriate handling of appeals and grievances is with the organization that is receiving payment from HCFA.

3. Limitations on Enrollment in an M+C MSA Plan (§ 422.56)

While most M+C eligible individuals can choose to receive benefits through one of the M+C plans defined in § 422.4, the statute places limitations on eligibility to enroll in M+C MSA plans.

Sections 1851(b)(2) and (b)(3) specifically exclude certain individuals from enrolling in M+C MSA plans. We have specified at § 422.56(b) of this section, that individuals who are enrolled in a Federal Employees Health Benefit program (FEHB) plan, or who are eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD) may not enroll in an M+C MSA plan. The statute provides that the restrictions on FEHB enrollment may be eliminated if the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted polices that will ensure that the enrollment of FEHB participants in M+C MSA plans will not result in increased expenditures for the Federal government. The Office of Personnel Management has indicated to HCFA that they would not be able to certify that FEHB costs would not increase at this time. Under our authority in section 1851(b)(2)(B), we intend to apply the same rules for enrollment restriction to individuals who are eligible for health benefits through the VA and DoD. Additionally, in § 422.56(c) we have incorporated the statutory requirement under section 1851(b)(3) that individuals who are entitled to Medicare cost-sharing under a State plan under title XIX are not eligible to enroll in M+C MSA plans. In addition, an individual who receives health benefits that cover all or part of the annual deductible under an M+C MSA plan may not enroll in an M+C MSA plan.

Note that M+C MSA plans are described in detail in Section III of this preamble.

4. Limited Enrollment Under M+C RFB Plans (§ 422.57)

Section 1859(e)(1) states that Religious Fraternal Benefit Society (RFB) plans may limit the enrollment of individuals to those who are members of the church, convention or group with which the society is affiliated. We have included the restrictions on enrollment in RFB plans at § 422.57.

5. Election Process (§ 422.60)

Under section 1851(c)(1) the Secretary is required to establish a process through which elections in M+C plans are made and changed, including the form and manner in which they are done. In § 422.60, we describe the election process for enrollment with the M+C organization. Where applicable we have included existing rules from 42 CFR § 417.430 with conforming changes.

As stated at § 422.66(a), M+C eligible individuals who wish to elect an M+C plan may do so by filing the appropriate election form with the M+C organization. At § 422.60(a), we specify that M+C organizations must accept without restriction, except as specified in § 422.57 for RFB plans, individuals who enroll in an M+C plan during the

election periods described in section 1851(e)(6) and set forth at § 422.62 of the regulation.

As provided by section 1851(e)(6), and stated at § 422.60(a), and displayed in the following chart, M+C organizations are required to accept enrollments during the initial coverage election period, the annual election period, and special election periods, but M+C organizations are not required to be open for enrollment during open enrollment periods.

WHEN ELECTIONS MAY BE MADE OR CHANGED*

Coverage Election Periods	When: § 422.62	M+C Plans Required to Accept Enrollments: § 422.60	Effective Date of Coverage: § 422.68
Initial Coverage Election Period	3 months before entitlement to Part A and Part B.	Yes	1st day of month of entitlement to Part A and Part B.
Annual Election Period	Annually in November	Yes	January 1.
Special Election Period	Starting 2002, if beneficiary moves, plan terminates, etc.	Yes	To Be Determined—depends on situation.
Special Election Period at Age 65	Starting 2002, in first 12 months after initial election of M+C plan.	No—Election is original Medicare	1st day of the month after month of election.
Open Enrollment Periods	Anytime 1998–2001 Jan–Jun 2002 Jan–Mar 2003+.	No—Plans have option of accepting enrollments.	1st day of the month after month of election.

*Refer to referenced regulation text for detail.
Note that different rules apply to M+C MSA plans.

As provided at § 422.306(a)(2) to reflect the requirements in section 1854(a)(1)(B), M+C organizations must submit by May 1 of each year the enrollment capacity of each plan they offer. Section 422.60(b) then provides that if HCFA determines that the M+C plan has a capacity limit, the plan may limit the enrollment of M+C eligible individuals if the plan accepts first those individuals who elected the plan prior to the HCFA determination and then accepts others in a manner that does not discriminate on the basis of health status.

We note that we have not included regulation text to address the last sentence of section 1851(g)(2) regarding ''nonrepresentative'' enrollment. As written, the sentence disallows a capacity limit if enrollment would become substantially nonrepresentative of the Medicare population in the plan's service area, as determined in accordance with regulations of the Secretary. We cannot envision circumstances under which the imposition of a capacity limit on enrollment would by itself lead to an enrollment ''substantially non-representative'' of the Medicare population in an M+C plan's service area. We particularly cannot envision circumstances under which the non-representativeness of enrollment would be so ''substantial'' as to justify possible risks to patient access and quality of services as the result of overloaded capacity. We accordingly are not promulgating regulations at this time implementing the authority in the last sentence in section 1851(g)(2). We invite comments on this provision, and would consider including guidance on this matter in a final regulation based upon comments received.

At § 422.60(c) we indicate requirements for the election form. The form must comply with HCFA instructions regarding content and format, must be completed and signed by the beneficiary (or the individual who will soon be entitled to Medicare benefits), and must include authorization for disclosure and exchange of necessary information between HCFA and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary. The forms must also be filed and retained by the M+C organization.

In general, and as indicated by our requirement that the beneficiary complete and sign the form, we believe that an M+C eligible individual should personally complete and sign any election form or disenrollment request (referenced at § 422.66(b)) whenever possible. If for some reason a beneficiary is unable to sign for himself or herself, we recognize and defer to state laws on who may sign for other persons, which is also the policy in the Section 1876 program.

In § 422.60(d), we specify that an election is considered to have been made on the date it is received by the M+C organization. We believe it is necessary that we define ''when an election is made'' because it is a determining factor in establishing the effective date of M+C plan coverage. Note that HCFA's liability for payment is not as of the election date, but rather, is as of the effective date of coverage. Effective dates of coverage are specified at § 422.68.

We have also set forth at § 422.60(e) a process for handling of forms, including for providing written notification of acceptance or denial in the M+C plan.

6. Election of Coverage Under an M+C Plan (§ 422.62)

Section 1876 background: Section 1876(c)(3)(A)(i) requires that HMOs and CMPs hold an open enrollment period for Medicare beneficiaries of at least 30 consecutive days during each contract year to qualify for a Medicare contract. For Medicare beneficiaries who enroll during the open enrollment period, § 417.450(a)(2) states that the effective date of coverage cannot be earlier than the first month, nor later than the third month, after the month in which HCFA received the information necessary to include the beneficiary in its records. In § 417.450(b), HCFA reserves the option to approve a later month if requested by the organization and the beneficiary. HMOs and CMPs can also offer continuous open enrollment outside of the 30-day period.

In the M+C program under section 1851(a)(1), M+C eligible individuals may elect to receive Medicare benefits under original Medicare or through election of an M+C plan. Section 1851(e) describes the various election periods available to M+C eligible individuals. Many of these provisions allow the individual to ''change the election under subsection (a)(1)'' during these periods. If section 1851(a)(1) were read narrowly, it arguably would only allow an eligible individual to change between original Medicare or the M+C program under Part C. We have taken a broader approach in interpreting section (a)(1) to allow eligible individuals to not only make a change between the original Medicare program and an M+C plan, but also among M+C plans. Therefore, an M+C eligible individual

who changes his or her election may change from an M+C plan to original Medicare, from an M+C plan to another M+C plan or from original Medicare to an M+C plan.

The BBA establishes specific parameters in which elections can be made and/or changed. Individuals who wish to elect an M+C plan or subsequently change their election, must do so during the periods established under section 1851(e). That section requires that elections or changes in election be made during the following periods: The initial coverage election period, continuous open enrollment periods, an annual coordinated election period or special election periods. Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

a. Initial Coverage Election Period. Section 1851(e)(1) requires that the Secretary specify an initial coverage election period during which an individual who is initially entitled to Part A and enrolled in Part B may elect an M+C plan. The statute further stipulates that if an individual elects an M+C plan during that period, coverage under the plan will become effective as of the first day on which the individual may receive that coverage. We believe that Congress intended that we give a newly eligible individual the opportunity to be enrolled in an M+C plan as soon as he or she would be entitled to actually receive both Medicare Part A and Part B coverage.

In other contexts, we have interpreted the concept of ''entitled'' to mean that an individual has met all of the necessary requirements for a benefit (that is, is eligible for the benefit), and has actually applied for and been granted coverage. An individual is considered to be ''enrolled'' under section 1837, on the other hand, when he or she has applied for Part B coverage (or is deemed to have applied). Under some situations, an individual may apply for or be deemed to have applied for Part B before he or she is actually entitled to receive coverage. For example, if an individual applies for Part B coverage and becomes ''enrolled'' after he or she reaches age 65, the individual may not actually be entitled to Part B coverage under section 1838 until one or several months after the month of application and enrollment. If we were to interpret section 1851(e)(1) to give effect to an M+C plan election when an individual has only enrolled in Part B, he or she could be entitled to the benefits of the M+C plan before actually being entitled to Medicare Part B coverage. In order to avoid such a result, we have interpreted ''enrolled'' in Part B as ''entitled'' to Part B.

We believe our interpretation is consistent with section 1851(e)(1), which requires the Secretary to specify an initial coverage election period that would result in coverage under the plan becoming effective as of the first day on which the individual may receive that coverage.

In establishing the initial coverage election period we considered the statutory process of entitlement to Part A and enrollment in Part B. Section 226 of the Act provides that individuals who are age 65 and entitled to retirement benefits under title II or the Railroad Retirement Board Act and those who are under age 65 and have been entitled (or deemed entitled) to disability benefits under title II or the Railroad Retirement Board Act for 24 months shall be entitled to Part A under the Medicare program and eligible to enroll in Part B. Part A coverage is effective the month an individual attains age 65, or the 25th month he or she is entitled to disability benefits. If an individual is entitled to disability or retirement benefits at least 3 months before reaching age 65 or, in the case of a disabled individual, three months before the 25th month in which he or she is entitled to disability benefits, the individual is deemed enrolled in Part B at that time. Under section 1838, Part B is effective with the month an individual reaches age 65 or in the 25th month he or she is entitled to disability benefits.

In order for an individual to have coverage under an M+C plan effective as of the first day on which the individual may receive such coverage, the individual must elect an M+C plan before he or she is actually entitled to Part A and Part B coverage. We have therefore defined the initial coverage election period as the 3-month period that 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.

This approach also permits individuals who do not enroll in Part B at initial eligibility (i.e. at age 65 or in the 25th month of disability entitlement) to elect an M+C plan at the time of subsequent enrollment in Part B. Section 1837(i) provides for a special enrollment period for individuals who defer enrollment in Part B because they are covered under a group health plan based on their own employment or that of a spouse (in the case of the disabled, the employment may be that of any family member). Enrollment in Part B may occur during any month the individual is covered under the group health plan based on current employment or during the 8-month period that begins the first full month the individual is no longer covered under the group health plan based on current employment. Under section 1838(e), Part B coverage is effective the first day of the month the application is filed or, at the individual's option, the first day of any of the following three months when enrollment occurs while the individual is covered under the group health plan based on current employment or during the first full month when not so covered. Therefore, an individual may file an application for Part B up to three months in advance of entitlement. Consequently, individuals who enroll in Part B during the special enrollment period may elect an M+C plan during the 3-month period prior to entitlement to Part B.

Additionally, section 1837(e) allows individuals who fail to enroll for Part B during their initial enrollment period (3 months before they are entitled to Part A or within 3 months after the month they are entitled to Part A) to enroll for Part B during a general enrollment period, which runs from January through March of every year, with coverage effective July 1 of the year of enrollment. In this case, the Part B application may be filed up to 6 months in advance of the month of entitlement. (Individuals who enroll in a general enrollment period are subject to an increased premium under section 1839(b), measured by the length of the delay in enrollment.)

In order to be consistent with the 3 month periods that can occur between timely enrollment for Part B and actual entitlement in existing sections of the Medicare statute, we have limited the period during which an individual may elect an M+C plan to the 3-month period prior to actual entitlement to Part B. We believe that this correlation with the 3-month period will be administratively more efficient than a shorter or longer time period.

b. Annual Coordinated Election Period. Section 1851(e)(6) establishes that organizations offering M+C plans in January, 1999 must open enrollment to Medicare beneficiaries in November, 1998. In addition, section 1851(e)(3) establishes the month of November of each year beginning in 1999 as the annual coordinated election period.

During the month of November, an M+C eligible individual may elect an M+C plan or change his or her election. Thus, the section 1876 requirement that plans be open any 30-day period is replaced by a requirement that plans

have to be open for enrollment during the month of November.

c. Open Enrollment Periods. Section 1851(e)(2) establishes open enrollment periods during which M+C eligible individuals may elect an M+C plan, if it is open to new enrollees, or change their elections. M+C individuals may not, however, as provided in section 1851(e)(5), elect an M+C MSA plan during open enrollment periods.

Note that as provided by section 1851(e)(6) and stated at § 422.60(a)(2), M+C organizations may, but are not required, to offer continuous open enrollment during open enrollment periods. This is similar to the section 1876 policy which also allowed, but did not require, continuous open enrollment outside of a 30-day period.

Section 1851(e)(2)(A) establishes that at any time during calendar years 1998 through 2001, there will be no limit on the number of elections or changes that an M+C eligible individual can make.

Section (e)(2)(B) establishes the first six months of 2002, (January through June) as the open enrollment period for that year. An M+C eligible individual may elect an M+C plan or change his or her election, but only once during the first six months of the calendar year.

Section (e)(2)(C) establishes the first three months of each year (January through March) beginning 2003, as the open enrollment period. An M+C eligible individual may elect an M+C plan or change his or her election, but only once during the first three months of the calendar year.

Section 1851(e)(2)(B)(i) allows that an individual who becomes an M+C eligible individual in 2002 and elects an M+C plan or original Medicare, to change that election once during the first 6 months of M+C eligibility in 2002. Beginning in the year 2003 and thereafter, a newly eligible individual who has made an election may change that election once during the first 3 months of M+C eligibility in that year. Consequently, those who become M+C eligible individuals late during the year may not have a full 6-month or 3-month open enrollment period. For example, an individual who becomes eligible in August 2002 has an open enrollment period of 5 months, August through December. The sixth month, January, does not occur during 2002 and cannot qualify as part of the open enrollment period.

The limit to one change during the open enrollment periods in the first six months of 2002 and the first three months of subsequent years does not apply to changes in elections that an individual makes during an annual coordinated election period or during a special election period.

In § 422.62, paragraphs (a)(4)(ii) and (5)(ii), we have interpreted the 6 and 3 month periods ''in which the individual is an M+C eligible individual'' in section 1851, paragraphs (e)(2)(B)(i) and (e)(2)(C)(i), as the periods that begin with the month the individual is first ''entitled to both Part A and Part B.'' The statute defines ''eligible for Medicare+Choice'' as eligible for Part A and enrolled in Part B, a definition that we have reflected in § 422.50(a)(1); however, this definition could cause problems for newly eligible individuals during the open enrollment period.

For example, individuals who are newly eligible for M+C in the year 2002 under section 1851(e)(2)(B) will have 6 months, beginning with their eligibility for M+C, to change their election. If we start counting this period from the time individuals enroll in Part B, some will have little or no opportunity to change. Some of these individuals may not actually be entitled to receive benefits for a delayed period, which can be up to 6 months after they have enrolled if they have enrolled during a general election period. Hence, the opportunity to change could have no meaning, with the open enrollment period expiring before the individuals have actually received any M+C coverage.

d. Special Election Periods. Section 1851(e)(4) establishes special election periods beginning in 2002, during which M+C eligible individuals may disenroll from an M+C plan or elect another M+C plan. Special election periods are available if: (1) The service area or continuation area is reduced or the plan terminates or is terminated in the area in which the individual resides; (2) the individual moves out of the plan's service area and the plan does not offer, or the individual does not elect, the continuation of enrollment feature, or there is some other change of circumstances specified by HCFA; (3) the individual demonstrates to HCFA, in accordance with guidelines established by HCFA, that the M+C organization offering the plan substantially violated a material provision of its contract with regard to the individual or the organization, its agent, representative, or plan provider materially misrepresented the plan's provisions in marketing the plan to the individual; or (4) the individual meets such other exceptional conditions specified by HCFA.

The last paragraph in section 1851(e)(4) provides that, effective January 1, 2002, an individual who, upon first becoming eligible for benefits under Part A at age 65, enrolls in an M+C plan (other than an M+C MSA plan), may discontinue the election and elect original Medicare at any time during the 12 month period beginning on the effective date of the M+C election. We have interpreted this provision to apply to individuals who elect an M+C plan (other than an M+C MSA plan) during the initial enrollment period, as defined under section 1837(d), that surrounds their 65th birthday. This period begins 3 months before and ends 3 months after the month of an individual's 65th birthday. We believe that this interpretation fulfills the intention of the statute, which is to provide this special election period to individuals who, upon turning 65 and first becoming entitled to Medicare, elect an M+C plan. Our interpretation takes into account the fact that many, if not most, individuals will be making an election during an initial enrollment period, rather than during the month that they turn 65.

e. Special Enrollment and Disenrollment Rules for M+C MSA Plans. Section 1851(e)(5) establishes special rules for individuals enrolling in M+C MSAs. M+C eligible individuals may elect the M+C MSA option only during an initial coverage election period or during November of any year, beginning in 1998. M+C MSA enrollees may discontinue their election only during November of 1998, during annual coordinated election periods in November of each subsequent year, and during special election periods described in the first sentence of section 1851(e)(4). Individuals who elect an M+C MSA for the first time during the annual coordinated election periods that begin in November of 1999 may revoke their election if they do so before December 15 of the year in which they make the election, i.e., before the M+C MSA coverage begins. M+C MSA plans are described in detail at the end of this preamble.

7. Information about the M+C Program (§ 422.64)

Once these regulations are effective and M+C plans are approved by HCFA, eligible Medicare beneficiaries will be able to choose to receive their Medicare benefits from a new array of health care options. New options will include coordinated care plans such as Health Maintenance Organizations, Preferred Provider Organizations, Provider Sponsored Organizations, as well as Private Fee for Service Plans and Medical Savings Accounts. Medicare beneficiaries will still be able to choose to remain in original Medicare. These choices are designed to offer Medicare beneficiaries a marketplace of options

similar to those available to the non-Medicare population.

Under section 1851(d)(2), the Secretary is obligated to mail an ''open season notification'' at least 15 days before the beginning of each annual coordinated election period to each M+C eligible individual residing in an area and, to the extent practicable, to a newly eligible individual not later than 30 days before the individual's initial coverage election period. The notice must include certain general information listed in section 1851(d)(3) and a list of plans and certain plan comparisons as described in section 1851(d)(4). Section 1851(d)(1) requires that HCFA provide for activities to broadly disseminate information to beneficiaries and prospective beneficiaries on their coverage options under M+C, and section 1851(d)(5) requires HCFA to maintain a toll-free line for M+C inquiries and an Internet site through which individuals can obtain electronic information.

To promote informed choice, HCFA will provide access, via the Internet and through distribution of print materials, to information about original Medicare and M+C options. In accordance with section 1851(d)(3) and reflected in § 422.64(c), HCFA will provide general information to M+C eligible individuals with respect to benefits available under Part A and Part B of original Medicare, including covered services, beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including any beneficiary liability for balanced billing. Such general information will also include instructions on how to exercise election options under M+C; procedural rights including the grievance and appeals procedures for original Medicare and M+C and the individual's right to be protected against discrimination based on health status related factors under section 1852(b), including the fact that an M+C organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract and the effect this may have on the individuals enrolled in the M+C plan. Finally, a general description of the benefits, enrollment rights, and other requirements applicable to Medicare supplemental policies under section 1882, including Medicare Select, will be included.

Under section 1851(d)(4) and reflected in § 422.64(c)(6), HCFA will also provide information to M+C eligible individuals comparing M+C plan options, including the benefits covered under the M+C plan; covered services beyond those provided under original Medicare; and beneficiary cost-sharing including maximum limitations on out-of-pocket expenses and, in the case of an MSA plan or M+C private fee-for-service plan, differences in cost-sharing, premiums, and balance billing as compared to other M+C plans and whether the organization offering the plan includes mandatory supplemental benefits in addition to its base benefit package or offers optional supplemental benefits and the premiums and other terms and conditions for such coverage. 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, will also be included. M+C eligible individuals will also be informed about the extent to which they may obtain benefits through out-of-network health care providers; the extent to which they may select among health care providers and the types of providers participating in the plan's network. M+C eligible individuals will be informed of the M+C organization's coverage of emergency and urgently needed care, service area of the plan, and, to the extent available, M+C plan quality and performance indicators.

The information comparing plan options is crucial to empowering beneficiaries with the knowledge that will help them evaluate M+C options and make informed decisions based on their individual needs. We wish to make clear that our provision of comparative data is intended neither to encourage or discourage beneficiaries from choosing one health care plan over another nor to favor a choice of an M+C plan over original Medicare.

We invite the public to comment or to provide specific guidance on the types of information that should be made available to beneficiaries. Once we have worked out what specific information we will require within the above categories, we will post these at our Internet site.

The Internet site, www.Medicare.gov, is a Medicare beneficiary-centered consumer website designed to provide a broad array of information on program benefits, health system performance, health care choices, healthy behaviors and health promotion. This site will be continuously improved to meet the mandate in section 1851(d)(2)(C) that we provide information in a style and format that is easy to understand. If necessary, we will publish regulations and allow for OMB review, pursuant to the requirements of the Paperwork Reduction Act of 1995.

HCFA's ''Medicare Compare,'' the Managed Care Plans Comparison Database, will be available on the Internet for public use. ''Medicare Compare'' provides a wealth of information on health care plans, allowing users to ''comparison shop'' for plans. Users can look up information in different areas, by state, county or zip code. They can also compare costs for premiums and types of services offered. The information in the database will be updated quarterly. Plan specific quality performance measures from the HEDIS information set and the Consumer Assessment of Health Plans Survey (CAHPS) will be incorporated into information provided to beneficiaries once the data and results have been validated and determined to be accurate and reliable. HCFA is committed to using a public process to determine information and data specifications, including the details of what information will need to be collected and the methods of collection to determine the remaining unspecified data elements that organizations are required to submit. HCFA will work collaboratively with organizations involved with quality and performance standards and measurements, including performance measurement experts, public and private purchasers, and beneficiary representatives in this process. In addition, HCFA will hold public meetings to invite interested parties to comment and provide input in the process of determining the data specifications for additional performance information, e.g., data about appeals or health outcome measures. Finally, HCFA will publish a notice regarding plan data elements to be collected and a summary of public processes used to determine the data elements in question and this document would be available at the discretion of the requestor. Educational information will be made available on the Internet site to prepare consumers on how to use this information when comparing plans and in making decisions about their health care.

In support of efforts to promote informed choice, HCFA will also maintain a toll-free line for M+C information.

Under section 1851(e)(3)(D), we are required to provide in the fall of 1998 for a ''Special Information Campaign'' in the form of an educational and publicity campaign that informs M+C eligible individuals about the availability of M+C plans offered in different areas, and about the election process. Section 1851(e)(3)(C) requires that we provide for a nationally coordinated educational and publicity campaign about M+C plans and the election process in November of each year, beginning in 1999. We may conduct these campaigns

using health fairs, as well as other methods for distributing information.

8. Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

a. Enrollment. Section 1851 (c)(1) and (c)(2) provide that individuals who wish to elect an M+C plan may do so through filing an appropriate election form with the organization during an election period specified in section 1851(e), and reflected in § 422.62. Section 1851(c)(1) requires that the Secretary establish a process through which elections in M+C plans are made. Therefore, we reserve the right to develop and provide additional mechanisms for electing an M+C plan. We have provided instructions on how M+C organizations must process elections at § 422.60(e). If necessary, we will publish regulations and allow for OMB review, pursuant to the requirements of the Paperwork Reduction Act of 1995.

b. Disenrollment. Section 1876 background: Under section 1876(c)(3)(B), which covers disenrollment from HMOs and CMPs, a Medicare beneficiary can disenroll from an HMO or CMP at any time. Under the HMO and CMP regulations in § 417.461(a), an enrollee who wishes to disenroll may, at any time, give the organization a signed, dated request in the form and manner we specify. The beneficiary can request a certain disenrollment date, but it can be no earlier than the first day of the month following the month in which the organization receives the disenrollment request. Under section 9312(h) of the Omnibus Budget Reconciliation Act of 1986, Medicare beneficiaries are also permitted to disenroll from an eligible organization under Section 1876 at a local Social Security office.

Section 417.461(b) describes the responsibility of the HMO or CMP to promptly submit a disenrollment notice to HCFA and provide the enrollee with a copy of the request for disenrollment and, in the case of a risk HMO or CMP, an explanation of the date of disenrollment. Section 417.461(c) provides that HMOs and CMPs must reimburse HCFA in cases where a disenrollment notice is not submitted timely to HCFA.

Currently, when an individual enrolls in one HMO or CMP while still enrolled in another, we regard this action as a disenrollment from the first HMO or CMP, and automatically amend our enrollment records to reflect the disenrollment. We do this so that the beneficiary does not have to both submit a disenrollment request to the first HMO or CMP, and an enrollment request to the new HMO or CMP.

To reflect these current policies, § 422.66(b)(1) provides that an individual who wishes to disenroll may change his or her election in the following manner: (i) Elect a different M+C plan during an election period specified in § 422.62 or (ii) submit a signed and dated request for disenrollment to the M+C organization during an election period specified in § 422.62. HCFA also reserves the right to develop and provide additional mechanisms for disenrollments in accordance with section 1851(c). Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

At § 422.66(b)(2) we specify that a disenrollment request is considered to have been made on the date it is received by the M+C organization. Note that HCFA's liability for payment ends not on the date the disenrollment request is received by the M+C organization, but rather, as of the date of disenrollment. The date of disenrollment is determined at § 422.68 for changes made by enrollees during coverage election periods and at § 422.74 for disenrollments made by M+C organizations.

At § 422.66(b)(3) and (4) we are continuing the § 417.461(b) and (c) requirements for M+C organizations to provide timely notice of disenrollment to HCFA and to provide the enrollee with a copy of the disenrollment request with information on the date of disenrollment and any lock-in requirements of the plan that apply until the effective date of disenrollment. We also state that disenrollment requests must be filed and retained as specified in HCFA instructions.

The regulation also provides that if the M+C organization fails to submit a correct and complete disenrollment notice to us promptly, the M+C organization must reimburse us for any capitation payments it has received after the month in which we would have stopped payment, had the M+C organization met the requirement.

c. Retroactive Disenrollment. Section 1876 background: In the case of section 1876 contractors, HCFA has permitted beneficiaries to be retroactively disenrolled from an HMO or CMP if it determines that there never was a legally valid enrollment, or a valid request for disenrollment was properly made but not processed or acted upon.

In the M+C program, HCFA will continue to consider retroactive disenrollments in cases in which we determine that there never was a legally valid enrollment, or a valid request for disenrollment was made but not processed or acted upon. We have reflected this provision in § 422.66(b)(5).

d. Fee-for-Service Election by Default. Section 1851(c)(3)(A)(i) establishes that newly eligible enrollees who do not choose an M+C plan during the initial coverage election period are deemed to have chosen original Medicare. We have reflected this provision in § 422.66(c).

e. Seamless Continuation of Coverage (Conversions). Section 1876 background: In regulations at § 417.432, an HMO/CMP is required to accept any individual who was already enrolled in the HMO/CMP for the month immediately prior to the month in which he or she was entitled to both Part A and Part B, or entitled to Part B only. HCFA refers to such enrollments as ''conversions'' or ''age-ins.'' The individual's effective month of enrollment in the HMO or CMP as a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B, or Part B only.

With the enactment of BBA, a new section 1851(c)(3)(A)(ii) is added to the statute that gives the Secretary discretion to establish procedures under which individuals who are enrolled in a health plan offered by an M+C organization at the time of their initial coverage election periods will ''default'' to or be deemed to have elected an M+C plan offered by the M+C organization, unless these individuals elect a different option. We have chosen not to have individuals default to the M+C plan offered by the organization. At this time we do not have a mechanism in place to capture the information we would need to implement such a process. A default process would require that M+C eligible individuals as well as their relevant health plan information be identified and captured prior to the individual's initial coverage election period. At present, we do not have access to information on which health plans individuals are enrolled in because such plans are private health plans. In addition, we are not given any information if individuals have not previously filed for title II (Social Security) and/or title XVIII (Medicare) benefits.

One option that we may consider would be to specify that M+C organizations which have individuals enrolled in private health plans must notify such individuals 4 months preceding the month in which the individual becomes an M+C eligible individual of their opportunity to ''age-in'' to the M+C plan or to select another option. This would give the individual

the opportunity to select from a range of health care options in a manner that would facilitate seamless continuation of coverage. M+C organizations would be required to transmit to us the necessary plan information for those individuals who are interested in exercising their opportunity to ''age-in''. HCFA would then have the information necessary to ''deem'' or ''default'' M+C eligible individuals into the appropriate M+C plan. We request public comments on this issue and will issue further clarification in the final rule. In the interim, we have retained the conversion of enrollment process described in § 417.432 with conforming changes.

In § 422.66(d) we specify that M+C plans must accept any individual who is enrolled in a health plan (other than an M+C plan) offered by the same M+C organization, during the month immediately preceding the month in which the individual is entitled to both Part A and Part B. Conversion may occur if the individual resides in the service area or continuation area of the plan and regardless of whether an individual has ESRD. We limit conversions to individual in a service area and continuation area in order to ensure that enrollees have access to the full range of services offered by the plan. This policy is also reflected in the section describing eligibility to elect a plan (§ 422.50(a)(2) and (a)(3)). Therefore, an M+C organization's obligation to accept current enrollees extends to enrollees in a service area or a continuation area, or who developed ESRD while enrolled with the organization under a private health plan. Converted beneficiaries who reside out of the plan's service area or who have ESRD cannot, however, later elect to enroll in a plan offered by another M+C organization unless they meet the statutory requirements at sections 1851(b)(1)(A) and 1851(a)(e)(B).

In addition, we allow M+C organizations to reserve vacancies for their plans to accommodate conversions in recognition that M+C organizations must accept conversions. We require the individual who is converting to file an election form in accordance with § 422.60(c)(1). We also stipulate that the M+C organization may not disenroll the individual except under the conditions described in § 422.74.

f. Maintenance of Enrollment. The statute provides at section 1851(c)(3)(B) that an individual who has made an election or is deemed to have made an election is considered to have continued to make that election until the individual changes it or the M+C plan is discontinued or no longer serves the area in which the individual resides. We have stated this rule at § 422.66(e).

9. Effective Dates of Coverage and Change of Coverage (§ 422.68)

Section 1851(f) establishes the effective dates for elections and changes to elections made during the various enrollment periods. Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

Section 1851(f)(1) states that an election made during the initial coverage election period will take effect on the date the individual becomes entitled to Part A and enrolled under Part B, but gives the Secretary discretion to interpret this provision in a manner, consistent with section 1838, that prevents retroactive coverage. We are interpreting ''enrolled in Part B'' as ''entitled to Part B'' in order to avoid retroactive coverage in an M+C plan that an individual might receive after enrolling in Part B but prior to the time the individual is actually entitled to Part B benefits. Therefore, we have established that an election made during the initial coverage election period is effective the first day of the month of entitlement to both Part A and Part B.

Under section 1851(f)(3), an election or change of election made during an annual coordinated election period is effective the first day of the following calendar year. We have reflected this provision in § 422.68(b).

Under section 1851(f)(2), an election or change of election made during an open enrollment period is effective the first day of the first calendar month following the month in which the election is made. We have reflected this provision in § 422.68(c).

Under section 1851(f)(4), an election that occurs as the result of a special election period is effective, to the extent practicable, in a manner determined by HCFA to promote continuity of coverage. We have reflected this provision in § 422.68(d).

At § 422.68(e) we are stating that an election of original Medicare made during a special election period by an individual age 65 as provided at § 422.62(c) is effective the first day of the first calendar month following the month in which the election is made.

10. Disenrollment by the M+C Organization (§ 422.74)

Section 1851(g)(3) specifies that M+C organizations may only disenroll individuals from an M+C plan for the following reasons: the individual fails to pay any basic and supplemental premiums on a timely basis; the individual engages in disruptive behavior; or the M+C organization terminates its coverage of all M+C eligible individuals in the area in which the individual resides.

In § 422.74, we have set forth the conditions under which M+C organizations can disenroll individuals. Section 1851(g)(3)(A) provides that, except as provided in section 1851(g)(3)(B), ''a Medicare+Choice organization *may not for any reason terminate*'' an individual's enrollment in ''a Medicare+Choice plan it offers.'' [Emphasis added.] We have included the three grounds for termination set forth in section 1851(g)(3)(B) in § 422.74. With respect to the ground in section 1851(g)(3)(B)(ii), under which an enrollee can be disenrolled for ''disruptive behavior'' as specified in standards established in regulations, we have implemented this ground for termination in two separate provisions. First, under § 422.74(b)(1)(ii), we refer to an individual who meets general standards for disruptiveness set forth in § 422.74(d)(2). Section 422.74(d)(2) refers to behavior of an individual that is ''disruptive, unruly, abusive, or uncooperative to the extent that his or her continued enrollment * * * seriously impairs the M+C organization's ability to furnish services. * * *'' We also separately refer to a different kind of ''disruption'' or failure to ''cooperate''; namely, fraud or abuse of the enrollee's enrollment card. This ground for termination is also based on section 1851(g)(3)(B)(ii), and standards for disenrollment on this basis are also included in § 422.74(d), in a separate paragraph (3).

In addition to implementing the grounds in section 1851(g)(3)(B), we also provide in § 422.74 for the termination of individuals who are no longer eligible for enrollment in the M+C plan, because they have left the area, lost entitlement to Medicare, or died. We believe that the prohibition in section 1851(g)(3)(A) on terminating an enrollee on grounds other than those set forth in paragraph (B) applies only to individuals who are otherwise *eligible* for enrollment in the plan. Clearly, if an individual does not meet the threshold requirements for eligibility, disenrollment is not only permissible but required.

We have established specific guidelines in § 422.74(d)(1) that the M+C organization must follow when disenrollment is based on failure to pay basic and supplemental premiums, including the requirement to send a notice of nonpayment within 20 days after the date that delinquent charges

are due. The notice must alert the individual that he or she is delinquent on a premium payment, provide the individual with an explanation of the disenrollment procedures and any lock-in provisions of the plan, and advise the individual that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage.

Note that in the section 1876 program, disenrollment for non-payment of premiums is treated differently. At § 417.460(c)(2), if a beneficiary pays the basic premium and other charges, but fails to pay the premium for optional supplemental benefits, the organization can discontinue the optional benefits, but cannot disenroll the beneficiary. However, under section 1851(g)(3)(B)(i), an M+C organization may terminate an election of a plan if any M+C monthly basic and supplemental beneficiary premiums are not paid on a timely basis.

We have retained the current processes described in § 417.460 for disenrollment for disruptive behavior and fraud and abuse. In the case of disenrollment for disruptive behavior, the M+C organization must ascertain that the individual's behavior is not related to the use of medical services or to diminished mental capacity. If an individual is disenrolled for disruptive behavior, HCFA will review the documentation submitted by the M+C organization and the beneficiary to determine whether the disenrollment requirements have been met.

We have included a qualifier for disenrollment when the individual no longer resides in the M+C plan's service area to conform to section 1851(b)(1)(B), which permits plans to offer a continuation of enrollment feature if the individual moves out of the service area. We have modified the existing regulatory text at § 417.460(h) which requires disenrollment when the individual loses entitlement to Part B benefits, to require disenrollment when an individual loses entitlement to Part A or Part B benefits. We have also addressed the process for disenrollment for plan termination or area reduction.

For all disenrollment situations, except those due to the death of the individual or loss of Part A or Part B benefits, we require M+C organizations to provide the individual with a written notice of the disenrollment that includes an explanation of why the M+C organization is planning to disenroll the individual and a description of the individual's right to a hearing under the M+C organization's grievance procedures.

The statute provides at section 1851(g)(3)(C) that individuals who are disenrolled from an M+C plan due to disruptive behavior or failure to pay basic or supplementary premiums will be deemed to have elected original Medicare. We have treated fraud and abuse by the enrollee in the same manner as other forms of disruptive behavior, with the individual being disenrolled into the original Medicare program. We believe that the result should be comparable because, in both cases, the individual's disruptive behavior has given the organization cause for the disenrollment. Individuals who lose entitlement to Part A or Part B benefits default to original Medicare because they no longer meet the requirements to receive Medicare benefits through an M+C plan, which requires entitlement to Part A and enrollment in Part B.

As previously discussed, special election periods are available to individuals who are disenrolled (or who disenroll) because of plan termination or service area or continuation area reduction or because they no longer reside in the M+C plan's service area or continuation area. Section 1851(g)(3)(C)(ii), however, stipulates that individuals who are disenrolled and who do not make an election during the special election period are deemed to have elected original Medicare.

11. Approval of Marketing Materials and Application Forms (§ 422.80)

Section 1851(h) contains requirements related to marketing by M+C organizations. These provisions are implemented in § 422.80. Section 422.80(a) implements the requirement in section 1851(h)(1) that all marketing material and application forms be submitted to HCFA for approval 45 days before distribution, and that such materials may only be used if HCFA does not disapprove such use by the end of this 45 day period. In section 422.80(b), we define ''marketing materials'' which must be submitted for approval under § 422.80(a).

Section 1851(h)(2) requires that M+C standards under section 1856 include guidelines for review of marketing materials under section 1851(h)(1) and § 422.80(a). Section 422.80(c) contains guidelines for HCFA's review of marketing materials under § 422.80(a). As provided for in section 1852(b)(2), these guidelines include existing marketing guidelines for HMOs and CMPs in § 417.428, which have been in effect since the inception of the existing Medicare risk contracting program.

Section 1851(h)(3) provides that, if HCFA has not disapproved the distribution of marketing materials or forms 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. This ''deemed approval,'' or ''1 stop-shopping,'' provision is included in the statute to address the needs of M+C organizations that operate in multiple states and within multiple HCFA Regional Office (RO) regulatory districts. Under the section 1876 program, a marketing piece submitted for HCFA review in multiple ROs was often susceptible to different regulatory interpretations by different RO staff; this occurrence could result in approval by one RO and a request for revisions by another RO. This phenomenon was primarily the result of RO staffs working within the environment of either an ''emerging'' market area or a ''mature'' area. The speed of review and approval of marketing materials should be enhanced by implementation of this statutory requirement.

Section 1851(h)(4) provides that M+C organizations shall conform to ''fair marketing standards'' included in the ''standards under section 1856,'' and requires that these standards prohibit an organization from providing cash or other monetery inducements for enrollment. Standards under section 1854(h)(4) are set forth in § 422.80(e). Again, as provided in section 1856(b)(2), these standards include existing section 1876 standards.

Section 1851(h)(4)(B) indicates that the fair marketing standards ''may include a prohibition against an M+C organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual.'' However, we have decided at this time not to prohibit an M+C organization (or agent of such an organization) from assisting beneficiaries in completing the election form. We recognize and understand that we must provide accommodations for persons with disabilities and for situations in which such a prohibition could represent a potential physical burden to beneficiaries. However, in general, we believe that it is good practice that the M+C eligible individual should complete and sign the election form. Currently, we have no way to check for any plan impropriety, especially in situations where beneficiaries require help in completing the enrollment form, except beneficiary allegations and requests for disenrollment. While we cannot

quantify the amount of inappropriate behavior, we know that some plans have completed election forms for beneficiaries fraudulently or have convinced beneficiaries to sign forms without explaining to them the contents and telling them the form is for enrollment (U.S. General Accounting Office report: ''HCFA Should Release Data To Aid Consumers, Prompt Better HMO Performance'', HS–97–23, October 1996.) Therefore, we request public comment on this issue and will provide further guidance in the final rule.

In the interim, we are providing at § 422.60(c) that persons who assist beneficiaries in completing forms should sign the form and indicate their relationship to the beneficiary. In addition, we encourage M+C organizations to use neutral parties such as family members, ombudsmen or counseling programs for those individuals who require assistance in completing forms.

Finally, in § 422.80(f), we specify that 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), HCFA will only review portions of these materials that relate to M+C plan benefits.

12. Medigap

Prior to the enactment of the BBA, Federal law provided only one opportunity for a Medicare beneficiary to purchase a Medicare supplement (Medigap) policy on a ''guaranteed issue'' basis. (Generally this means that the insurance company cannot deny the application, or charge extra, based on the individual's health experience.) This opportunity was during the 6-month period beginning with the date a beneficiary is both age 65 or over, and enrolled in Medicare Part B. Amendments made by the BBA now specify additional situations in which beneficiaries will, after July 1, 1998, be guaranteed access to certain types of Medigap policies on a guaranteed issue basis *if* they apply within 63 days after losing other coverage, and submit evidence of the date the prior coverage terminated. The law also requires the entity that provided the prior coverage to notify beneficiaries of these rights.

Therefore, while this regulation does not implement the Medigap provisions of the BBA, it is important to be aware of the implications for M+C organizations, since some of the situations covered by the Medigap provisions involve beneficiaries who leave M+C plans and return to original Medicare. The situations that will give rise to the obligation to notify the beneficiary will include, for example, termination of coverage by an M+C plan, or loss of coverage under an M+C plan due to a change in the individual's place of residence. The beneficiary also will have the right to guaranteed issue of a Medigap policy if he or she either enrolls in an M+C plan upon first becoming eligible for Medicare at age 65, or enrolls after previously being covered under a Medigap policy, and later disenrolls from the M+C plan within 12 months of the effective date of the M+C enrollment.

Because the Medigap provisions establish specific time deadlines for beneficiaries who wish to take advantage of these new rights, prompt action by M+C organizations to notify beneficiaries of their rights, and by HCFA to provide accurate evidence of recently terminated coverage, will be essential. CFA is committed to providing beneficiaries whose M+C coverage terminates under the specified circumstances with timely and accurate evidence of the recently terminated coverage. There are a number of ways in which we are considering providing the necessary evidence, including enabling Medigap insurers to query HCFA systems, if privacy and security issues can be resolved. HCFA is seeking comments on the most effective way to coordinate with Medigap insurers in order to protect beneficiaries' rights under the statute, and promote continuity of care.

We also urge M+C organizations to keep in mind that they will be obligated to notify beneficiaries whose coverage terminates of their rights under the Medigap provisions. Those provisions are complex—only certain beneficiaries will be entitled to guaranteed issue of Medigap policies, and their choice of policies will depend on the precise reason for termination of their coverage under the M+C plan. Further guidance is available from the National Association of Insurance Commissioners (NAIC), which on April 29, 1998 issued a revised Model regulation that incorporated the Medigap changes made by the BBA.

C. Benefits and Beneficiary Protections

1. General Requirements (§ 422.100)

Subpart C of these regulations details the scope of benefits a Medicare beneficiary is entitled to receive when electing coverage through an M+C plan. The statutory authority for most of the provisions of subpart C is found in section 1852, which outlines benefit requirements and provides authority for beneficiary protections under Medicare Part C. Many of the statutory provisions are the same as, or similar to, benefit provisions of section 1876. Therefore, much of the regulatory language of part 417 is retained for purposes of establishing M+C standards, as provided for in section 1856(b)(2) (which directs that the M+C standards be based on the analogous standards established under section 1876).

A principal difference between section 1876 provisions and the newly enacted law is that the new law permits a wider range of types of entities to assume risk for the coverage of benefits for Medicare enrollees. Section 1876 limited the Medicare contract option to organizations that operated as entities accepting full-risk, prepaid capitation for the provision of a comprehensive range of services and defined ''eligible organizations'' as a Federally qualified HMO (under title XIII of the Public Health Service Act) or a competitive medical plan (CMP). Except in a very few instances where waivers were granted during years when such waivers were authorized, the organizations had to offer such a product in the commercial marketplace in order to have a Medicare contract. From the point of view of benefit requirements imposed on plans, the new types of network plans are subject to the same benefit requirements applicable to organizations that would have met the definition of ''eligible organization'' under section 1876 (HMOs and CMPs). The requirements under the new law for network plans are in many cases identical to the requirements under section 1876.

While adding PPOs, indemnity insurers, and provider-sponsored organizations to the range of entities eligible for Medicare contracts, the BBA also permits non-network plans, such as private fee-for-service plans and M+C non-network MSA plans, to assume prepaid, capitated risk for services used by enrollees of these organizations. Medicare beneficiaries who elect these plans are not subject to the same constraints in use of providers that exist in network plans. Therefore, the benefit requirements applicable to these plans, and cost-sharing requirements, may be very different from those that apply to network plans. This section of the preamble mainly discusses the requirements for network plans. Sections III and IV of the preamble provide more extensive information about benefit requirements applicable to non-network M+C MSA plans and to

private fee-for-service plans, respectively.

All M+C organizations are required to cover the full range of Medicare benefits that enrollees would otherwise have been able to receive under original Medicare, subject to certain rules regarding available networks of providers. M+C organizations are further required to cover Medicare preventive benefits with the same frequency that they are covered under original Medicare (e.g., annual screening mammography examinations). Beneficiaries may be required to contribute to the cost of covered services in the form of cost-sharing provided for under the M+C plan. Beneficiaries may have to cover all costs until a deductible is met (including the high deductible provided for under an MSA plan (see section III of this preamble)), a percentage of costs in the form of coinsurance, or a fixed amount for services, in the form of a copayment. As discussed in subpart G below, there are limits that apply to the cost-sharing that can be imposed on beneficiaries under M+C plans. For benefits that are covered under original Medicare, the benefits must be obtained through providers meeting the conditions of participation of the Medicare program.

Organizations with network plans, which include coordinated care plans and network M+C MSA plans, are required to provide these services directly or through arrangements (i.e., written agreements with providers) in order to meet the availability and accessibility requirements of section 1852(d)(1) and § 422.112, discussed below.

In some situations, an M+C organization, for its network plan or plans, may be required to assume liability for services provided to Medicare enrollees through noncontracting providers. Under § 422.100(b), the organization is required to assume financial responsibility for the following items and services obtained from a provider that does not contract with the M+C organization:

- Emergency services as defined in § 422.2;
- Urgently needed services as defined in § 422.2;
- Renal dialysis services provided while the enrollee was temporarily outside the M+C plan's service area;
- Post-stabilization care as described in § 422.100(b)(iv); and
- For both network and non-network plans, services 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.

The requirements that the M+C organization assume financial liability for renal dialysis services, and post-stabilization care are new requirements introduced by the BBA that were not included in section 1876 requirements. The BBA also revised the definition of emergency services, as discussed elsewhere in the preamble.

''Post-stabilization care'' (also referred to in the Act as ''maintenance care'') means medically necessary, non-emergency services needed to ensure that the enrollee remains stabilized from the time that the treating hospital requests authorization from the M+C organization until—

- The enrollee is discharged;
- A plan physician arrives and assumes responsibility for the enrollee's care; or
- The treating physician and plan agree to another arrangement.

Section 422.100(b)(1)(iv) provides that an M+C organization is responsible for the cost of post-stabilization care provided outside the plan if they were pre-approved, if they were not pre-approved because the organization did not respond to the request by the provider of post-stabilization care services for pre-approval within 1 hour after the organization was asked to approve post-stabilization care, or if the M+C organization could not be contacted for pre-approval. M+C organization liability will extend until the organization has contacted the hospital to arrange for discharge or transfer. These requirements reflect comments we received on post-stabilization care in response to the **Federal Register** notice of January 20, 1998. The majority of commenters advocated that we establish a timeframe for an M+C organization's response to a request for approval. Because we agree that an untimely response to a request for approval would unduly delay the delivery of the post-stabilization care services, thereby compromising their effectiveness, we have established a 1-hour timeframe in the regulation as an enrollee protection. Because a completely accurate assessment of an enrollee's need for post-stabilization care services cannot be made until the enrollee is stabilized, we expect that the provider of the post-stabilization care services will not request the M+C organization's approval of the services until after the enrollee is stabilized, at which time enough details about the enrollee's condition should be known to allow the organization to make an informed decision on whether to approve the care almost immediately. We welcome comments on this issue.

In the case of payments to noncontracting providers for covered items and services, the M+C organization's obligation is met when it provides for payment in an amount the provider would have received under original Medicare (including payment from the organization and beneficiary cost-sharing under the plan).

The benefits offered by an M+C plan may be divided into two major components, ''basic benefits'' and ''supplemental benefits.'' Basic benefits in an M+C plan include all Medicare-covered services (except hospice) and additional benefits. Basic benefits are discussed below, and special rules for M+C enrollees electing hospice are set forth in § 422.266 and discussed in section II.F.9. of this preamble. Supplemental benefits include both mandatory and optional supplements, which we also discuss below.

Section 1852(a)(1) stipulates that M+C organizations offering an M+C plan (or plans) must offer it to all Medicare beneficiaries eligible to elect the plan who reside in the service area of the M+C plan at a uniform premium with uniform cost sharing. An organization may offer more than one plan in the same service area. The premium and cost-sharing may vary among plans within the same organization. We will review each M+C plan offered by the same organization to ensure that it is not designed to promote discrimination, discourage enrollment, steer specific subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services.

2. Requirements Relating to Basic Benefits (§ 422.101)

With the exception of special rules concerning hospice care and M+C coverage that begins during an inpatient hospital stay (described in §§ 422.266 and 422.264, respectively), a Medicare enrollee is entitled to have the M+C organization provide all Medicare-covered services that are available in the geographic area in which services are covered under the plan.

M+C organizations are required to provide their enrollees with services covered under original Medicare and available to beneficiaries residing in the geographic area in which services are covered under the plan, as we provide at § 422.101(a). Organizations must also abide by our national coverage decisions, as well as specific written policies of the Medicare carrier or intermediary with jurisdiction for claims (if the encounter had occurred under original Medicare) in the

geographic area served by the plan. (These policies are sometimes called ''local medical review determinations.'') In cases where services are covered under the plan in an area that includes jurisdictions of more than one contractor for original Medicare, and the contractors have different medical review policies, the plan must apply the medical review policies of the contractor in the area where the beneficiary lives.

In addition, the organization is required to provide ''additional benefits,'' which include health care services not covered by Medicare, as well as reductions in premiums or cost sharing for covered services. As discussed in section II.A of this preamble, we use the term ''basic benefits'' to encompass all Medicare-covered benefits (except hospice services) and additional benefits. These benefits are determined by our approval of an M+C organization's Adjusted Community Rate (ACR) proposal for a given M+C plan and must be provided uniformly to all Medicare enrollees electing that plan. Additional benefits are generated when the average payment rate for a plan exceeds the adjusted community rate, thereby producing a surplus known as the ''excess amount.'' (See section II.F of this preamble for a more thorough discussion of the requirements that apply to additional benefits, which are set forth under § 422.312.)

In the case of an M+C private fee-for-service plan or a non-network M+C MSA plan, the obligation to cover Medicare services is not limited to services available in the plan's approved service area. Rather, in this context, we interpret ''geographic area served by the plan'' in section section 1852(a)(1)(A) to mean the area within which the M+C private fee-for-service or non-network M+C MSA plan enrollee has the right to receive covered services under the plan.

Under our authority in section 1856(b)(1) to establish standards under the M+C program, § 422.100(h) establishes special rules for influenza vaccine, pneumococcal vaccine, and screening mammography. Section 422.100(h)(2) prohibits enrollee cost-sharing for influenza vaccine and pneumococcal vaccine. Under original Medicare, there is no cost-sharing imposed on these items, and we believe congressional intent is for Medicare beneficiaries to have maximum possible access to both vaccines. We note that original Medicare provides for beneficiary payment of coinsurance for mammography screening; therefore, a plan may also impose copayment or coinsurance for this service.

Also note that beneficiaries under original Medicare may ''self-refer'' and directly access screening mammography and influenza vaccine. We have established a similar standard in § 422.100(h)(1) for M+C enrollees.

3. Supplemental Benefits (§ 422.102)

Section 1852(a)(3) provides for supplemental benefits. These benefits are health care items and services beyond the basic benefits described above and are categorized as either mandatory or optional.

Mandatory supplemental benefits are benefits not included in basic benefits which must be purchased by all beneficiaries who enroll in the M+C plan under which they are included. Mandatory supplemental benefits may be offered under coordinated care plans and fee-for-service plans only, and must be approved by HCFA. HCFA will approve such benefits unless we determine that they would substantially discourage enrollment in the plan. Specifically, we will determine whether the inclusion of the mandatory supplemental benefits would discourage particular subcategories of Medicare beneficiaries from enrolling (e.g., those residing in certain parts of a plan service area). These benefits are addressed in § 422.102(a).

Section 1852(a)(3)(C) provides that nothing in paragraph (3) of section 1852(a), addressing supplemental benefits, shall be construed to prevent a fee-for-service plan from offering supplemental benefits covering the balance billing permitted under section 1852(k)(2)(A)(i) and § 422.216(b)(1) and additional services. See discussion of M+C private fee-for-service plans in section IV of this preamble. The only provision in section 1852(a)(3) that could possibly be construed to prevent a private fee-for-service plan from offering such benefits would be the right of the Secretary, and of HCFA under these regulations, to disapprove mandatory supplemental benefits. We accordingly wish to make it clear that HCFA will not disapprove such benefits in the case of a private fee-for-service plan. (As discussed below in subpart G, HCFA does not have the right to review or approve the amount that a private fee-for-service plan charges for supplemental benefits.) We believe that the foregoing statement is sufficient to give effect to section 1852(a)(3)(C).

Optional supplemental benefits are benefits beyond basic benefits that may be purchased by an M+C plan enrollee at his or her option. If a plan offer optional supplemental benefits, it must offer those benefits to all enrollees in the M+C plan. While optional supplemental benefits may be offered under all types of plans, in the case of MSA plans, there are limits, discussed in section III of the preamble, on the nature of optional supplemental benefits that can be offered.

Under mandatory supplemental benefits for coordinated care plans, an M+C organization may require an enrollee who elects an M+C plan to accept and pay for items and services beyond basic benefits if he or she wants to enroll in a particular M+C plan. If an organization requires supplemental benefits, it must do so uniformly for all Medicare beneficiaries enrolled in that plan. As provided for at section 1852(a)(3)(A), we will approve such offerings unless we determine that would substantially discourage enrollment in the plan. We will determine whether the mandatory supplemental benefits would discourage subcategories of Medicare beneficiaries from enrolling (e.g., those residing in certain parts of a plan's service area).

An organization may also offer optional supplemental benefits within an M+C plan. In this case, the beneficiary is free to choose to accept or decline the supplement. In the case of both mandatory and optional supplemental benefits, the benefits are paid for by (or on behalf of) the individual electing the M+C plan.

Sections 422.103 and 422.104, addressing benefits under MSA plans generally, and optional supplemental benefits under an MSA plan, are discussed in section III. below.

4. Special Rules for Point-of-Service (POS) Option (§ 422.105)

This section of the rule codifies our existing policy for point-of-service plans. Because these policies have not previously appeared in regulations, we welcome comments.

A POS benefit is an option that an M+C organization may offer through an M+C coordinated care plan or network M+C MSA plan to provide Medicare enrollees with additional choice in obtaining specified health care items and services from entities that do not have a contract with the M+C organization. A coordinated care plan may offer a POS option as an additional benefit, a mandatory supplemental benefit, or an optional supplemental benefit. A network MSA plan may only offer a POS option as a supplemental benefit.

Under POS, the health plan generally provides partial reimbursement to enrollees for items and services obtained from non-network providers. The enrollee may be required to pay a premium for the benefit unless the

benefit is offered as an additional benefit. The Act contains two mentions of the term ''point of service'' as it relates to M+C plans. Section 1851(a)(1)(A) states that an HMO may include a POS option, and section 1852(c)(1)(C), requires disclosure to enrollees of ''any point-of-service option (including the supplemental premium for such option).'' Therefore, the Act indicates that HMOs could offer POS products, and that there could be a supplemental enrollee premium for such a product.

We currently permit HMOs and CMPs to offer POS products. There is no specific statutory reference to such a product in section 1876; the statutory basis for allowing Medicare HMOs to provide POS products lies in the additional and supplemental benefit offerings an HMO may have under section 1876. We believe that under the structure of the M+C program, any coordinated care plan or network M+C MSA plan may offer a POS product.

The regulations at § 422.105 governing the POS benefit are largely a restatement of our previously issued guidelines. In issuing the guidelines, we were particularly concerned with assuring the continued accessibility and availability of medically necessary care within the Medicare plan's approved network. We also emphasized that organizations are responsible for: members' continuity of care; ensuring beneficiaries are fully informed about how the POS benefit would be implemented; and the potential financial liability of the individual. We also required organizations to provide data to us about the POS benefit, including expenditures and levels of POS utilization, and the effect on the financial status of the organization. Moreover, the guidelines required the plans to maintain a record-keeping system to make information on utilization of the POS benefit available to plan providers. These previous operational policy requirements are carried over into § 422.105.

There are some changes in § 422.105 to the guidelines we issued under section 1876, however. One has to do with POS coverage available for in-network items and services. Under the guidelines, we permitted HMOs and CMPs to include network providers who could be paid through the POS option. These regulations eliminate that option. Additionally, under § 422.105, we will now require plans to place a cap on a beneficiary's total annual financial liability under a POS benefit. In another change, we are eliminating separate solvency standards for POS products. Each of these changes is discussed below.

Although HCFA guidelines did permit a Medicare beneficiary to use a POS option to seek, for example, ''direct access'' to a specialist within the plan's network, and thereby avoid any prior authorization requirement or other plan rules relating to access to particular providers, we believe such a feature of a POS option is inconsistent with the concept of a network plan and not a desirable feature of a POS option. The basic access and availability requirements both of sections 1876 and 1852(d) require that benefits be made available, through providers selected by the M+C organization, in a manner that ensures availability, accessibility and continuity of care. If the care an individual seeks from a network provider is necessary care, the individual should be able to obtain that care through the network, following network rules. Although the enrollee might not receive treatment from the particular provider he or she prefers, the organization and its contractors are obligated to make covered services available to all enrollees through network providers. We do not believe it is appropriate to use the POS benefit to circumvent network rules.

In § 422.105 we also specify that an M+C organization offering a POS benefit establish an annual limit on a beneficiary's maximum financial liability when using a POS benefit. We require a financial limit to alert beneficiaries to their maximum potential financial liability in using their POS benefit. We consider it a critical part of beneficiary information that enrollees are clearly informed about all of their potential costs when enrolling in an M+C plan.

Another change from existing policy in § 422.105 is the elimination of the additional solvency requirements that have been imposed under the POS guidelines (though reporting requirements relating to solvency remain). The Act gives the States primary responsibility for setting and enforcing solvency standards for M+C plans (other than a provider-sponsored organization with a waiver of the State licensure requirement), and our imposition of additional solvency requirements on POS products is inconsistent with the States' responsibility. (In fact, because of solvency concerns, many States require licensure as an indemnity insurer if an HMO wishes to offer a POS product.) We will continue to require M+C organizations to comply with this reporting requirement, as was the case with Medicare contractors under section 1876. This reporting requirement is not superseded by the Act's preemption provision relating to benefits in section 1856(b)(3)(B).

5. Special Arrangements With Employer Groups (§ 422.106)

An M+C organization may negotiate with an employer group to provide benefits to Medicare members of the employer group who are enrolled in an M+C plan offered by the organization and these benefits must be provided uniformly to members of the group. While these negotiated employer group benefits may be designed to complement benefits available to Medicare beneficiaries enrolled in the plan, they are offered by the employer group independently as the product of private negotiation. These benefits may include contributions on the employee group member's behalf toward M+C plan premiums or cost-sharing for which the Medicare eligible group member is responsible, or benefits not covered by the M+C plan, for which premiums and cost-sharing may be charged. We do not review such employer group benefits, premiums, or cost-sharing amounts.

6. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

As specified in section 1852(a)(4), if a Medicare enrollee receives covered items and services from an M+C organization for which the enrollee is entitled to benefits under a State or Federal workers' compensation law or plan, any no-fault insurance, or any liability insurance policy or plan (including a self-insured plan), the M+C organization may charge the insurance carrier, employer or other entity that is responsible to pay for the provision of those items and services. The M+C organization may also charge the Medicare enrollee to the extent that the enrollee has been paid by the carrier, employer, or other entity for those items and services. In addition, an M+C organization may charge a group health plan or large group health plan for items and services for which Medicare is a secondary payor.

In this area, pursuant to section 1856(b) (1) and (2), we are retaining for M+C organizations the requirements that applied to HMOs and CMPs under part 417.

7. Effect of National Coverage Determinations (NCDs) (§ 422.109)

This provision implements section 1852(a)(5). Under this rule, M+C organizations are not required to assume risk for the costs of certain ''significant cost'' NCDs until an adjustment has

been made in the per capita rate to reflect the NCD. A national coverage determination is a national policy statement regarding the coverage status of a specified service that HCFA makes as a program memorandum or manual instruction. The term does not include coverage changes mandated by statute. Past NCDs have included items such as heart transplants.

On February 22, 1994 HCFA published a notice of proposed rule making (NPRM) to define ''significant cost'' and other requirements for NCDs as they applied to section 1876 risk contracting plans. With one exception discussed below, we are including in this rule the policies included in the February 22, 1994 proposed rule. For example, we have maintained the definition of ''significant cost'' as $100,000 for a single NCD service for calendar years 1998 and 1999. We are providing for an automatic adjustment of a single service threshold amount to reflect rising costs, and will adjust the dollar threshold by the national per capita growth percentage used to calculate the annual capitation rates to pay M+C organizations. We are also providing an alternative definition for lower cost services that will affect a large number of beneficiaries. For the cost of all of the services furnished nationwide as a result of a particular NCD, we have redefined significant cost as 0.1 percent of the national standardized annual capitation rate (which is used in calculating the annual capitation rates used to pay M+C organizations) multiplied by the total number of Medicare beneficiaries nationwide for the applicable calendar year.

This rule also describes how the NCD will be provided to M+C plan enrollees during the period the M+C organization is not at risk for the new or expanded benefit established by the NCD, including procedures to pay M+C organizations and the policies affecting beneficiary liability. It is in this area that this rule differs from the February 22, 1994 proposed rule. That proposed rule reflected the NCD provision that applied to HMOs with risk contracts under section 1876. There is one key difference between the NCD provision in section 1876 and the NCD provision under the new M+C. Like the new NCD provision in section 1852(a)(5), section 1876(c)(2)(B) provided that services required under certain mid-year NCDs were excluded from risk contracts until the first year in which payment for the services is reflected in capitation payments. However, under Section 1876(a)(6), original Medicare coverage of such NCD services was identified as an exception to the rule that only the risk-contracting HMO could receive Medicare payment on behalf of one of its enrollees. Therefore, an HMO enrollee was not required to receive NCD services excluded from the HMO's contract through the HMO, and could receive the services either from the HMO or from any other Medicare provider, and Medicare would pay. This was reflected in the February 2, 1994 proposed rule.

Under the M+C program, however, there is no similar exception for excluded NCD services providing that only an M+C organization may be paid by Medicare on behalf of an enrollee in an M+C plan offered by that organization. We believe that this difference reflects Congress' intent that beneficiaries be required to receive services through their M+C organization, under the same rules that apply to any other non-urgent and non-emergency services. Under the new NCD provision, only the method that HCFA pays the organization for the services, and the cost-sharing that applies to such services differs from other services. If the excluded NCD services are received from, or through, the M+C organization, the organization will be paid on a fee-for-service basis for those services. If the services are not available from the plan, the organization will pay the authorized provider after receiving fee-for-service from the intermediaries or carriers.

Pursuant to our authority under section 1856(b)(1), we are expressly requiring that the M+C organization provide the NCD services in question on a fee-for-service basis.

8. Discrimination Against Beneficiaries Prohibited (§ 422.110)

The current rule reflects section 1852(b), and the details provided in § 422.110 are consistent with existing policy and regulation. In general, M+C organizations may not discriminate among Medicare beneficiaries based on health-related factors with the exception that organizations may not enroll new beneficiaries with end-stage renal disease. For further discussion of discrimination provisions affecting M+C enrollees with ESRD, see the discussion in section II.B.1 of this preamble.

9. Disclosure Requirements (§ 422.111)

In section 1852(c), the Act lists several areas where an M+C organization must disclose specific information to each M+C plan enrollee. These requirements are, in large part, a codification of existing program administration requirements under section 1876, and we detail these requirements in § 422.111 of the regulations. In general, an M+C organization is required to provide in a clear, accurate, and standardized form information relating to: service area; benefits access; out-of-area coverage; emergency coverage; supplemental benefits; prior authorization rules; plan grievance and appeals procedures; disenrollment rights and responsibilities; and information about the M+C organization's quality assurance program.

M+C organizations are also required to provide further information on a beneficiary's request, which we also detail in § 422.111 of the regulation text. These ''upon request'' requirements include: general coverage and comparative plan information; information on utilization control procedures; information on grievances and appeals; information on the financial condition of the M+C organization; and a summary of physician compensation arrangements.

10. Access to Services (§ 422.112)

The requirements of section 1852(d) of the Act (concerning access to services) are being implemented through this rule, in part, by applying existing regulations and policies pursuant to our authority in section 1856(b)(1) to establish standards under the M+C program. We are also addressing recommendations from the President's ''Consumer Bill of Rights and Responsibilities'' (CBRR), and incorporating the ''Quality Improvement System for Managed Care'' (QISMC) standards.

For example, our existing policy shaped the language in § 422.112(a)(1)(i) requiring M+C organizations to maintain and monitor a network of appropriate providers, supported by written agreements sufficient to certify beneficiary access to covered services. The CBRR shaped the access to (and continuity of) specialist services text in § 422.112(a), as well as provisions for provider credentialing and timeliness of access, among other consumer protections. We also include a provision at § 422.112(a)(4)(vii)for M+C organizations to ensure ''cultural competency'' in the provision of health care. This provision reflects CBRR recommendations that M+C organizations make a particular effort to ensure that enrollees with limited English proficiency, limited education, or other socioeconomic disadvantages receive the health care to which they are entitled.

The Consumer's Bill of Rights and Responsibilities also recommends that women be able to choose a women's

health care specialist within network for the provision of routine and preventive women's health care services. In support of this recommendation, § 422.112(a)(1)(iii)(A) requires M+C network plans to provide direct access to a women's health specialist within the network for routine and preventive women's health care services provided as basic benefits, as defined in § 422.2. We note that coverage of routine and preventive health services under original Medicare is limited. For example, original Medicare covers a screening pap smear and a screening pelvic exam, including a clinical breast exam, once every 3 years under normal circumstances. M+C plans must cover routine and preventive health services with at least the same frequency as they are covered under original Medicare and may offer expanded services in these areas as additional benefits.

M+C plans satisfy the requirement in § 422.112(a)(1)(iii)(A) by providing direct access to gynecologists, certified nurse midwives, and other qualified health care providers for provision of routine and preventive women's health services. At the same time, M+C plans are required to provide women enrollees with continued access to their primary care physician to ensure continuity of care. We welcome comments on this issue.

In § 422.112(a)(1)(iii)(B), we require that plans have HCFA-approved procedures—

- To identify Medicare enrollees with complex or serious medical conditions;
- For assessment of those conditions, including medical procedures to diagnose and monitor them on an ongoing basis; and
- For 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. To meet these requirements and those of § 422.112(a)(5)(v)(A), M+C plans must conduct a baseline and establish a treatment plan for people with complex or serious medical conditions. This assessment should be completed within timeframes deemed appropriate by M+C plans based on the needs of its enrollees, but, in general, should occur within 90 days of the effective date of enrollment.

Section 422.112(a)(5)(v)(A) also requires M+C plans to conduct a baseline health assessment for all new Medicare enrollees (i.e., not limited to those with complex or serious medical conditions) in a timely manner. We believe that this initial assessment should also be performed based on timelines deemed appropriate by the plan, but not later than 90 days after the effective date of enrollment. We welcome comments regarding timely baseline assessments both for new enrollees and those with complex or serious medical conditions.

Note that, as indicated in the heading of § 422.112(a), some access provisions apply only to network organizations, (i.e., coordinated care plans and network MSAs), while others (§ 422.112(b)) apply to all M+C organizations.

Section 422.112(b) states that M+C organizations must provide coverage of emergency services and urgently needed services even in the absence of the organization's prior approval and without regard to the provider's contractual relationship with the M+C organization. For definitions of emergency and urgently needed services, see § 422.2.

This section continues the prohibition at § 417.414(c)(1) on prior authorization requirements for emergency services as explicitly provided by 1852(d) and continues the § 417.414(c)(1) regulatory prohibition on prior authorization requirements for urgently-needed services. This section also establishes a prohibition on prior authorization requirements for emergency services provided within the plan because the prohibition on prior authorization at section 1852(d) applies to services provided both within and outside the organization.

Consistent with the new definition of ''emergency medical condition'' in section 1852(d)(3)(B), we are codifying longstanding *HMO/CMP Manual* policy (§ 2104) of prohibiting retrospective denial for services which appeared, to the prudent layperson, to be emergencies, but which turn out to be nonemergency in nature.

We are establishing that when a physician or other representative affiliated with the organization instructs the enrollee to seek emergency services within or outside the organization, the organization is responsible for payment for medically necessary emergency services provided to the enrollee.

We are codifying in regulation an *HMO/CMP Manual* policy (§ 2104) specifying that the decision of the examining physician treating the individual enrollee prevails regarding when the enrollee may be considered stabilized for discharge or transfer.

We are establishing limits on cost-sharing for emergency services obtained outside of the M+C plan's provider network equal to of the lesser of $50 or what the organization may charge for emergency services provided within the plan's provider network. We are imposing this requirement in order to facilitate and ensure access to covered emergency services provided other than through the organization. We do not view this requirement as overly burdensome. A review of 1997 data on what Medicare HMOs and CMPs charged for emergency services found that 93 percent of contracts charged $50 or less. We believe that it may be appropriate to lower this limit or eliminate cost-sharing altogether, and would welcome comments on this subject.

Note that an M+C organization's failure to provide medically necessary emergency services could result in intermediate sanctions for failing to provide coverage, or payment, or through actions (such as a prospective refusal of payment) that could result in discharge or transfer of an unstabilized patient. The new coverage requirements for M+C enrollees do not affect the rights of all persons (whether or not they are Medicare beneficiaries) to receive emergency services at any Medicare-participating hospital that offers emergency services (under the patient ''anti-dumping'' statute in section 1867).

11. Access to Services Under an M+C Private Fee-for-Service plan (§ 422.114)

In the case of an M+C organization that offers an M+C private fee-for-service plan, that organization must demonstrate that it has a sufficient number and range of providers willing to furnish items and services under the plan. An M+C organization meets this requirement if, with respect to a particular category of providers, the organization has:

- Payment rates that apply under original Medicare for the provider and service in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the items and services covered under the M+C private fee-for-service plan; or
- A combination of the two.

Additionally, an M+C private fee-for-service plan must permit enrollees to obtain items and services from any entity that is authorized to provide items and services under Medicare Parts A and B and agrees to provide services under the terms of the M+C private fee-for-service plan. For a fuller discussion of M+C private fee-for-service plans, see section IV of this preamble.

12. Confidentiality and Accuracy of Enrollee Records (§ 422.118)

M+C organizations are required to safeguard the confidentiality and

accuracy of enrollee records that identify a particular enrollee, including both medical documents and enrollment information. An M+C organization may circulate this information within the organization to coordinate care for a Medicare enrollee. The M+C organization may not, however, circulate this information outside the organization without specific authorization from the Medicare enrollee. M+C organizations are prohibited from selling (or circulating outside the organization) names and addresses of enrollees for any purpose, including scientific study.

Additionally, the M+C organization must maintain records in an accurate and timely manner and ensure timely access to enrollees who wish to examine their records. Moreover, the M+C organization must abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, other health information, and enrollee information.

13. Information on Advance Directives (§ 422.128)

Advance directives are documents signed by a patient that explain the patient's wishes concerning a given course of medical care should a situation arise where he or she is unable to make these wishes known. The M+C organization is responsible for documenting advance directives in a prominent part of the Medicare beneficiary's medical record. Accordingly, pursuant to our authority in section 1856(b)(1) and (2) to establish M+C standards, we are retaining for M+C organizations the requirements that applied to HMOs and CMPs under part 417.

14. Protection Against Liability and Loss of Benefits (§ 422.132)

Each M+C organization must adopt and maintain satisfactory arrangements to protect Medicare enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization. By reference in § 417.407(f) (implementing regulations for section 1876), enrollee protections described in § 417.122 are unchanged by the BBA, and their application to M+C organizations are carried forward in this section.

Medicare law requires that Medicare contracting M+C organizations make Medicare covered services ''available and accessible.'' Section 1852(d)(1), in describing access to services, allows M+C organizations to select the providers from whom benefits may be obtained so long as ''the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness * * *'' We believe these sections require health plans to provide the same accessibility afforded by HCFA to beneficiaries under original Medicare.

D. Quality Assurance

1. Overview

Subpart D of part 422 contains the quality assurance requirements for M+C organizations. These requirements implement and are based on the provisions of section 1852(e) of the Act. They also incorporate the requirements of section 1851(d)(4)(D), which provides that the information made available to Medicare beneficiaries for plan comparison purposes should include plan quality and performance indicators, to the extent available. Section 1852(e)(1) sets forth the general rule that each M+C organization must establish an ongoing quality assurance program, consistent with implementing regulations, for the health care services it provides to enrollees in the organization's M+C plans. The rest of section 1852(e) contains the required elements of the quality assurance program, requirements for external review, and provisions concerning the use of accreditation organizations to determine compliance with the quality assurance requirements.

The provisions of section 1852(e) represent a significant expansion in the scope of the statutory quality assurance provisions applicable to managed care organizations that contract with the Medicare program. Existing section 1876(c)(6) contains a general requirement similar to that of section 1852(e)(1) that an organization must have a quality assurance program, but it provides very limited guidance as to the nature of this program. The only required elements of a quality assurance program under section 1876(c)(6) are that it stress health outcomes and include physician review of the procedures used in the provision of health care services. Like section 1876(c)(6), existing quality assurance regulations (§ 417.418 and, by reference, § 417.106(a)) contain few detailed requirements concerning quality assurance. The regulations basically restate the statutory requirements relating to health outcomes and physician review and then add two broad requirements regarding data collection and the need for written procedures for taking remedial action.

In contrast, section 1852(e) sets forth a series of specific elements that now must be addressed in an M+C organization's quality assurance program. As discussed in detail below, these requirements focus on the need for an M+C organization, with respect to each M+C plan that it offers, to operate an outcome-oriented quality assessment and performance improvement program that achieves demonstrable improvements, across a broad spectrum of care and services, in the health, functional status, and satisfaction of its enrollees. (Note that some of the specific performance improvement requirements of the statute do not apply to M+C non-network MSA plans or PFFS plans, as addressed under § 422.152(e).) The collection, evaluation, and reporting of the data necessary to demonstrate quality improvements are also critical elements of each M+C organization's quality-related responsibilities.

2. Origins of the Quality Assessment and Improvement Requirements

The regulations to implement sections 1852(e)(1) and (2) and section 1851(d)(4)(D) incorporate each of the explicit statutory requirements into new subpart D. Consistent with our explicit statutory authority under section 1851(e), these regulations include additional detail to clarify how an M+C organization can meet the statutory requirements. Like Congress, we recognize that the state of the art in quality assurance has evolved from a problem-focused approach, with an emphasis on remedial action, to a proactive approach aimed at achieving continuous, systemic quality improvement. In recent years, HCFA, the States, and other managed care purchasers have been involved in a series of initiatives aimed at improving the quality of care and services provided to managed care enrollees. Examples of such efforts include:

- The Quality Assurance Reform Initiative (QARI), which developed and tested standards for States to use in monitoring and improving quality in Medicaid contractors, with a particular emphasis on plans' own internal quality improvement efforts.
- Uniform data collection and reporting instruments, such as the Health Plan Employer Data and Information Set (HEDIS 3.0), which was developed by the National Committee for Quality Assurance (NCQA). Use of HEDIS 3.0 is now a contract requirement for Medicare risk-based managed care plans, under section 1876 and is intended to allow assessment and comparison of plan performance.
- Projects to enhance the role of Medicare Peer Review Organizations (PROs) in evaluating and improving managed care plan quality, including

the development and testing of a minimum set of performance evaluation measures and quality improvement projects developed through collaboration between PROs and managed care organizations. States have undertaken similar efforts through Medicaid External Quality Review Organizations (EQROs).

Among the most comprehensive of recent quality-related initiatives is the Quality Improvement System for Managed Care (QISMC). During the past 2 years, HCFA has been working closely with other Federal and State officials, as well as representatives of beneficiary advocacy groups and the managed care industry, to develop quality standards that can better ensure that managed care organizations that contract with HCFA protect and improve the health and satisfaction of their enrollees. QISMC is the product of these efforts. Originally drafted based on the authority of section 1876, it builds on a variety of recent HCFA and State efforts, like those mentioned above, to promote the assessment and improvement of managed care quality. The QISMC standards are in the final stages of development at this time and are being modified to reflect the quality-related requirements under the BBA. Once QISMC is complete, we believe it will offer a uniform set of quality standards that can be used by HCFA and the State Medicaid agencies to determine whether a managed care organization can meet the quality assurance requirements necessary to become and remain eligible to enter into a Medicare or Medicaid contract.

The QISMC initiative is substantially in accord with the quality assurance requirements of new section 1851(e). For example, both the statutory requirements and the QISMC quality standards emphasize measurement of health outcomes, consumer satisfaction, the accountability of managed care organizations for achieving ongoing quality improvement, the need for intervention to achieve this improvement, and the importance of data collection, analysis, and reporting. Moreover, as noted above, representatives of all segments of the managed care community have contributed to the development of QISMC, and generally support HCFA's intention to eventually require managed care organizations to meet the QISMC standards. Given the shared goals of the BBA and QISMC standards, and HCFA's implementation plans for QISMC, we believe it is appropriate to establish new M+C quality assurance regulations that reflect those QISMC standards that mirror the intent of the statute. Although we have not included in the regulations the level of detail embodied in QISMC, we have attempted to build into the regulations some principles from QISMC that can guide M+C organizations in meeting the quality requirements established by the statute. For example, § 422.152(d) establishes objective standards concerning the improvement projects that are required of M+C organizations, in accordance with the statutory requirements concerning an organization's responsibility to take action to improve quality (such as section 1852(e)(2)(A)(xi) of the Act.

Although QISMC remains an evolving document, several of the discussions below of the ways in which organizations can meet the M+C quality requirements are informed to some degree by the underlying details contained in QISMC. Also, as discussed below, we anticipate that requirements pertaining to a plan's quality assessment and performance improvement responsibilities may be implemented as part of the M+C contracting process. QISMC standards may be a guide in implementing the requirements in the BBA and these regulations. Eventually, we believe QISMC can serve to define what HCFA's expectations are with regard to an M+C organization's quality assessment and improvement responsibilities. (A copy of the most recent version of QISMC is available at HCFA's website, www.hcfa.gov/quality/qlty-3e.htm.)

3. Quality Assessment and Performance Improvement Requirements (§ 422.152)

This section of the regulation implements paragraphs (e)(1) and (2) of section 1852. Subject to certain exceptions for M+C PFFS and non-network MSA plans, which are discussed below, the statute requires that an organization's quality assurance program meet the following requirements with respect to each plan that it offers:

(i) Stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that HCFA recognizes) that will permit measurement of outcomes and other quality indices.

(ii) Monitor and evaluate high-volume and high-risk services and the care of acute and chronic conditions.

(iii) Evaluate the continuity and coordination of the care that enrollees receive.

(iv) Be evaluated on an ongoing basis as to its effectiveness.

(v) Include measures of consumer satisfaction.

(vi) Provide HCFA access to the information it needs to monitor and ensure the quality of the care provided.

(vii) Provide for physicians and other health care professionals to review the process followed in providing health care services.

(viii) Establish written protocols for utilization review, based on current standards of medical practice.

(ix) Have mechanisms to detect both underutilization and over utilization of services.

(x) Establish or alter practice parameters when areas needing improvement are identified.

(xi) Take action to improve quality and assess the effectiveness of that action through systematic follow-up.

(xii) Make available to HCFA information on quality and outcomes measures to facilitate beneficiary comparisons and choice of health care options (in such form and on such quality and outcomes measures as HCFA determines is appropriate).

As noted above, section 1852(e)(1) also requires that the organization's quality assurance program be consistent with any regulation developed by HCFA. Therefore, § 422.152 reflects the statutory requirements listed above, as well as those implementing requirements that are consistent with, and necessary to accomplish, the intent of the Act. While certain requirements in section 1852(e)(2) that expressly refer to ''improvement'' in quality do not apply to all types of M+C plans, we believe that all of the requirements in section 1852(e) are geared toward improving quality, not simply monitoring it. For this reason, we are using the term ''quality assessment and performance improvement program'' to refer to the program that is required of all M+C plans, which section 1852(e)(1) refers to as a ''quality assurance program.'' We accordingly use the term ''quality assessment and performance improvement program'' in the heading of § 422.152 and in the general rule at § 422.152(a).

a. Requirements for M+C Coordinated Care Plans and Network MSA Plans. Sections 422.152(b) through (d) set forth requirements that M+C organizations must meet with respect to M+C coordinated care plans and network MSA plans. As alluded to above, as directed by section 1852(e), these requirements reflect a departure from the problem-focused approach to ensuring quality that was prevalent in the past. Thus, under these regulations, it will no longer be sufficient for organizations to identify and correct problems in their operations—they must now focus on systemic quality

improvement as well. This approach is also consistent with HCFA's responsibility to demand value in the form of positive outcomes from the organizations with which we contract.

To implement this approach, § 422.152(b) establishes two basic quality assessment and performance improvement requirements: (1) measurement and reporting of performance; and (2) conducting performance improvement projects that achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of both clinical care and nonclinical care areas that can be expected to affect health outcomes and member satisfaction. The specific requirements associated with the measurement and reporting of performance and the execution of performance improvement projects are set forth under § 422.152(c) and (d), as discussed in detail below. Before turning to that discussion, however, we note that § 422.152 also incorporates statutory requirements from section 1852(e)(2)(viii), (ix), and (xii), as listed above, concerning written utilization review protocols, the identification of underutilization and overutilization of services, and the availability of information on quality and outcome measures as needed to facilitate beneficiary comparisons and choices among M+C plans.

b. Performance Measurement and Reporting. Section 422.152(c) elaborates on paragraph (b)(1) by requiring that the organization: (1) measure and report its performance to HCFA using measures required by HCFA, and (2) for M+C coordinated care plans, achieve any minimum performance levels that may be established locally, regionally, or nationally by HCFA. The first requirement is based directly on the requirement under section 1852(e)(2)(A)(i) of the Act concerning outcome measurement and reporting. Thus, it applies both to M+C coordinated care plans and network MSA plans (as well as to M+C non-network MSA plans and PFFS plans, as discussed below in section II.D.2.d of the preamble). The second requirement enables HCFA to evaluate a plan's ability to meet the objectives of sections 1852(e)(2)(A)(x) and (xi) of the Act concerning quality assessment and improvement. It also reflects HCFA's responsibility to require that the services we purchase meet minimum quality standards. (We note that although the requirements of sections 1852(e)(2)(A)(x) and (xi) of the Act apply to M+C network MSA plans as well as to M+C coordinated care plans, we are not requiring in this interim final rule that M+C network MSA plans achieve minimum performance levels. In keeping with the demonstration status of the M+C MSA plans, we intend to evaluate the performance of these plans in the context of the evaluation provisions of section 1851(b)(4)(B) of the Act.)

Health plan performance measurement and reporting is in its early stages. Consensus regarding what aspects of plan performance can and should be measured, how this information should be reported, how it should be audited, and which measures are collectible for which types of organizations, is only now being developed. HCFA, large private purchasers, managed care organizations, and others have made important progress in defining and measuring health plan performance. This regulation must move us toward enhancing health plan accountability while leaving flexibility for the specific reporting and performance requirements to progress as we learn more about performance measurement. We want to be able to respond rapidly to new developments in the state of the art of quality measurement and improving performance levels.

We do not intend to adopt a ''one size fits all'' approach that assumes that reporting under all types of M+C plans will be possible in the same manner for all measures. We will balance our efforts to increase uniformity to facilitate consumer comparison of plans with sensitivity to the different organizational structures of plans and their different abilities to affect provider behavior.

In general, an M+C organization should not be held accountable for improving services that it does not promise to provide under a plan, nor for reporting information to which it does not reasonably have access under a plan. At the same time, an organization should be held accountable for improving plan performance with respect to the benefits provides under the M+C program and all applicable M+C standards, and for having the information needed to maintain and improve the quality of the services it delivers or arranges for. Organizations should be expected to improve their capacity to collect and analyze information about the delivery of M+C benefits, consistent with changes that are occurring in the health plan market place. We believe that Congress intended us to take the actions that any prudent purchaser would take to hold M+C organizations accountable for the benefits they promise to provide under a plan.

For these reasons, we are not specifying the particular measures for which reporting will be required or the minimum performance levels that M+C coordinated care plans will be expected to achieve. Instead, the regulation clarifies the general clinical and nonclinical areas to be addressed by the performance reporting, such as effectiveness of care, use of services, and access to services. The performance measures to be reported and the minimum performance standards that the M+C plan or plans offered by an organization will be required to meet will be addresses on an organization and plan-specific basis, as described below.

Section 422.152(c)(1) establishes that standard performance measures may be specified in data collection and reporting instruments required by HCFA. For example, as mentioned earlier, HCFA has already begun requiring reporting of standardized quality measurement data through instruments such as HEDIS © 3.0, as well as reporting of standardized consumer satisfaction data through the Consumer Assessment of Health Plans Study (CAHPS). We expect that in contract year 1999, the standard performance measures for M+C organizations will include most HEDIS measures and a member survey, with the possibility of additional measures. (Where data on particular measures are not reasonably available with respect to a given plan, organizations can report ''not available''. HCFA will work with M+C organizations to identify those measures for which data are and are not reasonably available for a given plan.) To the extent that we do include HEDIS measures, we will use the HEDIS measurement specifications. Before the beginning of the next contract year, we will decide on the measures on which reporting will be required for contract year 1999 and will notify organizations of those measures through the contracting process.

We expect to develop a core set of measures on which reporting will be required under all plans. We also expect to identify additional reporting requirements to reflect the plan's characteristics (such as supplemental benefits, type of delivery system) and past performance.

In adopting minimum performance requirements for coordinated care plans, we intend to ensure that the targets are achievable, meaningful, and equitable. We intend to move toward minimum uniform national performance standards

based on what plans across the nation are able to achieve.

We expect to start with standards that are adjusted to reflect performance in the plan's region and the individual plan's or organization's historical performance (or performance in Medicare fee-for-service where the plan has no history). Performance requirements will be established only for measures for which there are sufficient historical data available to establish regional standards based on actual performance of a number of plans. (We will therefore require reporting on measures for which performance standards have not been established.) Other criteria will also guide the selection of measures for which minimum performance levels will be established, including their significance for the health of the enrolled population under a plan and the likelihood that they fairly reflect the organization's performance.

Because the process of identifying achievable, meaningful and equitable minimum performance levels will require a significant amount of data collection and analysis, we expect that it will be several years before a full complement of minimum performance levels can be established. At this point, it is uncertain whether any minimum performance levels will be established for the 1999 contract year. We will identify minimum performance levels on a measure by measure basis, after evaluating baseline data and the distribution of organization performance and considering potential opportunities for improvement. The process of identifying minimum performance levels will evolve as new methods of performance measurement develop.

HCFA is committed to public involvement in the selection of measurement topics. HCFA will also work collaboratively with organizations involved with quality and performance standards and measurements, including performance measurement experts, health plans, public and private purchasers and beneficiary representatives in the selection of specific measures and setting of minimum performance levels. As we develop minimum performance standards, we will consider how our goal of maintaining maximum consumer choice in the M+C program should affect our expectations concerning plan performance.

When we have identified minimum performance levels, we plan to establish them prospectively upon contract initiation and renewal, so that an organization will have the entire contract year in which to take action to meet them. By the end of the contract year, the organization must meet any identified minimum performance levels. In some cases, we believe that the next contract year will have already begun by the time HCFA learns whether the organization has met the minimum performance levels established for the previous year. Therefore, we specify that HCFA may decline to renew an organization's contract in the year that HCFA determines that the organization failed to meet the minimum performance levels, even if the failure itself was in the prior contract year.

c. Performance Improvement Projects. Section 422.152(d) establishes the requirements for performance improvement projects, beginning with the requirement that performance improvement projects focus on specified areas of clinical and nonclinical services. It also explains that HCFA will set M+C organizational and plan-specific requirements for the number and distribution of these projects among the required areas. In addition, it authorizes HCFA to direct an M+C organization to undertake specific performance improvement projects and participate in national and State-wide performance improvement projects. Section 422.152(d) reflects many of the provisions of section 1852(e)(2) of the statute, including for example the requirements for projects in areas such as high-volume and high-risk services and continuity and coordination of care (sections 1852(e)(2)(A)(ii) and (iii), respectively).

Section 422.152(d)(1) explains what is meant by a project. All projects must involve the measurement of performance, system interventions (including the establishment or alteration of practice parameters), improving performance, and systematic follow-up on the effect of the interventions.

Section 422.152(d)(2) requires that projects address the entire population to which the performance measure is relevant. Thus, once a topic has been selected, the organization must assure that its measurement and improvement efforts are at least plan-wide. (Note that we do not intend to prohibit an M+C organization from conducting performance improvement projects that would cut across plans.) We expect that, to the extent feasible, each project should reach all enrollees and providers in the plan network who are involved in the aspect of care or services to be studied. This does not mean that a project must involve review of the performance of each provider who furnishes the services that are the subject of the project, or that it must survey every affected enrollee. Sampling is acceptable if the organization can demonstrate that its samples are genuinely random. An organization could do so by showing, for example that:

- Each relevant provider and enrollee has a chance of being selected; no provider or enrollee is systematically excluded from the sampling.
- Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees.
- Providers and enrollees who were not included in the sample for the baseline measurement have the same chance for being selected for the follow-up measurement as providers and enrollees who were included in the baseline.

Section 422.152(d)(3) states that HCFA will establish M+C organizational and M+C plan-specific obligations for the number and distribution of projects among the required clinical and non-clinical areas. Sections 422.152(d)(4) and (5) then specify the minimum clinical and nonclinical focus areas that must be addressed through these projects. These minimum focus areas are:

- Clinical areas—prevention and care of acute and chronic conditions; high volume services and high risk services; continuity and coordination of care.
- Nonclinical areas: appeals, grievances, and other complaints; access and availability of services.

Note that these areas represent minimum requirements, and organizations are likely to carry out projects in other areas in order to meet their contractual performance improvement obligations. The length of the performance improvement cycle, that is, the period of time during which an organization must conduct a project that demonstrates improvement in each of the required focus areas, will be one of the contractual performance improvement obligations. Within each clinical and nonclinical focus area, an organization will have considerable freedom to select its own particular topics for measurement and improvement, so that it can initiate projects relating to aspects of care and services that are significant for its plan-specific population. Our goal is to achieve a balance between encouraging flexibility and innovation and ensuring that every organization conducts meaningful projects over a broad spectrum of care and services. As noted above, however, there may be instances where it is necessary for HCFA to direct the organization to address a specific

topic within a given focus area. Thus, § 422.152(d)(6)(i) provides that, in addition to requiring that an organization initiate its own performance improvement projects, HCFA may direct an organization to conduct particular performance improvement projects that are specific to the organization. We believe this could be necessary, for example, when an organization demonstrates a significant weakness in a particular performance area, but the area is not addressed in the organization's own performance improvement projects. Similarly, § 422.152(d)(6)(ii) provides that HCFA may require an organization to participate in national or statewide performance improvement projects. These performance improvement projects would focus on aspects of care that we believe are of high priority, and would be designed by HCFA (or possibly by other entities, such as the external quality review organizations affiliated with Medicaid managed care organizations).

In general, we believe that when an organization initiates a project, the clinical or nonclinical issue selected for study should affect a substantial portion of the plan's M+C enrollees (or a specified subpopulation of enrollees) and have a potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which less frequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes; however, the prevalence of a condition or volume of services involved should be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization—for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, the project should be focused clearly on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone. This is not to say that an organization may not make efforts to address overutilization, but only that such efforts may not meet the requirements of § 422.152, unless the primary objective is to improve outcomes. Thus, it would be acceptable for a project to focus on patterns of overutilization that present a clear threat to health or functional status, for example, a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of demonstrable improvement is a central criterion in the evaluation of projects, the projects should necessarily address areas in which meaningful improvement can be effected through system interventions by the organization. Thus, organizations should focus on areas in which there is significant variation in practice and resulting outcomes within a plan, or in which performance as a whole falls below acceptable benchmarks or norms.

Organizations are encouraged to undertake complex projects or innovative projects that have a high risk of failure but that offer potential for making a significant difference in the health or functional status of enrollees. We recommend that M+C organizations look to the independent quality review and improvement organizations with which they have agreements (see the discussion below about the external review requirements of § 422.154) for assistance in designing and executing performance improvement projects.

Section 422.152(d)(7) requires that an organization assess performance for each project using one or more quality indicators, that are objective, clearly defined, and based on current clinical knowledge or health services research. In accordance with the emphasis section 1852(e)(2)(A)(i) places on outcomes, the regulation requires that the quality indicators measure outcomes such as changes in health status, functional status, and enrollee satisfaction, or measure valid proxies of these outcomes. We recognize that relatively few existing standardized performance measures actually address outcomes. For example, of the 16 effectiveness measures in HEDIS 3.0, only one (health of seniors) is truly outcome-based. Even when outcome measures are available, their utility as quality indicators for projects may be limited if the outcomes are dictated largely by factors outside the organization's control.

Therefore, we do not require that quality indicators be limited to outcome measures. Process measures are acceptable so long as the plan can show that they are valid proxies, that is, there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. An M+C organization may furnish its own similar evidence of association between a process and an outcome, as long as this association is not contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process/outcome linkage is limited. At a minimum, an organization should be able to demonstrate that there is a consensus among relevant practitioners as to the importance of a given process.

While we consider enrollee satisfaction an important aspect of care, improvement in satisfaction may not be the sole demonstrable outcome of a project in any clinical focus areas. Some improvement in health or functional status must also be measured. (Note that this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may be an acceptable indicator.) For projects in the nonclinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. However, there may be some nonclinical projects for which enrollee satisfaction indicators alone are sufficient.

Section 422.152(d)(8) requires that performance assessment be based on systematic, ongoing collection and analysis of valid and reliable data. Data will most commonly be derived from administrative data generated by an organization's health information system or from review of medical records. (In assessing nonclinical services, other sources such as enrollee or provider surveys may be appropriate.) When data are derived from the health information system, their reliability is obviously a function of the general reliability of the system. When data are derived from direct review of medical records or other primary source documents, steps must be taken to assure that the data are uniformly extracted and recorded. Appropriately qualified personnel must be used; this will vary with the nature of the data being collected and the degree of professional judgment required. We expect there to be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data are collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

Section 422.152(d)(9) requires that interventions achieve improvement that is significant and sustained over time. In general, we will judge improvement to be significant when a benchmark level of performance is achieved in the percentage of enrollees who exhibit a negative outcome defined by the indicator.

Again, specific acceptable performance measures will be defined for each M+C organization and M+C

plan. Currently, we are considering requiring a 10 percent reduction in negative outcomes as evidence of significant improvement. An organization would meet this requirement if, for example, its flu immunization rate under a plan is 80 percent in the baseline and increases to 82 percent, because the percentage of enrollees *not* immunized has dropped from 20 percent to 18 percent, a 10 percent reduction. A plan whose baseline rate was 60 percent would have to reach 64 percent (a reduction in nonimmunized enrollees from 40 percent to 36 percent).

We are considering requiring a 10 percent reduction in adverse outcomes as evidence of significant improvement for several reasons. First, the use of a constant percentage reflects the likelihood that change is harder to achieve when an organization's baseline performance is already superior. Thus, under a plan with an 80 percent immunization rate, we would expect a 2 percentage point improvement, while under a plan with a 60 percent rate, a 4 percentage point improvement would be expected. Second, the 10 percent level is consistent with results HCFA has observed in successful improvement projects sponsored by the agency. Finally, we believe that smaller improvements would generally be of little clinical significance. We invite comment on the issue of whether § 422.152(d)(9) should be revised to provide for a 10 percent reduction in adverse outcomes.

Note that improvement in an *indicator* is not necessarily the same as improvement in the health or functional status of enrollees. For example, the ''health of seniors'' indicator under HEDIS 3.0 will track, over time, changes in the functional status of elderly enrollees. Each enrollee's functional status may remain stable or actually decline. However, an organization would demonstrate improvement on the indicator if it slowed the rate of decline, whether or not it actually improved enrollees' functional status. HCFA is considering judging improvement to be sustained under a plan if it can be demonstrated through continued measurement that performance gains have endured for at least one year.

We recognize that many organizations still have limited experience in conducting well-designed performance improvement projects, and that any given project may take some time to produce measurable improvement. Therefore, we intend to permit a gradual phase-in of the number of focus areas for which improvement must be demonstrated consistent with the individual circumstances of an M+C organization.

Section 422.152(d)(10) concludes the performance improvement requirements by providing explicitly that an organization must report the status and results of each project to HCFA upon request. This requirement is necessary to implement the reporting requirements embodied in sections 1852(e)(2)(A)(vi) and (xii) and 1851(d)(4)(D) and (d)(7), which call for HCFA to make available to M+C eligible individuals information comparing M+C plan options, including information on quality and performance.

d. Requirements for M+C Private Fee-for-Service and Non-Network MSA Plans. In enacting the quality assurance provisions of the BBA, Congress recognized that not all of the quality assessment and performance improvement activities that are appropriate for a plan with a defined provider network would be appropriate for an M+C non-network MSA plan or an M+C private fee-for-service plan. (Section 1852(e)(2)(C) defines a non-network MSA plan as an MSA plan that does not provide any of the covered benefits through a defined set of providers under contract to the organization or under arrangements made by the organization, and we have incorporated this provision into § 422.4(a)(2)(ii).) As a result, section 1852(e)(2)(B) establishes different required elements of a quality assessment and performance improvement program depending on the type of plan involved. Specifically, the Act exempts M+C non-network MSA and PFFS plans from the requirements of paragraphs (e)(2)(A)(vii) through (xii) of section 1852, which include the utilization review requirements discussed above as well as the explicit requirement to take action to improve quality and assess the effectiveness of such action through systematic follow-up. However, the statute continues to require that organizations offering these types of plans stress outcomes, provide for the data collection, analysis, and reporting necessary to measure outcomes, and monitor and ensure the quality of care they provide.

Consistent with the statute, the specific requirements to achieve minimum performance levels and undertake performance improvement projects will not apply to M+C non-network MSA and PFFS plans. Both requirements are derived primarily from the statutory requirements from which these types of plans have been exempted (that is, sections 1852(e)(2)(A)(x) and (xi). Instead, we have established separate requirements that apply for these types of plans under § 422.152(e). These requirements parallel the requirements for other types of plans to the extent permitted under the statute. For example, § 422.152(e)(1) requires that under these plans, an organization must measure its performance, using standard measures established or adopted by HCFA. These measures will focus on the prevention and care of acute and chronic conditions, high-volume and high-risk services, and enrollee satisfaction. We invite comment on whether additional areas for standard measures should be added to § 422.152(e)(1). Section 422.152(e)(2) requires evaluation of the continuity and coordination of care that enrollees receive. Together, the requirements under § 422.152(e)(1) and (2) reflect the requirements of paragraphs (e)(2)(A)(i), (ii), (iii), and (v) of section 1852.

Sections 1852(e)(2)(B)(ii) and (iii) specify that if an M+C non-network MSA or PFFS plan has written protocols for utilization review, those protocols must be based on current standards of medical practice, and have mechanisms to evaluate utilization services and inform providers and enrollees of the results of such evaluation. These requirements are incorporated into § 422.152(e)(3).

e. *Requirements for All Plans: Health Information.* In order to support the measurement of performance levels and the conduct of its performance improvement projects, if applicable, all plans must maintain a health information system that collects, analyzes, integrates, and reports data. This requirement is covered at § 422.152(f). Although an encounter data system may often be the most efficient means of meeting the requirements of this standard, the plan may use any methods or procedures for the collection of quality data, so long as it can demonstrate that its system achieves the objectives of the requirement.

The strategy of relying on performance measurement and performance standards to assess and improve quality is heavily dependent on the validity of the data collected and reported by plans. Therefore, § 422.152(f)(1)(ii) requires that an organization ensure that the information received from its providers is reliable and complete. If the organization receives individual encounter data directly from providers, it must have a system for comparing reported data to a sample of medical records, to verify the accuracy and timeliness of reporting or transmission. The objective is to assure that, to the extent feasible, there is a

one-to-one correspondence between items included in an organization's summary data and specific services entered in medical records or equivalent source documents. (That is, no reported service was not performed, and no service performed was not reported.) If the organization receives aggregate information, instead of individual patient encounter reporting, from any provider, under a plan the organization must approve the provider's own system for collecting, recording, aggregating, and reporting the data, and must assure that the provider has its own mechanisms for validation. Identified deficiencies in reported data should be addressed through provider education or other corrective action. The organization's process for recredentialing or recontracting with practitioners and providers should specify the actions to be taken in the event of ongoing failure by a contractor to meet the organization's health information standards.

In addition to requiring that the information collected be accurate and complete, § 422.152(f)(1)(iii) requires that the organization make all information collected available to HCFA. This requirement reflects section 1852(e)(2)(A)(vi), which recognizes that HCFA cannot adequately monitor and ensure the quality of health care services without access to appropriate information. For example, access to this information will allow HCFA to validate the accuracy and completeness of the information and to evaluate performance improvement projects. Note that although HCFA may disclose whether an organization has met its requirements for performance improvement, we will not make public the results of an organization's performance improvement projects, as these results may involve enrollee-specific information.

f. *Program Review.* Section 422.152(f)(2) requires that for each plan an organization have a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the quality assessment and performance improvement program strategy. The evaluation should assess both the progress in implementing the strategy and the extent to which the strategy is in fact promoting the development of an effective quality assessment and performance improvement program. It should consider whether quality-related activities in the organization's workplan are being completed on a timely basis or whether commitment of additional resources is necessary. The evaluation should include recommendations for needed changes in program strategy or administration. These recommendations should be forwarded to and considered by the policymaking body of the organization. These requirements reflect the evaluation provisions of section 1852(e)(2)(A)(iv).

4. External Review (§ 422.154)

Section 1852(e)(3) requires, subject to the exceptions discussed below, that each M+C organization, 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 chapter 42, which establishes review responsibilities for utilization and quality control Peer Review Organizations (PROs). This requirement appears in § 422.154(a).

PROs are physician-sponsored or physician-access organizations that review services ordered or furnished by other practitioners in the same professional field for the purpose of determining whether such services are or were reasonable or medically necessary, and whether the quality of such services meets professionally recognized standards of health care. Because PROs generally are already accomplished at the activities the statute requires of review organizations, HCFA will approve as review organizations the PROs and PRO-like entities who are currently under contract with HCFA to perform the functions of part 466. The current PRO contract will expire on March 31, 1999. The entities awarded the next contract, known as the Sixth Scope of Work, will be approved to serve as review organizations as of April 1, 1999.

An important element of both the current and next contract is a strategy to continuously improve quality of care and strengthen the ability of health care organizations and practitioners to assess and improve their own performance. Under this strategy, known as the Health Care Quality Improvement Program, part 466 contractors use statistical information to examine medical processes and outcomes of health care and provide feedback to providers so that this information can be used to benchmark progress toward improved practice and outcomes.

HCFA will establish guidelines for the agreements between M+C organizations and review organizations modeled on the guidelines found in part 466. The guidelines will specify that an M+C organization must allocate adequate space for the review organization to carry out its review (during the period of the review); and that the organization must provide enrollee care data and other pertinent data to the review organization on a timely basis as needed to facilitate making its determinations. These requirements appear in § 422.154(b)(1).

With respect to M+C non-network MSA and PFFS plans, for which utilization review is not a requirement, section 1852(e)(3)(A) of the statute exempts organizations from the requirement that there be an agreement with a review organization. Section 1852(e)(3)(B) also provides an exemption for review organization activities with respect to accredited plans that HCFA determines would be duplicative of activities conducted as part of the accreditation process. In the case of review of quality complaints, this exemption does not apply, however, and the requirement for investigation by the review organization would apply even with respect to an accredited plan. This exemption appears in § 422.154(b)(2). While the statute only mandates that the Secretary exempt accredited plans from the duplicative review by review organizations, we believe that the same logic extends to review activities that would be duplicative of HCFA monitoring review. Thus, pursuant to our general authority under section 1856(b)(1) to establish standards under Part C, we are providing in § 422.154(b)(2) that M+C organizations are also exempt from review by a review organization that would be duplicative of HCFA monitoring review.

Under section 1852(e)(3)(C), HCFA may waive the requirement that an M+C organization have an agreement with a review organization if HCFA determines that an organization has consistently maintained an excellent record of quality assessment and performance improvement and compliance with the other requirements of this part. As discussed in detail above, § 422.152 establishes requirements for a plan's quality assessment and performance improvement (QAPI) program. After the rule is effective, and HCFA has had the opportunity to assess QAPI implementation, we will be in a position to establish waiver criteria, which we intend to promulgate through notice and comment rulemaking.

5. Deemed Compliance Based on Accreditation (§§ 422.156 Through 422.158)

a. *Compliance Deemed on the Basis of Accreditation (§ 422.156).* Section 1852(e)(4) gives HCFA the authority to deem that an M+C organization meets certain requirements if the M+C organization is accredited and

periodically reaccredited by a private organization under a process that HCFA has determined ensures that the M+C organization, as a condition of accreditation, meets standards that are no less stringent than the applicable HCFA requirements. We do not believe that HCFA could effectively determine whether a potentially unlimited number of small, regional accreditation organizations meet the standard in section 1852(e)(4). Section 422.156 accordingly limits the deeming provided for under section 1852(e)(4) to national accreditation organizations. National accreditation organizations are those that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status.

The process that HCFA will use to deem compliance with M+C requirements will mirror the process used for deeming compliance with fee-for-service requirements, because that process is equally applicable to the managed care setting. Therefore, many of the requirements of this section, as well as those in §§ 422.157 and 422.158, are essentially restatements of their fee-for-service equivalents in subpart A of part 488 of existing Medicare regulations.

Section 422.156(a) specifies the conditions under which an M+C organization may be deemed to meet the HCFA requirements permitted to be deemed under section 1852(e)(4). (These requirements are identified in the regulations at § 422.156(b).) The first condition is that the M+C organization be fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by HCFA. Only full accreditation offers HCFA adequate assurance that the M+C organization meets the applicable HCFA requirements. M+C organizations that are conditionally or provisionally accredited (or the equivalent thereof) by their accreditation organization do not meet all of their accreditation organization's requirements, and for this reason, will not be deemed to meet the HCFA requirements. The second condition is that the M+C organization be accredited using the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements. Given that certain accreditation organizations have multiple accreditation processes (for example, other product lines aside from their Medicare product line), this requirement is necessary to ensure that only M+C organizations with the appropriate accreditation are deemed to meet HCFA requirements.

Section 422.156(b) specifies the requirements that may be deemed. In accordance with the statute, these include the quality assessment and performance improvement requirements of § 422.152, and the requirements of § 422.118 related to confidentiality and accuracy of enrollee records. An M+C organization accredited by an approved accreditation organization may be deemed to meet any or all of these requirements, depending on the specific requirements for which its accreditation organization's request for approval was granted.

Given the complexity and breadth of the benefits and services offered under the M+C program, we believe that we should analyze the standards applied by accreditation organizations on a standard-by-standard basis. In the past, in the context of original fee-for-service Medicare, we have taken an ''all or nothing'' approach in approving accreditation organizations. If an organization was approved, it was approved for purposes of all requirements, and all requirements were accordingly deemed. Since section 1852(e)(4) refers to deeming of ''the requirements involved,'' however, we intend under this authority to determine on a standard-by-standard basis whether an accreditation organization applies and enforces requirements no less stringent than those in part 422 with respect to the standard at issue. We will determine the scope of the accreditation organization's approval (and thus the extent to which M+C organizations accredited by the organization are deemed to meet HCFA requirements) based on a comparison of the accreditation organization's standards, and its procedures for assessing compliance, with the deemable HCFA requirements and our own decision-making standards.

As mentioned above, the requirements that may be deemed are the quality assessment and performance improvement requirements of § 422.152, and the confidentiality and accuracy of enrollee records requirements of § 422.118. We will approve an accreditation organization only for those requirements for which it applies and enforces standards that are as least as stringent as the HCFA requirements. For instance, § 422.152(e) requires that an M+C organization conduct performance improvement projects that achieve significant and sustained improvement. An accreditation organization will not be approved for this requirement unless we determine that, as a condition of accreditation, the accreditation organization's requirements concerning the conduct of performance improvement projects are as rigorous as the HCFA requirements, with a similar emphasis on outcomes. We will make such determinations on the basis of the application materials submitted by accreditation organizations seeking HCFA approval in accordance with § 422.158. We would also do surveys to validate the accreditation organization's enforcement on a standard-by-standard basis.

Section 422.156(c) establishes when deemed status is effective. Deemed status is effective on the later of the following dates: the date on which the accreditation organization is approved by HCFA, or the date that the M+C organization is accredited by the accreditation organization.

Section 422.156(d) establishes the obligations of deemed M+C organizations. An M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to HCFA a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements.) These two activities are part of HCFA's ongoing oversight strategy for ensuring that the accreditation organization applies and enforces its accreditation standards in a manner comparable to HCFA's.

Section 422.156(e) addresses removal of deemed status. HCFA will remove part or all of an M+C organization's deemed status if: (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; or (3) the M+C fails to meet the requirements of paragraph (d) of this section.

The final paragraph, § 422.156(f), explains that 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 the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We expect the accreditation organization to have a system in place for enforcing compliance with its standards, perhaps sanctions for motivating correction of deficiencies, but HCFA cannot delegate to the accreditation organization the authority to impose the intermediate

sanctions established by section 1857(g) or termination of the M+C contract.

b. *Accreditation organizations (§ 422.157).* This section of the regulation discusses three conditions for HCFA approval of an accreditation organization. HCFA may approve an accreditation organization if the organization applies and enforces standards for M+C organizations that are at least as stringent as Medicare requirements (as discussed above); the organization complies with the application and reapplication procedures set forth in § 422.158, ''Procedures for approval of accreditation as a basis for deeming compliance;'' and, the organization is not controlled by the managed care organizations it accredits, as defined at 42 CFR 413.17. Control exists if the accredited organizations have the power, directly or indirectly, to significantly influence or direct the activities or policies of the accreditation organization. We have included this requirement to preclude any conflict of interest that should compromise the integrity of the accreditation process.

Section 422.157(b) describes notice and comment procedures. Because the approval of an accreditation organization could have broad impact upon large numbers of organizations, providers, and consumers, we are providing notice and comment opportunities similar to those provided in the fee-for-service arena. HCFA will publish a proposed notice in the Federal Register whenever it contemplates approving an accreditation organization's application for approval. The proposed notice will specify the basis for granting approval; describe 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 accreditation; and provide opportunity for public comment. HCFA will publish a final notice in the Federal Register whenever it grants an accreditation organization's request for approval. Publication of the final notice will occur after HCFA has reviewed the public comments received in response to the proposed notice. The final notice will specify the effective date of the approval, and the term of approval, which will not exceed 6 years.

Section 422.157(c) establishes ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the requirement at § 422.157(c)(4) that an accreditation organization notify HCFA in writing within 3 days of identifying, with respect to an accredited M+C organization, a deficiency that poses immediate jeopardy to the M+C organization's enrollees or to the general public. Although the existing counterpart for this requirement under original Medicare (§ 488.4(b)(3)(vii)) allows an accreditation organization 10 days to provide this notice, we believe that a 3-day time period will better enable HCFA to take any necessary action to protect the health and safety of enrollees or the general public in a situation that poses immediate jeopardy. (Note that we also intend to address this issue in our planned comprehensive revision of the deeming requirements under original fee-for-service Medicare.)

Section 422.157(d) establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

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 HCFA imposes new requirements or changes its survey process; an accreditation organization proposes to adopt new standards or changes in its survey process; or the term of an accreditation organization's approval expires.

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 indicate (1) 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; or (2) indicate any disparity at all on standards that constitute immediate jeopardy to patient health and safety if unmet. Our beneficiary-centered approach to managed care oversight dictates zero tolerance of accreditation organization failures to identify noncompliance that expose beneficiaries to such serious risks. At the conclusion of a validation review, HCFA also identifies any accreditation programs for which validation survey results indicate, irrespective of the rate of disparity, that 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. Accreditation programs identified as noncompliant through validation review may be subject to withdrawal of HCFA approval.

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.

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

HCFA may withdraw its approval of an accreditation organization at any time if we determine that deeming based on accreditation no longer guarantees that the M+C organization meets the Medicare requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health; or the accreditation organization has failed to meet its obligations under §§ 422.156, 422.157, 422.158.

The final provision of § 422.157(d) addresses reconsideration. 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.

c. *Application and reapplication procedures for accreditation organizations (§ 422.158).* As mentioned, the process that HCFA will use to deem compliance with M+C requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. This section of the regulation is modeled on § 488.4, ''Application and reapplication procedures for accreditation organizations.'' One requirement that appears in § 422.158 does not appear in § 488.4 is the requirement that an

accreditation organization applying for approval of deeming authority submit the name and address of each person with an ownership or control interest in the accreditation organization. Such information will be used to determine whether the accreditation organization is controlled by the organizations it accredits, for the purposes of § 422.157. The remaining requirements of this section, which pertain to other required information and materials, the mechanics of the approval process, and the reconsideration of an adverse determination, are essentially restatements of the requirements of § 488.4.

E. Relationships With Providers

Subpart E focuses on requirements for relationships between M+C organizations and health care professionals with whom they contract or enter agreements to provide services to Medicare beneficiaries enrolled in an M+C plan. These requirements encourage communication, coordination, and cooperation between organizations and health care professionals on plan rules and policies. This subpart also includes other new provider protections enacted as part of the BBA; incorporates provisions affecting health professionals that are consistent with the recommendations contained in the Consumer Bill of Rights and Responsibilities, as recommended by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, the model act adopted by the National Association of Insurance Commissioners, credentialing standards of nationally accepted accrediting bodies, and QISMC standards; and incorporates policies already applicable to provider and plan relationships included in the current part 417 or other policy issuances. In February 1998, an executive order was issued directing the Secretary to comply to the extent possible through administrative activities with the standards contained within the Consumer Bill of Rights presented to the President in November 1997. Many of the issues were addressed in the BBA and implementation of the regulations will expand compliance with the directive.

1. Participation Procedures (§ 422.202)(a))

Section 1852(j)(1) requires an M+C organization that offers benefits under an M+C plan through agreements with physicians to establish reasonable procedures relating to their participation under the plan. This is a new federal requirement for Medicare contracting managed care organizations. Current rules in part 417 do not mandate that HMOs/CMPs adopt provider participation rules. However, some Medicare contractors have adopted provider participation policies in response to state laws or plan policies.

We are interpreting this provision to apply to all M+C organizations that operate M+C plans providing benefits through a limited network of contracting health care professionals or groups of health care professionals, that is, all types of M+C coordinated care plans, such as HMOs, PPOs, etc., as well as network M+C MSA plans. In the case of M+C private fee-for-service plans and non-network M+C MSA plans, there are no limits on the number of health professionals who may provide services covered under the M+C plan, as long as they accept the plan's terms and conditions for payment. These plans in essence operate on an ''any willing provider'' approach to which the procedures in section 1852(j)(1) would not be relevant. Since any provider has the right to participate, rules requiring a notice of adverse participation decisions, and appeals from such decisions could have no applicability. It also would not be feasible to provide the notices required under section 1852(j)(1) and § 422.202(a) (discussed below) to the virtually unlimited number of providers who would be entitled to provide services to a M+C private fee-for-service or non-network M+C MSA plan enrollees.

The statutory requirements in section 1852(j)(1) focus on three procedural aspects—ensuring that providers are aware of the plan participation rules; requiring written notice when participation decisions are adverse; and affording the provider an opportunity to appeal adverse plan participation decisions. The statute specifies that these procedures apply to plan relationships with physicians. In reviewing the model act of the National Association of Insurance Commissioners (NAIC), QISMC standards, and many state laws and regulations, we found that these procedural protections generally have been applied to all health care professionals who are responsible for delivering services to beneficiaries of the plan, not just physicians. Since Medicare-payments can be made to practitioners other than physicians and since M+C organizations may furnish services utilizing a range of licensed health care professionals, we believe it is appropriate to apply these requirements to all health care professionals if coverage for their services is provided under the M+C plan. For purposes of § 422.202 and § 422.204, these include, but are not limited to, a physician, podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, speech-language pathologist, audiologist, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, and certified nurse-midwife and licensed certified social worker. Thus, under our authority under section 1856(b)(1) to establish standards for M+C organizations, § 422.202 requires that all professionals as listed above should be provided with rules of participation, written notices of participation decisions and an appeal process.

With regard to types of procedures that are subject to disclosure, written notification and appeal requirements, we are adopting a broad definition of procedures that might affect participation in the plan or network. In § 422.202 we specify that procedural requirements should include any rules that affect the process of direct delivery of services by a health professional to a Medicare beneficiary. The examples include terms of payment, utilization review, quality improvement programs, credentialing, data reporting, confidentiality, guidelines or criteria for furnishing services, and other rules related to administrative policy. All of these procedures affect how a health care professional would participate in a plan and should therefore be divulged up front prior to a health care professional's agreement to participate in the plan. In addition, we believe that full disclosure in advance, to potential participating health care professionals, of the broad range of procedures relating to participation should reduce subsequent challenges or appeals. While the disclosure requirement in § 422.202(a)(1) does not apply directly to M+C private fee-for-service plans, as discussed below, M+C organizations offering such plans will be required to make the information described in § 422.202(a)(1) available to providers treating enrollees of the plan.

Section 1852(j) requires the provision of written notice of the participation rules. We are requiring in § 422.202 that any material changes in rules must be provided in writing in advance of implementation. Such advance communication would enable health care professionals to evaluate their continued participation prior to instituting a formal appeal process regarding any rules they believe are adverse. This benefits M+C organizations and providers in allowing the health care professional to judge what is adverse as this can vary among

individual health care professionals; what is adverse to one physician or health care professional may not be adverse to another.

2. Consultation (§ 422.202(b))

Consistent with section 1852(j)(2), § 422.202(b) requires an M+C organization to consult with physicians or relevant health care professionals who have entered into participation agreements/contracts with the organization regarding the organization's medical policy, quality and medical management procedures. Pursuant to our authority in section 1856(b)(1) to establish standards under the M+C program, in addition to requiring consultation on any aspect of clinical policy, we have included three specific standards relating to the development of practice guidelines—(1) practice guidelines and utilization management guidelines must be based on reasonable medical evidence or consensus of relevant practitioners, developed in consultation with participating practitioners, and reviewed and updated periodically; (2) the guidelines must be communicated to practitioners and, as appropriate, enrollees; and (3) decision making in utilization management, enrollee education, interpretation of covered benefits, and other areas to which the guidelines are applicable must be consistent with the guidelines. These three standards are taken from QISMC discussed in section II.D. of this preamble. These national standards also are consistent with the NAIC model act and language adopted for state laws regarding managed care. We believe these standards ensure that practitioners are fully consulted in all aspects of the use of practice guidelines from development to application.

3. Treatment of Subcontracted Networks (§ 422.202 (c))

In today's business environment, managed care organizations delegate not only the provision of services to subcontracted networks, but also a variety of policy making and implementation responsibilities. Each health care professional is an integral part of the organization's health care delivery system, whether he contracts directly with the organization or through an intermediary entity, such as an Independent Practice Association (IPA). Therefore, under our authority in section 1856(b)(1) to establish M+C standards, in § 422.202(c) we require provider protections not only for direct contracting physicians and health care professionals but also for all subcontracted arrangements. Extension of the BBA provisions to subcontracts means that providers within subnetworks (e.g. an IPA) receive the rules of participation, written notices, and have an opportunity to appeal. Thus, health care professionals within the subcontracted groups should be included in the procedures established for participation appeals and in the formulation of medical policy for the organization. In cases where subnetworks maintain most of the medical records for the Medicare beneficiaries they serve, it is essential that the formulation of policy includes all of the resources that contribute to fair and equitable treatment for beneficiaries. We also believe that subnetworks should have the ability to grieve or appeal decisions for the providers within their subnetworks.

4. Provider Credentialing and Provider Rights (§ 422.204)

Section 422.204(a), ''Basic Requirements,'' states that the M+C organization must have a system for credentialing physicians and other health care professionals. The M+C organization must ensure that providers meet applicable State and Federal requirements. 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. Also, 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. An M+C organization may not employ or contract with providers excluded from participation in Medicare. M+C organizations, at a minimum, should check the OIG website at http://www.dhhs.gov/progorg/oig for the listing of excluded providers and entities. These requirements are promulgated pursuant to our authority under section 1856(b)(1) to establish M+C standards by regulation, and are based on (1) the requirement in section 1852(a)(1) of the Act that Medicare covered services be furnished through Medicare qualified providers, (2) existing requirements in § 417.416, and (3) detailed standards developed under QISMC, discussed in section D. above.

Section 422.204(b), ''Discrimination Prohibited,'' prohibits M+C organizations from discriminating with respect to provider participation, provider reimbursement, or provider indemnification to any provider acting within the scope of his license or certification under applicable State law, solely on the basis of such license or certification. These requirements are based on section 1852(b)(2). This does not prohibit plans from including providers only to the extent necessary to meet the needs of the plan's enrollees, ensure quality and control costs, and does not prohibit an organization from reimbursing different specialty providers differing fees for their services. It is however, the responsibility of the organization to adopt policies related to participation, reimbursement, and indemnification based on reasonable criteria. Organizations may want to consider such measures as health outcomes, satisfaction surveys, market saturation of the provider type or other legitimate reasons.

Under § 422.204(c), ''Denial, suspension, or termination of a contract,'' organizations offering coordinated care or network MSA plans are required to provide information on their plan participation criteria and an appeals process for participation decisions, including decisions involving denial, suspension or termination of contracts. We have incorporated the timeframes for contract termination notification between the M+C organization and its providers contained within the NAIC model act. As discussed in section C. above, we have incorporated similar timeframes for notice to enrollees about changes in the provider network, including changes that result from a termination covered under § 422.204(c).

The notice and appeals requirements in this part are based on the requirement in section 1852(j)(1)(C), requiring a process for appealing adverse participation decisions, and, as noted above, on the NAIC model act, and our authority under section 1856(b)(1) to establish standards under Part C.

5. Interference With Health Care Professionals' Advice to Enrollees Prohibited (§ 422.206)

Section 422.206 (a) incorporates the requirements set forth in section 1852(j)(3)(A). This section prohibits an M+C organization from interfering with the advice of a health care professional to an enrollee who is his or her patient. Thus the health professional may act within his or her scope of practice in advising the enrollee about their health status, all relevant medical or treatment options available regardless of whether care or treatment is provided under the plan. For purposes of § 422.206, the term health care professional includes those listed in section 1852(j)(3)(D) of the Act. Pursuant to our authority in section 1852(b)(1) to establish standards

under the M+C program, § 422.206(a) includes standards from the Consumer Bill of Rights that further delineate the types and mode of communication between patients and health care providers regarding health care treatment options within which interference is prohibited. While the scope of this section governs communication regarding care or treatment advice, we recognize that patients seek advice from physicians regarding insurance coverage choices as well as treatment option choices. Physicians can disclose their participation in M+C organizations, however, we are concerned about any inappropriate steerage based on knowledge of a beneficiary's health status or the physician's financial interest. Program instructions will be issued as HCFA continues to clarify policy in the area of provider marketing and the role of physicians and other health care professionals in disseminating M+C information to beneficiaries.

6. Conscience Protection (§ 422.206)

Section 422.206(b) incorporates the requirements of section 1852(j)(3)(B). The regulations state that the prohibition against interference with the content of advice a health care provider gives to enrollees regarding medical treatment should not be construed as requiring counseling by a professional or a referral to a service by that professional, if there is an objection based on moral or religious grounds, and the M+C organization fulfills certain notification requirements to prospective and current enrollees. The regulation incorporates the notification process and time frames included in the law and clarifies that the plan must also notify HCFA at the time of application and within 10 days of submitting its ACR proposal. With respect to current enrollees, the organization is eligible for the exception to the rule in § 422.206(a)(1) 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 provided in advance.

7. Physician Incentive Plans (§§ 422.208 and 422.210)

Consistent with section 1852(j)(4), regulations at §§ 422.208 and 422.210 outline the limitations on the operation of physician incentive plans. The provisions in this section are the same as those previously included in § 417.479 with some reduction in the amount of data that must be disclosed by the organization. HCFA has determined that the capitated data is no longer required because other sources of data, such as encounter data required by the Act and the National Data Reporting Requirements (NDRR) are available. The provisions are consistent with the provisions under section 1852(j)(4) which prohibit specific payments as a disincentive to provide services to an individual enrollee and which place limits on the transfer of substantial financial risk for referral services to physicians or physician groups contracting with the M+C organization. The provisions in these sections apply to all coordinated care and network MSA plans. M+C private fee-for-service plans are prohibited from having a physician incentive plan because they may not place their providers at financial risk. The physician incentive plans regulations require that M+C organizations conduct customer satisfaction surveys of both enrollees and disenrollees if any physician or physician group in an M+C organization's network is placed at substantial risk for referral services as defined in § 422.208. (Please note that there are at least two other uses of the term ''substantial financial risk'' contained in legislation or regulation. Specifically, section 216 of the Health Insurance Portability and Accountability Act of 1996 addressing safe harbors from the anti-kickback statute and the determination of substantial financial risk related to PSOs (63 FR 18124, April 14, 1998)) M+C organizations may satisfy their requirement for enrollee surveys either by their mandated inclusion in HCFA's national administration of the Consumer Assessments of Health Plans Study (CAHPS) or, if the organization is excluded from CAHPS due to not having contracted with us for at least one year, by conducting their own surveys.

8. Limitation on Provider Indemnification (§ 422.212)

Section 422.212 prohibits an M+C organization from having a provider, or group of providers, indemnify the organization against any liability arising from the organization's denial of medically necessary care. This prohibition is a very narrow exception for a civil action brought by, or on behalf of, an enrollee where the damage is due to a determination by the M+C organization to deny medically necessary care. The regulation includes the statutory language from section 1852(j)(5) without elaboration.

9. Special Rules for Services Provided by Noncontract Providers (§ 422.214)

Consistent with section 1852(k) and section 4002(e), the regulations in § 422.214 require any health care provider that does not have a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan to accept as payment in full, the amounts that could have been collected if the beneficiary were enrolled in original Medicare. An M+C organization (other than an M+C MSA plan) satisfies its liability for Medicare covered services if the provider receives the total amount that would have been received if the beneficiary were enrolled in original Medicare. This amount equals the total of Medicare's payment (including any applicable deductible and coinsurance amounts) and any balance billing amount that would have been allowed by original Medicare. In the case of a participating physician or supplier, this amount would equal the Medicare fee schedule amount for the service. For a nonparticipating physician, this amount would equal 115 percent of the fee schedule amount for nonparticipating physicians (which is 95 percent of the fee schedule amount applicable to participating physicians). Of these amounts, the provider could collect from the M+C plan enrollee the cost sharing amount required under the M+C plan, as approved by HCFA under subpart G of part 422 and the remainder from the M+C organization.

Section 1866(a)(1)(O) places a limitation on what a provider of services (as defined in section 1861(u)) must accept as payment in full for services furnished to an M+C plan enrollee. The limit is applicable to those institutional type providers of service that do not have in effect a contract with the M+C organization establishing payment amounts for services furnished to an enrollee. The limitation equals the amount that would have been payable for a beneficiary enrolled in original Medicare less any payments that could be collected directly from Medicare representing graduate medical education (both direct and indirect).

10. Special Rules for M+C Private Fee-for-Service Plans

Special rules for M+C private fee-for-service plans are discussed in section IV of this preamble.

11. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

Section 422.220 prohibits an M+C organization offering an M+C plan from paying for services furnished to an

enrollee by a physician or other health care professional who has signed a private contract as described in section 1802(b). Section 4507 of the BBA specifies that nothing in title XVIII of the Act shall prohibit a physician or practitioner from privately contracting with a beneficiary to furnish services for which no claim shall be submitted to Medicare and no Medicare payment shall be made directly or indirectly or by any organization paid by Medicare where the physician or practitioner has opted out of Medicare for 2 years. Therefore, no payment may be made by an M+C organization for services furnished to Medicare enrollees by a physician or practitioner who opts out of Medicare where he or she has signed a private contract with an enrollee. There is one exception: the physician or practitioner who has opted out of Medicare may not ask a beneficiary who requires emergency or urgent care to sign a private contract. Therefore, where a physician or practitioner who has opted out of Medicare provides emergency or urgent care to an enrollee of an M+C organization, the organization must pay for the emergency or urgent care the enrollee required. For purposes of this provision, we consider ''urgent care'' to mean urgently needed services as defined in § 422.2.

12. M+C Plans and the Physician Referral Prohibition

One other item that relates to M+C organizations but is not contained within the part 422 regulations is the physician referral prohibition.

a. *The prepaid health plan exception:* Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (through an ownership interest or a compensation relationship), the physician may not refer Medicare patients to that entity for any of 11 designated health services, unless an exception applies. Under an exception in section 1877(b)(3), the prohibition on referrals does not apply to services furnished by certain prepaid health plans. To qualify for the exception, the services must be furnished by one of the following organizations to its enrollees:

- Organizations with a contract under section 1876, which authorizes us to enter into contracts with HMOs and competitive medical plans (CMPs) to furnish covered items and services on a risk-sharing or reasonable cost basis.
- Organizations with health care prepayment plans, as described in section 1833(a)(1)(A), which authorizes payment for Medicare Part B services to prepaid health plans on a reasonable cost basis.
- Organizations receiving payments on a prepaid basis under a demonstration project under section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972.
- Qualified health maintenance organizations, within the meaning of section 1310(d) of the Public Health Service Act.

As discussed in section I. of this preamble, beginning in January 1999, the new M+C program replaces the HMO and CMP risk contracting program provided for in section 1876.

In enacting the BBA, Congress failed to revise section 1877(b)(3) to except the services furnished under M+C coordinated care plans. We believe that this must have been an oversight, since Congress expressed no intention in the legislative history for the BBA of subjecting existing managed care entities to the self-referral law. In addition, subjecting physicians who have an ownership interest in an M+C organization offering a coordinated care plan in which the physicians participate, to the self-referral rules would be contradictory to Congress' purposes in establishing PSOs as coordinated care plans. PSOs are defined in the BBA provisions as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). These providers must share a substantial financial risk for the provision of items and services and have at least a majority financial interest in the entity. The self-referral provisions, on the other hand, are specifically designed to discourage physician ownership of entities that provide a broad range of services to Medicare beneficiaries.

b. *No risk of program or patient abuse exception—Coordinated Care Plans:* Although there is no statutory exception for services furnished under coordinated care plans, section 1877(b)(4) allows us to create an exception to the referral prohibition for a financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse. An example of program abuse is Medicare payment for unnecessary services. We will pay M+C organizations for enrollees in coordinated care plans on a capitated basis and beneficiaries will be responsible for premiums and cost sharing. Section 1854 limits HCFA's capitation amount and the total amount of beneficiary premiums and cost-sharing. Because M+C organizations offering coordinated care plans will not be paid for each additional service they provide, we believe that there is no risk of over-utilization of services. Because HCFA's capitation amount and the total amount of beneficiary premiums and cost sharing is limited, we believe that there is no risk of program or patient abuse.

Therefore, we are excluding from the physician referral prohibition services furnished under a coordinated care plan to an enrollee. This exception applies in all cases in which a physician has an ownership interest in or a compensation relationship with the M+C organization offering the coordinated care plan. We are making a change in the regulation text at § 411.355(c)(5).

c. *No risk of program or patient abuse exception—M+C MSA Plans:* M+C organizations offering an M+C MSA plan are paid a fixed capitation amount for beneficiaries enrolled in the plan, and section 1853(a) limits HCFA's capitation amount and section 1859(a)(3)(A) limits the amount that M+C organizations under M+C MSA plans will pay entities for furnishing covered services. Section 1859(a)(3)(B) limits the annual deductible amount. However, the Act does not similarly limit the amount that a beneficiary will have to pay as premiums and costsharing; that is, there is no limit on beneficiary balance billing by the entities that furnish health care services. *See* section IV. below. Thus, although there is no risk of program abuse, there is a risk of patient abuse. Therefore, we are not excluding from the physician referral prohibition services furnished under an M+C MSA.

d. *No risk of program or patient abuse exception—Private fee-for-service plans:* Section 1853(a) also limits HCFA's capitation amount to be paid to M+C organizations under private fee-for-service-plans. Because there will not be excessive payments by the Medicare program, there is no risk of program abuse. However, section 1859(b)(2)(A) provides that the plans will pay an individual or entity furnishing services on a fee-for-service basis. Since beneficiaries are responsible for coinsurance amounts, copayments, and balance billing amounts under private fee-for-service plans (*see* section IV. of this preamble), beneficiaries are subject to added out-of-pocket liability if physicians providing services under a fee-for-service plan order additional unneeded services in order to obtain additional fee-for-service payments from the M+C organization offering the private fee-for-service plan. Thus,

although there is no risk of program abuse in this case, excessive Medicare payment, there is a risk of patient abuse. Therefore, we are not excluding from the physician referral prohibition services furnished under a private fee-for-service plan.

F. Payments to M+C Organizations

1. General Provisions (§ 422.250)

Subpart F of part 422 sets forth rules that govern Medicare payment to M+C organizations, including the methodology used to calculate M+C capitation rates. These rules also apply for 1998 under section 1876 risk contracts.

Payments and Adjustments: We provide in § 422.250(a)(1) that, with the exception of payments under M+C MSA plans and payments for ESRD enrollees in all other plans, which we discuss below, we will pay M+C organizations for each enrollee in an M+C plan they offer, a monthly payment that is equal to 1/12th of the county-wide (or, in the case of ESRD enrollees, 1/12th of the State rate) ''capitation rate'' under § 422.252 that applies for the county in which the enrollee lives, adjusted by demographic factors applicable to that enrollee. Effective January 1, 2000, however, section 1853(a)(3)(C) directs us to implement a risk adjustment methodology that accounts for variation in per capita cost based on health status and demographic factors. Implementation of health status risk adjusters has implications for M+C plan data submissions, and we discuss this issue further below.

In addition to health status and demographic risk adjustments, we make an adjustment, under § 422.250(a)(2)(i)(A), to the payment rate for M+C enrollees with end-stage renal disease (ESRD). Under § 422.250(a)(2)(i)(B), we make an adjustment that is the equivalent to a 50 cent reduction for each renal dialysis treatment that we will use to help pay for the ESRD network program in the same manner as other reductions are used in original Medicare. Finally, under § 422.250(b), we provide for making retroactive adjustments to the aggregate monthly payment to an M+C organization to reflect any difference between the actual number of enrollees and the number upon which we had based the organization's advance monthly payment.

Under § 422.250(a)(2)(ii) for M+C MSA plan enrollees, we make a monthly payment to the M+C organization as described above less the amount (if any) identified in § 422.262(c)(1)(ii) to be deposited in the M+C MSA. In addition, we deposit in the M+C MSA the lump sum amounts (if any) determined in accordance with § 422.262(c). See section III. below for a more complete discussion of payments under M+C MSA plans.

In § 422.250(a)(2)(iii), we provide for adjustments to be made to payments under RFB plans (which are limited to members of a religious and fraternal benefit plan) to ensure that the payment level is appropriate for the actuarial characteristics and experience of [RFB plan] enrollees.

Payment Areas: In § 422.250(c)(1), we reflect the general rule, under section 1853(d) of the Act, that the M+C payment area is a county or equivalent area specified by HCFA. Under § 422.250(c)(2), in the case of beneficiaries with ESRD, the payment area is the State or equivalent area we specify. Additionally, in a significant change to payment area policy from the section 1876 program, section 1853(d)(3) permits Governors of States to request that we approve alternative geographic areas for payment rates. These alternatives are either a single State-wide M+C payment area or 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:

- All portions of each single metropolitan statistical area within the State.
- All portions of each primary metropolitan statistical area within each consolidated metropolitan statistical area within the State.
- A consolidation of noncontiguous counties.

Section 1853(d)(3) directs us to approve a Governor's request; however, this section of the Act also directs us to subject these requests to a budget neutrality requirement, and any payment for alternative geographic areas cannot exceed the aggregate payments for that State absent the adjustment. Additionally, the Governor's request must be submitted to us no later than February 1 of the year preceding the contract year. This provision is implemented in § 422.250(e).

2. Annual Capitation Rates (§ 422.252)

Among the more significant payment changes in section 1853 is the incremental separation of capitated Medicare payments from local fee-for-service rates. Previously, Medicare had paid risk contractors according to the Adjusted Average Per Capita Cost (AAPCC) payment methodology. The AAPCC was based on Medicare fee-for-service expenditures by county and was used to pay risk contractors through December 31, 1997. These fee-for-service expenditures were adjusted for demographic factors (that is, age; sex; institutional, welfare, and employment status).

The AAPCC had been legitimately criticized for its wide range of payment rates among geographic regions—in some cases it varied by over 20 percent between adjacent counties. It was also criticized for its poor risk adjustment capabilities and inappropriate provision of graduate medical education funds to some Medicare risk plans. Moreover, the AAPCC was criticized for setting erratic annual payment updates, which often made it difficult for contracting health plans to engage in long-term business planning. The BBA introduces a new payment methodology that addresses these and other concerns, and we discuss them in detail below.

''Greater of'' Payment Rate: Since January 1, 1998, Medicare capitation rates paid to section 1876 risk contractors for each calendar year have been the greater of a blended capitation rate, a minimum amount rate, or a minimum percentage increase. This same methodology will apply to payments under M+C contracts.

- The blended capitation rate is a blend of the area-specific (local) rate and the national rate, with the latter adjusted for input prices. The blended capitation rate is then adjusted by a budget neutrality factor.
- The minimum amount rate will equal $367 per month per enrollee in 1998 for all areas in the 50 States and the District of Columbia. Outside the 50 States and the District of Columbia, the rate is not to exceed 150 percent of the 1997 AAPCC for those areas. The minimum amount rate will be adjusted each year using the update factors described below. (On an individual basis, our monthly payment may be more or less than the minimum amount due to the demographic or other risk factors applicable to that individual used to adjust the minimum amount rate.)
- The minimum percentage increase is 2 percent. The minimum percentage increase rate for 1998 is 102 percent of the 1997 AAPCC. Thereafter, it is 102 percent of the prior year's rate.

3. Calculation and Adjustment Factors (§ 422.254)

Blend of Area-Specific and National Percentages: The 1997 AAPCC capitation rates serve as the base for both the area-specific rates in the blend and the minimum percentage increase rates. Section 1853(c)(2) stipulates that the blended area-specific/national rate

(discussed further below) will be implemented over a 6 year transition period from 1998 through 2002 according to the following schedule:

- 90 percent area-specific/10 percent national in 1998
- 82 percent area-specific/18 percent national in 1999
- 74 percent area-specific/26 percent national in 2000
- 66 percent area-specific/34 percent national in 2001
- 58 percent area-specific/42 percent national in 2002
- 50 percent area-specific/50 percent national in 2003 and thereafter.

Section 1853(c)(6) also provides for a ''national per capita M+C growth percentage.'' Each year, from 1998 through 2002, this national growth percentage is applied to the national and local components of the blended rate and to the floor rate (discussed below). The national per capita growth percentage is HCFA's projection of per capita expenses, reduced by the following amounts established in section 1853(c)(6): 0.8 percentage points in 1998 and 0.5 percentage points each year from 1999 through 2002. After 2002, the reduction amount is zero. This provision is implemented in § 422.254(d).

As indicated above, the blended rates are adjusted by a budget neutrality factor. Section 1853(c)(5) provides for a ''budget neutrality'' adjustment to the blended capitation rate under § 422.252(a), designed to ensure that the aggregate amount paid under the M+C payment methodology equals the amount that would have been paid if payments were based entirely on area-specific rates (as they were under section 1876(a)). The statute requires that this budget neutrality adjustment apply only to the blended capitation rate under § 422.252(a), rather than to the final capitation rate under § 422.252. Since the capitation rate is based upon the *highest* of the blended capitation rate, the minimum payment, and the prior year's payment plus 2 percent, the budget neutrality adjustment cannot produce any further savings once the blended capitation rate is reduced to the point where it is lower than the other two amounts in every county. This is what happened for 1998 and 1999. For these years, the budget neutrality adjustment reduced the blended rate to the point where no county's payment rate is based upon the blended rate, since one of the two other rates is higher in every county. Yet, even with this reduction, the goal of the budget neutrality provision in section 1853(c)(5) was not met for 1998 and 1999. We are considering seeking a statutory change to address this problem.

Area-Specific Component of the Blended Capitation Rate: Above we discussed the relationship between area-specific and national rates and how they are intended to develop into a 50/50 balance by the year 2003. Here we discuss features of the area-specific (local) rate and, directly below, features of the national rate.

In 1998, the base for the area-specific rate is the 1997 AAPCC, adjusted for 20 percent of the indirect medical education/direct graduate medical education (GME) carve-out. This is a significant change to payment policy under section 1876 Medicare ''risk'' contracts. In accordance with section 1853(c)(3)(B), under § 422.254(e)(2), we will remove all graduate medical education payments in the base rate between 1998 and 2002 on the following schedule: 20 percent in 1998; 40 percent in 1999; 60 percent in 2000; 80 percent in 2001; and 100 percent in 2002 and thereafter. These GME funds will be removed from the area-specific portion of the blended rate. Since the national portion of the blend is computed based on the adjusted local rates, it also reflects removal of these GME funds. Teaching hospitals will be paid directly for the GME costs associated with Medicare managed care enrollees under § 412.322.

Additionally, pursuant to section 1853(c)(3)(C)(ii), in § 422.254(e)(3), to the extent we estimate that the 1997 per capita base rate reflects payments to State hospitals under section 1814(b)(3), we will make appropriate adjustments to the M+C payment rate. Payments are made to hospitals located in Maryland under this provision.

Finally, pursuant to section 1853(c)(3)(D), in § 422.254(e)(4), we provide that HCFA may substitute a rate for the 1997 capitation rate a rate that is more representative of the costs of the enrollees in the area if the 1997 rate varied by more than 20 percent from the 1996 rate.

National Component of the Blended Capitation Rate: The national component of the blended capitation rate has two major features: (1) the national standardized annual capitation rate; and (2) the national input-price-adjusted capitation rate.

The national standardized annual capitation rate is a weighted average of all area-specific rates adjusted for risk factor weights used to calculate payments as though all eligible individuals were members of an M+C plan. The calculation for the national standardized annual capitation rate is described at § 422.254(f).

The input-price-adjusted annual national capitation rate is adjusted for geographic variation in the prices of goods and services used to produce medical services and is the sum of the products of three amounts:

- The national standardized annual capitation rate for the year, which consists of the weighted average of all area-specific capitation rates.
- The proportion of the rate that is attributable to each type of service.
- An index that reflects (for that year and that type of service) the relative input price of services in the area, as compared to the national average input price for these services.

The input-price-adjusted annual national capitation rate is described in § 422.254(g).

4. Adjustments to Capitation Rates and Aggregate Payments (§ 422.256)

Beginning with 1999 payment rates, we will adjust all area-specific and national capitation rates (and beginning with the 2000 payment rates, the minimum amount rate) for the previous year to reflect any differences between the projected national per capita growth percentages and the current estimates of those percentages.

We will also adjust for national coverage determinations (NCD) that were significant cost as defined in § 422.109 and defined above. An NCD is a national policy statement regarding the coverage status of a specified service that we make under administrative authority and publish in the **Federal Register** as a notice of HCFA Ruling. (The term does not include coverage changes mandated by statute.)

If we determine that the cost of furnishing a service subject to an NCD is ''significant,'' we will adjust capitation rates for the next calendar year to take into account the cost of that service. Until the new capitation rates are in effect, the M+C organization would be paid through original Medicare for the provision of such services.

Risk Adjustment: Section 1853(a)(3) requires us to develop and submit to the Congress, by March 1, 1999, a report on a proposed method of risk adjustment of M+C payment rates. We are also required to implement a risk-adjustment methodology for payment periods beginning on or after January 1, 2000. We provide for such risk adjustment in § 422.256(d). Under the previous payment methodology, the AAPCC, we used a demographic risk adjuster that has been criticized as an inadequate predictor of health care costs.

Nonetheless, until the new risk adjustment methodology is implemented in 2000, we will be using the same demographic adjusters used under the AAPCC method to make demographic adjustments under § 422.256(c) to the capitation rate determined under § 422.252. Section 1853(a)(3)(C) specifically directs HCFA to implement health-status based risk adjusters, as well as ''other demographic factors.'' Section 1853(a)(3)(D) requires that, with the exception of enrollees in M+C RFB plans, the same risk adjustment methodology be used for all enrollees in M+C plans, regardless of plan type. The implementation of health-status based risk adjusters has major implications for M+C organizations' data requirements, as discussed directly below.

5. Encounter Data (§ 422.257)

Section 1853(a)(3)(B) addresses the collection of encounter data from M+C organizations needed to implement the risk adjustment methodology. The Act requires that the collection of inpatient hospital data for discharges beginning on or after July 1, 1997 and allows the collection of other data no earlier than July 1, 1998. The statutory language is tied to the creation of risk-adjusted payment rates, as defined at § 422.256(c) and (d) of this rule. Requirements concerning collection of encounter data apply to M+C organizations with respect to all their M+C plans, including and private fee-for-service plans.

There are two different ways encounter data are used for risk-adjustment purposes. To calculate payment rates, encounter data are necessary to tie payment to expected patient resource use using diagnosis codes. The initial risk-adjusted payment will be based on inpatient hospital encounter data. However, use of an inpatient-based system in the long run has two major weaknesses: (1) It provides M+C organizations with an incentive to hospitalize their enrollees in order to receive additional payment; and (2) a risk-adjustor system based only on inpatient hospital diagnosis codes will not allow more accurate payment for the chronically-ill-but-not-hospitalized. For both of these reasons, we have developed a more comprehensive risk-adjustment methodology that uses diagnosis data from physician services and hospital outpatient department encounters. In addition, physician services data include data from limited license practitioners, such as clinical psychologists and nurse midwives who provide services independently, but do not include nonprofessional services ordered by physicians as a result of the initial physician services furnished, such as laboratory services and durable medical equipment.

Encounter data are also necessary to ''recalibrate'' any risk-adjusted payment model. Recalibration is necessary to adjust the payment models for improved coding. For example, upcoding may occur if plans improve coding of beneficiary diagnoses and, as a result, the average use of resources for enrollees in a particular category may be less than when the relative payment rates were determined. When this happens, the average actual expenditures per enrollee for these diagnoses are less than the average expenditures used to assign the original payment weights. The result is overpayment for some diagnoses in the risk adjustment model. To account for possible coding changes, all risk adjustor payment model diagnosis weights would be recalculated, or ''recalibrated'' based on encounter data gathered after implementation of risk adjustment. A preferred method for full recalibration requires that all services provided to each M+C plan enrollee be priced and the total cost of care determined for each enrollee. This approach would require that organizations submit encounter data for all services provided to each enrollee. An alternative approach would require the organizations to submit to HCFA the cost of providing medical care for each Medicare enrollee, but organizations might oppose such a requirement as too intrusive.

While the purpose of collecting the encounter data will be to calculate risk-adjusted payments, there are a wide variety of other uses of whatever data we collect. Quality improvement targets can be identified using encounter data. Our ability to monitor the care received by M+C enrollees through targeted special studies (such as an examination of post-acute care utilization patterns) will be greatly enhanced by the availability of encounter data. Encounter data will also be useful for program integrity functions, both by providing additional utilization norms for original Medicare billing and by providing additional information regarding M+C organizations' behavior.

Timing of Encounter Data Collection: The first issue to address with regard to data collection is the ability of the organizations to generate the necessary data and to ensure accurate transmission. While some organizations will be able to transmit encounter data quickly and with little difficulty, others will be further behind in their internal information systems development. To the extent that organizations have capitated arrangements with their providers, they may not currently require encounter-type data from those providers. The ability to generate encounter data may well vary by type of service provided as well as by type of organization submitting the data. All organizations will have to conform to the HIPAA information system standards regarding encounter data formats by 24 months (36 months for small organizations) after the effective date of the final rule (currently estimated to be published in the fall of 1998), so the main issues with regard to the organizations should be transition issues rather than long run implementation issues.

HCFA has issued instructions delineating a specific timetable for M+C organizations to submit inpatient hospital data. M+C organizations will be required to select a fiscal intermediary designated by HCFA to transmit data.

Given any start date, comprehensive risk-adjusted payments will be made about 3 years after the year of the initial collection of outpatient hospital and physician encounter data. Similarly, recalibration of the risk-adjusted payments to reflect managed care practice patterns could occur about 3 years after the complete data are collected. In order to minimize the period for which payments are determined based on inpatient hospital data only, we will provide advance notice to M+C organizations to collect and submit physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and all other data HCFA deems necessary beginning no earlier than October 1, 2000.

Because M+C organization payments will depend on the data transmitted and because M+C organizations are the entities with which HCFA contracts, we will hold the M+C organization responsible for transmission of the data. If the M+C organization is held responsible, it follows that they should transmit the data directly, rather than monitoring the transmission by their providers. We will allow organizations to hire third party data transmitters, but the M+C organization will be responsible for the accuracy and completeness of the data transmitted.

Data Format: The format of the data we will require will be identical to the data we require of original Medicare providers of similar services, because pricing of the data using original Medicare's methods is necessary for recalibration. The data will be processed using designated HCFA contractors. Providers are familiar with the HCFA

1500 (or its electronic equivalent) and the electronic UB–92 (or other electronic equivalent) through their original Medicare billings. In addition, organizations will have mechanisms in place to receive UB–92 data from hospitals and send it to fiscal intermediaries by July 1, 1998, because of the requirements for submission of inpatient encounter data. It would clearly be beneficial to all parties to use the UB–92 and this transmission format for any other required data that is currently submitted on the UB–92 in original Medicare. There are no current organization-to-carrier links for data HCFA currently processes on the electronic version of the HCFA 1500. From the provider, contractor, and HCFA point of view, it is clear that use of the electronic version of the HCFA 1500 would minimize any data collection burden.

Data Accuracy: Audit of the data will be necessary to ensure accuracy; any audit efforts will include medical record review for a portion of the submitted data. Statistical analysis (for example, examination of hospitalization rates for various organizations and inquiry into outliers) will be combined with traditional audit methods in order to maximize our examination of the data while managing the amount of contractor resources used for audit.

6. Announcement of Annual Capitation Rates and Methodology Changes (§ 422.258)

Previously, under section 1876, we were required to announce Medicare risk contractor payment rates by the first week in September, no later than 45 days after publishing for comment our mid-July announcement of payment methodology changes. This schedule was designed to allow HMOs and CMPs time to consider the coming year's payment rates, decide about their continued participation in the Medicare program, calculate their Adjusted Community Rate (ACR) proposal, and, finally, afford us the time to approve or disapprove the ACR proposal prior to the January 1 contract effective date.

Under section 1853(b)(1), starting in 1998, we must announce rates by March 1 of the year prior to the year the rates apply. We must include in this announcement a description of the risk and other factors and explain the methodology in sufficient detail to enable M+C organizations to compute monthly adjusted capitation rates for individuals in each of their payment areas.

The March 1 announcement will ensure that subsequent events can occur to meet the November annual coordinated election period stipulated in section 1851(e)(3). As under prior law, 45 days prior to announcing payment rates on March 1, section 1853(b)(2) requires us to provide notice of changes in the methodology and assumptions used in the previous year.

7. Special Rules for Beneficiaries Enrolled in M+C MSA Plans (§ 422.262)

The BBA establishes special rules for beneficiaries enrolled in M+C MSA plans, and we discuss them in detail under section III. below.

8. Special Rules for Coverage That Begins or Ends During an Inpatient Hospital Stay (§ 422.264)

The BBA contains special payment rules for situations where an M+C enrollee's coverage begins or ends while the Medicare beneficiary is a hospital inpatient. Section 1853(g) provides that, where a beneficiary is receiving inpatient hospital services from a hospital covered under original Medicare's prospective payment system (PPS) or another M+C organization on the effective date his or her M+C election of a new M+C plan, payment for inpatient services (up until the date of discharge) would continue to be the responsibility of the original Medicare program or previous M+C organization. The M+C organization offering the newly elected M+C plan would not be responsible for inpatient hospital service payment until the date of discharge, and original Medicare or the previous M+C organization would pay the full amount for that beneficiary for that inpatient episode, even if it extends beyond the effective date of a beneficiary's M+C election.

In the case of a beneficiary's M+C plan election ending while he or she is a hospital inpatient, the M+C organization remains responsible for payment for inpatient hospital services furnished by a hospital after expiration of enrollment up until the date of discharge. Payment for these services would not be made under Medicare's PPS system, and the responsible M+C organization would not receive any payment from us for the hospitalized individual during the period the individual was not enrolled.

9. Special Rules for Hospice Care (§ 422.266)

Section 1853(h) of the BBA contains special provisions for Medicare beneficiaries who elect hospice care concurrent with their enrollment in an M+C organization. Specifically, an M+C organization must inform each Medicare enrollee eligible to elect hospice care under section 1812(d)(1) about Medicare hospice programs within the M+C plan's service area. If it is common practice to refer patients to hospice areas outside the service area, the organization must inform the M+C enrollee of that as well. This information must be provided to beneficiaries in a manner that objectively presents all available hospice providers, including a statement of any ownership interest held by the M+C organization or a related entity. If the M+C organization has an ownership or other financial interest in one or more of the available hospice providers, M+C plan enrollees cannot be required to use that hospice provider.

BBA payment provisions for hospice care state that our monthly payment to the M+C organization will be reduced to an amount equal to the adjusted excess amount in the M+C plan's approved ACR. Beyond the adjusted excess amount, we pay through original Medicare for hospice care furnished to the M+C plan enrollee. We also pay through original Medicare (to the M+C organization), for other Medicare-covered services furnished to the hospice patient.

Unless the individual disenrolls from the M+C plan, an M+C enrollee electing hospice continues his or her enrollment in the plan and is entitled to receive through the plan any benefits, other than those that are the responsibility of the Medicare hospice.

10. Source of Payment (§ 422.268)

As under the section 1876 risk program, we will determine which proportion of payments to M+C organizations comes from the Hospital Insurance Trust Fund (Part A) and which proportion of payments comes from the Supplementary Medical Insurance Trust Fund (Part B). We determine these proportions based on the actuarial value of total benefits under both parts.

G. Premiums and Cost-Sharing

Subpart G of part 422 details provisions found in section 1854 for the M+C program. In this subpart we discuss how limits on M+C plan enrollee premiums and other cost sharing are established through the ACR approval process. The ACR process is applicable to all M+C plans except M+C MSA plans. M+C MSA plans are not required to submit an ACR, but other information must be submitted for HCFA's review (see discussion below). We discuss limitations that the process imposes on other cost-sharing that M+C organizations may impose on Medicare enrollees for the M+C plan they elect.

Note that there are a number of terms pertinent to the following discussion, and they are defined in § 422.302 of this rule. ACR and APR are terms that were used under section 1876 risk program. Section 1854(b) discusses the definition of the terms relating to beneficiary premiums. The term additional revenues is discussed in detail in section 5 below.

As under the section 1876 risk program, the ACR process under the BBA serves three important purposes. First, HCFA examines an M+C organization's ACR proposal for each M+C plan to determine whether Medicare payments in excess of the amount the organization would charge commercially for Medicare-covered benefits are passed on to beneficiaries in the form of added additional benefits. Second, we review ACR proposals to determine whether the structure of premiums, deductibles, copayment, and coinsurance charged to beneficiaries are within the limits established by law as required under section 1854(f)(1)(A). Third, benefit package information is reviewed to determine whether the benefit package is in compliance with the principles contained in subpart C.

We have taken into account that the M+C program is a significant departure from the section 1876 risk contracting program it replaces. Therefore, we are allowing a special period during which organizations will be able to add benefits (at no additional cost to the M+C plan enrollee) or lower premiums or cost-sharing mid-year. We also are providing for the submission of ACRs on a date other than May 1 if a contract will begin on a date other than January 1. The transition rules for this period are found in § 422.300(b). This special period will end on December 31, 2001.

1. Rules Governing Premiums (§ 422.304)

This section of the regulation implements provisions of the BBA relating to premiums paid by (or behalf of) beneficiaries. Each Medicare enrollee must be afforded the opportunity to pay the M+C plan premium on a monthly basis and, as under the section 1876 risk program, pursuant to Section 1128B(b) of the Act, the M+C organization may not provide for cash or other financial rebate as an inducement for enrollment (or for any other reason).

As discussed in above, section 1852(a)(1) requires an M+C organization to include in its M+C plan all services covered under original Medicare (except hospice care) that are available to Medicare beneficiaries in the area in which services are covered under the M+C plan. In addition, additional benefits must be provided to all enrollees electing the M+C plan (see section 1854(f)(1)). Section 1852(a)(3) allows an M+C organization to add supplemental benefits to the M+C plan either at the M+C organization's discretion (with our approval) or at the enrollee's election. For these benefits offered through a coordinated care plan, section 1854(e) does not allow the M+C organization in total, for the year, to impose a total average cost to the beneficiary, with an actuarial value greater than the actuarial value of original Medicare's deductibles and coinsurance for items and services covered by original Medicare plus the actuarial value approved through the ACR process for supplemental services. For M+C PFFS and M+C MSA plans, see discussion below.

Section 1854(c) provides that M+C basic and supplemental beneficiary premiums and M+C MSA premiums may not vary among individuals enrolled in the plan. This means that all enrollees in a given M+C plan must be charged the same premium amount for basic benefits and for any supplemental benefits the M+C organization may choose to offer. In the case of coordinated care plans, this uniform premium counts toward an overall limit on the actuarial value of beneficiary liability in section 1854(e) (discussed further below). Thus, in the case of coordinated care plans, the actuarial value of any cost-sharing imposed under the plan would also be uniform, since a uniform premium would be subtracted from a uniform overall limit to determine the amount that can be charged in cost-sharing.

We believe that section 1854(c) reflects congressional intent that all beneficiaries enrolled under a particular M+C plan pay the same amount. While cost-sharing amounts are not expressly mentioned, in the case of coordinated care plans, there is a uniform limit on the actuarial value of cost-sharing. Accordingly, pursuant to our authority in section 1856(b)(1) to establish M+C standards, we are providing in § 422.304(b) that M+C organizations may not vary the level of copayments, coinsurance, or deductibles charged for basic benefits or supplemental benefits among individuals enrolled in an M+C plan.

2. Submission of Proposed Premiums and Related Information (§ 422.306)

Section 1854(a) requires each M+C organization to submit no later than May 1 information about the M+C plan the organization wants to offer in the subsequent year. As under the Medicare section 1876 risk program, except in the case of M+C MSA plans, such information includes a complete description of the services included in the M+C plan, ACR and service area information, premium amounts, and descriptions of enrollee cost sharing. For M+C MSA plans, organizations have to submit the MSA premium that is used to determine the MSA deposit. No ACRs are required for M+C MSA plans. Pursuant to our authority in section 1856(b)(1), we have added a new requirement that M+C organizations also submit information on amounts collected in the previous contract period for basic benefits. We have done this to assure Medicare enrollees are not being charged cost-sharing that exceeds the limits in section 1854(e)(see § 422.308).

Section 422.306(a) reflects the requirement in section 1854(a)(1) that the information in paragraphs (b), (c), and (d) of § 422.306 be submitted by May 1 of the year prior to the year for which the information is submitted. This information is needed timely in order for HCFA to comply with the requirement in subpart B that comparative information on M+C plans be provided to Medicare enrollees. As noted above, during the transition period prior to 2002 provided for in § 422.300(b), M+C organizations may be permitted, at HCFA's discretion, to submit applications and ACR information on a flow basis and as discussed in section K below, under § 422.504(d) contracts could begin on a date other than January 1. In such a case, benefit package and pricing structures must be approved before the contract can take effect. Beginning with the 2002 calendar year, however, anyone wishing to offer an M+C plan in that year *must* submit an ACR by May 1 of the previous year (May 1, 2001 in the case of 2002).

If the information submitted is not complete, accurate, or timely, HCFA has the authority to impose sanctions under subpart O or may choose not to renew the contract.

We will review and approve all information submitted except for any amounts submitted by M+C MSA plans and premiums submitted by M+C private fee-for-service plans. Premiums and cost sharing will be reviewed in accordance with the rules established in § 422.310. Benefits offered under the M+C plan will reviewed in accordance with the rules established in Subpart C.

3. Limits on Premiums and Cost-Sharing Amounts (§ 422.308)

The rules in this section set the limits on the amount an M+C organization may charge a Medicare enrollee of an M+C plan. Section 1854(b) specifies that

the premium that a beneficiary is charged under an M+C plan other than an M+C MSA plan is the M+C monthly basic premium, plus any M+C supplemental premium. In the case of an M+C MSA plan, the beneficiary is charged only any M+C supplemental premium that may apply. The limits of Medicare enrollee liability are:

- For M+C basic benefits (Medicare covered services and additional benefits) offered by coordinated care plans: 12 times the basic monthly premium, plus the actuarial value of plan cost-sharing (copayments, coinsurance, and deductibles) for the year, cannot exceed the actuarial value of original Medicare's deductibles and coinsurance for the year or, if less, the amount authorized to be charged in the ACR (see § 422.310).
- For M+C basic benefits (Medicare covered services and additional benefits) offered by M+C private fee-for-service plans: the actuarial value of plan cost sharing (copayments, coinsurance, and deductibles) for the year, cannot exceed the actuarial value of original Medicare's deductibles and coinsurance for the year or, if less, the amount authorized to be charged in the ACR (see § 422.310).
- For supplemental benefits offered by a coordinated care plan: 12 times the M+C monthly supplemental premium plus the actuarial value of plan cost sharing (copayments, coinsurance, and deductibles) cannot exceed the ACR for such benefit or, if less, the amount authorized to be charged in the ACR (see § 422.310).

It is possible for an M+C organization to have M+C plan enrollees that are entitled to Medicare Part B benefits only. Section 1876(k)(2) specifies that existing Part B enrollees under section 1876 risk contracts on December 31, 1998 may remain as enrollees of the organization in accordance with regulations under section 1856(b)(1) if the organization enters into an M+C contract on January 1, 1999. Pursuant to sections 1876(k)(2) and 1856(b)(1), this final rule provides for such continued Part B-only enrollment, and § 422.308 provides that the limit on enrollee charges is the same as the limit that applies to other enrollees, except that the limit is based only on the actuarial value of cost sharing paid under Part B of original Medicare.

Also pursuant to our authority in sections 1876(k)(2) and 1856(b)(1), in § 422.308(a)(3), we impose a limit on the liability of Part B-only enrollees for an M+C organization's coverage of services that would be covered by Medicare Part A if the enrollee had Part A coverage. Specifically, we provide that the premium and cost sharing charged for such coverage may not exceed the lesser of what Medicare would pay an M+C plan in capitation for the services, plus the actuarial value of Medicare Part A deductibles and coinsurance, or the ACR for such services.

The above-described limits on enrollee liability apply to enrollee costs incurred for services furnished by noncontracting providers as well as providers that contract with the M+C organization offering the M+C plan in which the beneficiary is enrolled. In the case of contracting providers, limits on enrollee liability would generally be delineated in the contract between the provider and the M+C organization. Also, in the case of most coordinated care plans (for example, HMOs), it could be assumed that most nonemergency services will be obtained through contract providers.

Thus, to the extent an M+C coordinated care plan provides for different cost sharing in the case of noncontracting providers, it is not difficult to estimate the percentage of services that will be obtained at that level of cost sharing, when making the overall projection of the actuarial value of the cost sharing structure. In the case of M+C private fee-for-service plans, it is less clear to what extent noncontracting providers will be used, and the information on actual cost sharing from the prior year will be particularly valuable in assessing the accuracy of actuarial projections by the M+C organization. We note that in all cases, beneficiary liability is limited to the cost sharing provided for under the plan in the case of noncontract provider services. While sections 1852(k) and 1866(a)(1)(O) require noncontracting providers to accept as payment in full the amounts that they would be required to accept under original Medicare, balance billing to the beneficiary may be permitted under original Medicare but it is not permitted under the M+C plan in question. The M+C organization must hold beneficiaries harmless against any such balance billing. *See* section IV. below for a discussion of this issue in connection with M+C private fee-for-service plans and section III in connection with M+C MSA plans.

4. Incorrect Collections of Premiums and Other Cost Sharing (§ 422.309)

This section contains procedures to be used in situations where an M+C organization collects more than the amount that is allowed to be charged to the Medicare enrollee. These procedures were developed using the rules previously applied under section 1876 and promulgated under our authority in section 1856(b)(1) to establish standards under Part C.

Section 1857(d) requires that at least ⅓ of the M+C organizations be audited for, among other things, data used in the submitted ACR and all charges to the M+C plan enrollee for benefits covered under the M+C plan. These audits may reveal that the M+C organization has been overcharging the M+C plan enrollees. Section 422.309 requires the M+C organization to refund these over collections through an adjustment to current and future premiums allowed to be charged across all M+C plan enrollees.

We note that in addition to the above requirements for refunding amounts incorrectly collected, an M+C organization that collects amounts in excess of those permitted is subject to intermediate sanctions and civil money penalties under subpart O. *See* section 422.752(a)(2) and discussion below in section II. O. of the preamble. Refunding amounts improperly collected, at a minimum, would be a prerequisite to the lifting of such sanctions.

5. ACR Approval Process (§ 422.310)

Section 1854 requires that an ACR proposal be submitted each year for each M+C coordinated care plan or M+C private fee-for-service plan, and that premiums be filed for MSA plans. Section 422.310 of this rule sets forth the rules M+C organizations must follow to determine the limits placed on an M+C plan's price structure (premiums, copayments, coinsurance, deductibles, etc.). Since this regulation was not published until after May 1, 1998, new requirements under this rule discussed below will apply to contract periods beginning on or after January 1, 2000. For contract periods beginning before January 1, 2000, M+C organizations shall use the rules promulgated in accordance with section 1876 for risk contractors to determine the limits placed on M+C plan's price structure.

Under the existing ACR process, a M+C organization must establish an initial rate for non-Medicare enrollees for each M+C plan offered. This rate is determined through a community rating method (defined in section 1308 of the Public Health Service Act) or an aggregate premium method. The initial rate is then modified by the relative difference in utilization characteristics of the Medicare population compared to the non-Medicare population included in the initial rate. Additional adjustments may be made with our agreement. Those M+C organizations that do not have a non-Medicare

population cannot establish an initial rate. These M+C organizations will be allowed to use an estimate of the ACR value for a service or services offered using generally accepted accounting principles. These estimated values will be treated as additional adjustments for our review.

The ACR computation places a limit on the beneficiary premiums and cost-sharing amounts of an M+C plan, and we will only approve the beneficiary premiums and cost-sharing amounts proposed by an M+C organization for a specific M+C plan if they do not exceed the ACR limits.

As noted above, § 422.310 contains new requirements for calculating ACRs that will require existing section 1876 contractors to change the methodology they have used to calculate their ACRs under section 1876. We recognize that section 1856(b)(2) provides that consistent with the requirements of Part C, standards established under Part C should be based on standards established under section 1876 to carry our analogous provisions of that section. The requirements in § 422.310 are based on, and fully consistent with, the existing section 1876 requirements in § 417.594. An M+C organization following the methodology set forth in § 422.310 would fully comply with the existing ACR provisions in § 417.594.

However, based upon our years of experience under the section 1876 program, we have determined that the language in § 417.594 permitted HMOs and CMPs to use methods for calculating their ACRs that produced ACRs that we do not believe accurately reflected the statutory standard implemented in that section. Indeed, the existing methodology has been criticized by the General Accounting Office and the Office of the Inspector General as inaccurate, and subject to modification by organizations. The existing methodology also did not provide for necessary adjustments (for example, based upon changes in utilization assumptions in anticipation of changes in cost sharing structures, or changes in Medicare coverage) that we provide for in § 422.310. Also, as discussed below, some of these changes accommodate the fact that some organizations do not maintain data used under the old methodology (service statistics) but do maintain data (cost data) used under the new methodology in § 422.310. Finally, the existing ACR form necessarily has to be changed to adapt to the new options under the M+C program.

For all of the above reasons and others discussed below, pursuant to our authority in section 1856(b)(1) to establish standards for M+C organizations, and consistent with the provision in section 1865(b)(2) that such standards be based on section 1876 standards, we have built on the existing ACR methodology in § 417.594 but refined this methodology in order to ensure the accuracy of ACRs under the M+C program.

Specifically, we have added the following new requirements to the provisions in § 417.594:

1. Revision of data requirements used to develop differences in utilization characteristics of the Medicare population from a relative service ratio to a relative cost ratio (for additional revenue, a relative excess revenue ratio) experienced in a prior period.

2. Separation of the administrative component into two parts—an administrative cost component and a component that reflects revenues collected in excess of costs.

3. Provision for an M+C organization to adjust for relative differences that the organization expects to encounter in the period covered by the ACR that were not reflected in the prior period. Below we discuss each in turn, including where the new process diverges from the former ACR methodology.

Revision of Data Requirements Used to Develop Differences in Utilization Characteristics of the Medicare Population from a Service Ratio to a Cost Ratio Experienced in a Prior Period: Currently, risk contracting plans (HMOs) under section 1876 of the Act use a relative volume/complexity (V/C) factor to modify commercial premiums for each health care component (e.g. inpatient hospital, physician) to account for differences in utilization characteristics between commercial members and Medicare members. The modified commercial premium is the ACR value for that health care component applicable to the Medicare enrollee.

Currently, HMOs are directed to develop the V/C factors using comparative service statistic ratios on a health care component basis. Service ratios require HMOs to supply a large amount of service statistics.

Risk contractors assert that they, as a rule, do not keep service statistics in the same manner, format, and/or detail needed to compute these ratios. Some HMOs have resorted to using statistics gathered from one commercial package to be compared to all Medicare enrollee statistics. Others have used estimations of service statistics (especially for those services not offered by the HMO in the past).

Managed care organizations keep detailed records on the cost of care included in the benefit packages sold. Since the cost of providing medical care is a function of both volume (number of services) and complexity (price of the service), M+C organizations could compare the direct cost of medical care (incurred in a previous period) between the organization's commercial and Medicare populations on an average per enrollee basis to account for differences in utilization characteristics of the respective populations. For those services not offered in the past, the M+C organization could use an estimate of the cost to establish an ACR value for the new service.

We believe this modification of data requirements will make the ACR more accurate, easier to process, and ultimately, easier to verify. Costs could be compared from year to year to establish the reasonableness of the data provided. In addition, cost data as reported could be compared to other required reports and the organization's financial statements. Later, during monitoring visits, costs could be compared to the organization's financial records.

This approach is justified in view of the expanded participation of different types of M+C plans authorized in the BBA. BBA provisions include organizations offering new types of M+C plans that may not have an enrolled commercial population and, without an enrolled commercial population, these organizations would be unable to complete the current ACR. Under the new method, these M+C organizations would be allowed to develop a cost estimate for the purpose of establishing an ACR value for the Medicare population.

Separation of Administrative Component into Two Components—an Administrative Cost Component and a Component that Reflects Revenues Collected in Excess of Costs: Currently, HMOs are directed to bundle that part of the commercial premium that represents any excess revenue over expenses with administration into one component. In § 422.302, we refer to the component of the premium that represents revenue in excess of costs incurred as ''additional revenues.'' Specifically, we define ''additional revenues'' to mean 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.) The combined component representing administrative and excess revenues was then converted to a Medicare value using the same method the HMO used to compute the amount for commercial enrollees. HMOs have consistently claimed they use a percentage method (For example, administration is calculated as a specific percentage of health care components). In effect, this increases the administration and additional revenues anywhere from 300 percent to 500 percent for Medicare. In addition, this bundling assumes that both administration and additional revenues are similar in nature and should be treated the same.

Under the new ACR, we are requiring M+C organizations to divide the administrative component into two parts and modify each part with a factor that is consistent with each part. We believe this will provide HCFA with data that is both more accurate and more useful.

Administrative costs will be included in the ACR computation in the same manner as they are incurred in commercial premiums. M+C organizations will be required to reveal projected amounts of additional revenues to HCFA for each population group (commercial and Medicare). M+C organizations would be required to justify larger additional revenues projected for the Medicare population in relation to their commercial population.

Construction of a Method for an Organization to Adjust for Relative Differences the Organization Expects to Encounter in the Period Covered by the ACR that Were not Reflected in the Prior Period: Section 1876 allowed for modification of the initial rate by a relative factor of services furnished in a prior period. Implementing regulations did not allow for any other modifications to the initial rate in establishing the ACR for a service or services, and we have since recognized that additional modifications to the initial rate may be necessary. For example, Medicare coverage may be increased from one year to the next. If the organization did not provide the service in the past and no additional modifications to the initial rate were allowed, the organization could not adjust for the new service in its ACR. Organizations also had no method for making adjustments to take into account projected changes in utilization patterns that would result from changes in cost sharing amounts. We have included a provision in this rule to allow for such changes.

M+C organizations will be allowed to further reduce the ACR values so that the ACR values equal the actuarial value of the charge structure of the M+C plan.

6. Requirement for Additional Benefits (§ 422.312)

If the ACR calculation for an M+C plan produces an excess amount (the difference between the average of the M+C per capita rates of payment (APR) and the ACR value (less the actuarial value of original Medicare's deductibles and coinsurance)) for Medicare covered services, the M+C organization is required to use that amount as follows:

- First, the M+C organization may elect to contribute part or all of the excess amount to a stabilization fund;
- Second, the M+C organization may use the remainder to fund additional services not covered by Medicare; and
- Third, the M+C organization must use any remainder to reduce the premium and/or cost sharing allowed for services covered by original Medicare.

A number of rules contained in this section were developed using the rules under section 1876, though certain changes to those rules were made to comply with new provisions in the BBA. For example, the rules for the stabilization fund under section 1876 were largely incorporated in this section. However, section 1854(f)(2) revised the time period and disposition of those funds at the end of that time period. We have incorporated these changes in § 422.312(c).

H. Provider-Sponsored Organizations

This interim final rule makes certain technical and conforming changes to existing subpart H of part 422. These changes are discussed in section II.R. of this preamble.

I. Organization Compliance With State Law and Preemption by Federal Law

1. State Licensure (§ 422.500)

Among the organizational and financial requirements for M+C organizations, section 1855 of the Act requires that an organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan. (An exception to the licensure requirement is made for PSOs, as provided for in part 422 subpart H.) Section 1855(b) specifies the level of risk that an organization assumes under an M+C contract (i.e., full risk for the M+C benefit package), and the extent to which the organization may insure against such risk or may pass off all or part of the risk to subcontracting providers. The requirements of the statute result in a two-pronged test of appropriate licensure, consisting of the licensure requirement itself and a scope of licensure requirement.

Licensure and Scope of Licensure: With regard to the licensure requirement, although the BBA uses the term ''licensure,'' we have interpreted the provision as requiring a license or some other type of certification (such as a certificate of authority) that represents permission granted by the appropriate State authority for the organization to operate within the State as a risk-bearing entity offering health insurance or health benefits. Having met the State licensure requirement, an organization must also show that the ability to offer an M+C plan of the type they wish to offer is within the scope of its State licensure or State authorization. For example, an organization that offers only a prepaid dental plan in a State could be licensed as a risk-bearing entity, but its licensure status may not permit the organization to offer a health benefits plan that includes a comprehensive range of services, as would be necessary under an M+C contract. Similarly, a State may require an organization that is a licensed HMO to obtain separate licensure as an indemnity insurer in order to offer an M+C point-of-service (POS) plan, on the basis that the HMO scope of licensure does not include the ability to offer what is considered an indemnity product. (A State's requirement that an organization have an indemnity license in order to offer a POS product is not superseded by the Federal preemption provisions discussed below.)

In some States, a Medicaid HMO may operate without a license from the department of insurance or other State agency that licenses organizations offering health benefits or health insurance in the commercial and Medicare markets. The Medicaid plans operate under the authority of the State Medicaid agency, which may be the agency establishing solvency standards for such organizations, as required by section 1903(m)(1)(A)(ii). The State authorization for these plans may be viewed as a limited scope licensure, enabling plans to operate as Medicaid contractors only, and not in other segments of the health insurance market.

To establish the licensure status of organizations, and in particular to determine compliance with scope of licensure requirements, we will require, as part of the application process for

new applicants, documentation that both the licensure and scope of licensure requirements are met. Organizations must provide verification from the appropriate State regulatory body authorized to license Medicare risk products demonstrating that the licensure status of the organization enables it to offer the M+C plan, or plans, it intends to offer. This would ensure that, in the case of an organization only authorized to offer a Medicaid plan, for example, solvency standards appropriate to an M+C product are met. In the case of non-commercially licensed entities, we are requiring that they obtain a special certification from the State that they meet appropriate solvency standards.

As noted in the BBA, ''The fact that an organization is licensed in accordance with paragraph [1855(a)](1) does not deem the organization to meet other requirements imposed under this part'' (1855(a)(3)). That is, while the State licensure requirement is imposed on all plans as a prerequisite for contracting as an M+C organization, licensure in and of itself does not guarantee that an organization will be able to obtain an M+C contract. The organization must meet other applicable requirements of this part in order for us to grant an M+C contract.

2. Federal Preemption of State Law (§ 422.502)

Section 1856(b)(3)(A) of the Act provides for a Federal preemption of State laws, regulations, and standards affecting any M+C standard if the State provisions are inconsistent with Federal standards (a preemption policy we refer to below as a general preemption). There is also a specific preemption of State laws (1856(b)(3)(B)) in three areas where Federal standards ''preempt the field''; that is, regardless of whether State laws are inconsistent or not, Federal standards preempt State law, regulations, and standards. The general and specific preemption of State law applies to ''Medicare benefits and Medicare beneficiaries,'' as stated in the conference report that accompanied the BBA. The BBA preemption provisions do not extend to non-Medicare enrollees or activities or non-Medicare ''lines of business'' of organizations that have M+C contracts.

Prior to the BBA, section 1876 of the Act (governing Medicare risk and cost contracts with HMOs and competitive medical plans) did not contain any specific preemption provisions. However, section 1876 requirements could preempt a State law or standard based on general constitutional Federal preemption principles, consistent with the provisions of Executive Order 12612 on Federalism. Under the guidelines of the Executive Order, section 1876 requirements did not preempt a State law or standard unless the law or standard was in direct conflict with the Federal law, or it prevented the organization from complying with the Federal law. Put another way, if Federal law permitted the HMO to do what State law required, there was no preemption. In practice, rarely, if ever, did Federal law preempt State laws affecting Medicare prepaid plans. For example, Medicare risk plans operating in States with mandated benefit laws were generally required to comply with such State laws. Compliance with the State mandated benefit law was not viewed as interfering with the ability of plans to function as Medicare risk contractors under Federal standards. (Because the BBA preemption applies only to M+C plans, this approach to preemption issues will continue to apply to cost contracts governed by section 1876 rules.)

General Preemption: The general preemption provision of the BBA will be applied in the same way that the Executive Order has been applied, in that State laws or standards will be preempted only when they are inconsistent with M+C standards, as clearly indicated in the statute. Because the BBA requires that PSOs operating under a waiver of the State licensure requirement must comply with State quality and consumer protection standards, it seems clear that the Congress expected States, in some cases, to have more rigorous or more comprehensive standards for quality and consumer protection which would enhance, rather than duplicate or be subsumed under, the M+C standards for quality and consumer protection. Thus, unless one of the specific preemptions discussed below applies, State laws or standards that are more strict than the M+C standards would not be preempted unless they prevented compliance with the M+C requirements. This is consistent with the BBA conference report language that notes that State laws apply if they provide ''consumer protections in addition to, or more stringent than'' the BBA. The BBA also provides that the quality and consumer protection standards with which PSOs must comply include only those requirements ''generally applicable to M+C organizations and plans in the State'' which are ''consistent with the standards'' of the BBA. That is, there are likely to be quality and consumer protection standards imposed by States that all M+C plans must comply with, and for which there is no Federal preemption.

Specific Preemption: Though the general preemption provision will be applied in the same way that the Executive Order has been applied, for the three areas in which the Congress provided for a specific preemption of State laws, the M+C standards supersede any State laws and standards. These three areas are:

- Benefit requirements:
- Requirements relating to inclusion or treatment of providers; and
- Coverage determinations (''including related appeals and grievance processes'').

We are adopting a narrow interpretation of the applicability of the three areas of specific preemption, which we believe is justified by the conference report language and the overall structure of the BBA in its delineation of the relative roles of the State and Federal governments. Under the BBA, States have exclusive authority (other than in the case of PSOs) to make the determination of whether organizations are eligible to enter into M+C contracts, while under section 1876 of the Act, it was the Federal Government that designated ''eligible organizations'' (HMOs under title XIII of the Public Health Service Act (a Federal designation) or competitive medical plans (also a Federal designation)). Under section 1876, the Federal Government also determined solvency standards for organizations, while under the BBA this becomes a State responsibility (other than for PSOs). The conference report (p. 638) also clarifies the intended scope of preemption in the three specific areas. The report indicates the conferees seek to put M+C on a par with ''original fee-for-service,'' where the ''Federal government alone set legislative requirements regarding reimbursement, covered providers, covered benefits and services, and mechanisms for resolving coverage disputes.'' The conferees wish to ''[extend] the same treatment to private M+C plans providing Medicare benefits to Medicare beneficiaries.''

Using the analogy of original Medicare, Federal law preempts State laws and standards in certain specific areas. Under original Medicare: States cannot specify what must be included as a Medicare benefit; States do not specify the conditions of participation of Medicare providers (though they license providers and practitioners and determine their scope of practice); States may not specify how a coverage determination is to be made with respect to whether or not the Medicare program covers a benefit; and a State

does not determine the type of appeal mechanism that is to be used to appeal a coverage decision made by a Medicare carrier or intermediary with respect to a Medicare benefit. For M+C plans, the specific preemption of State laws in the three areas would prevent, for example, the application of mandated benefits laws; ''any willing provider'' laws and other laws mandating the inclusion of specific types of providers or practitioners; or laws that supplant or duplicate the Medicare coverage determination and appeal process as it relates to coverage of benefits under the M+C contract. However, States may have various laws and requirements that could still apply to

- Benefits (for example, a plan could be required to have a toll free number to answer benefit questions),
- Providers and practitioners generally in the State (e.g., they must all be licensed by the State and comply with scope of practice laws), and
- Laws and standards which could apply to disputes between members and health plans, as discussed below.

Under our narrow construction of the specific preemptions, and consistent with our definition of the term ''benefits'' at § 422.2, the specific preemption of benefit laws does not extend to State laws and standards relating to cost sharing or other financial liability standards for enrollees of health plans, though we are inviting comments on our position, outlined below, that cost sharing should not fall under the benefits preemption, as well as comments on whether there are types of cost sharing that should or should not be included in the benefits preemption.

Thus, a State law prescribing limits on cost sharing generally, or limits on cost sharing that can be imposed for specific benefits, would not be preempted. If the benefit to which the State cost sharing limits apply is not a Medicare covered benefit, however, the limits on cost sharing would only apply if the M+C organization *chooses* to offer the benefit in question. Thus, to the extent that limits on cost sharing are linked to a benefit mandate, the cost sharing limits could be seen to be *indirectly* ''preempted'' in that the obligation to provide the benefit to which they apply is preempted. If the M+C organization chooses not to provide the benefit that would otherwise be mandated under a preempted benefit mandate, the cost sharing limits that apply to that benefit would never come into play. We note that while cost sharing limits are not specifically preempted under the benefits preemption in section 1856(b)(3)(B)(i) and § 422.402(b)(1), cost sharing limits are still subject to the general preemption in section 1856(b)(3)(A) and § 422.402(a). Thus, to the extent the cost sharing limit would be inconsistent with M+C provisions, it would be preempted. An example of State cost-sharing requirements being preempted because they are inconsistent with M+C provisions would be a State requirement that requires all insurers and health plans to pay 100 percent of the cost of a particular service (e.g., mammography screening or other preventive care). In the case of an M+C MSA plan, we would argue that the general preemption provision applies, because the State requirement is inconsistent with the basis structure of a high-deductible plan under which covered services are not payable under the plan until the deductible is met.

To address a specific question that has arisen, State laws requiring direct access to particular providers (either contracted by the M+C organization or not under contract), and State laws requiring, for example, a second opinion from non-contracted physicians, would be superseded by the benefit and provider participation preemptions (though M+C standards in these regulations dealing with access to particular providers may have an effect that is similar to that of State laws that are superseded). This is because these requirements in essence mandate the ''benefit'' of access to a particular provider's services even where the services of that provider would not otherwise be a covered benefit.

We are also adopting a narrow interpretation of the scope of preemption of coverage determinations. Coverage determinations are made initially by M+C organizations and may be appealed as provided for under subpart M of these regulations. Our view is that the types of decisions related to coverage included in this specific preemption are only those determinations that can be subject to the appeal process of subpart M. These are decisions about whether an item or service is covered under the M+C contract and the extent of financial liability beneficiaries have for the cost of covered services under their M+C plan. The Medicare appeal process applies to basic benefits, mandatory supplemental benefits, and optional supplemental benefits offered under an M+C contract. The specific preemption makes the Medicare appeal process the exclusive remedy for disputes over coverage determinations, displacing any State grievance or appeal process that might otherwise be available in such cases. However, the specific preemption does not preempt State remedies for issues other than coverage under the Medicare contract (i.e. tort claims or contract claims under State law are not preempted). The same claim or circumstance that gave rise to a Medicare appeal may have elements that are subject to State remedies that are not superseded. For example, an M+C organization's denial of care that a beneficiary believes to be covered care is subject to the Medicare appeals process, but under our interpretation of the scope of the specific preemption on coverage decisions, the matter may also be the subject of a tort case under State law if medical malpractice is alleged, or of a state contract law claim if an enrollee alleges that the M+C organization has obligated itself to provide a particular service under State law without regard to whether it is covered under its M+C contract.

We are seeking public comments on our interpretation of the applicability of the three areas of pre-emption specifically the exclusion of cost sharing and financial liability standards from the federal pre-emption and the exclusion of direct access to particular providers.

As noted above, where the BBA preempts State laws and standards, any Federal preemption based on the BBA applies only to the Medicare ''line(s) of business'' of an M+C organization (i.e., Medicare enrollees). As such, there would be no Federal preemption of State laws which are applicable to other enrollees of the organization. Additionally, there would be no Federal preemption of State laws which are applicable to arrangements outside the scope of the BBA, such as arrangements between employers and M+C plans for the provision of negotiated employer group benefits discussed at § 422.106 of these regulations. Neither the specific nor the general preemption would apply to any aspect of such arrangements.

3. Prohibition on State Premium Taxes (§ 422.404)

Section 1854(g) of the Act, introduced in the BBA, provides that ''No State may impose a premium tax or similar tax with respect to payments to M+C organizations under section 1853.'' Section 4002(b)(4) of the BBA makes the prohibition on premium taxes applicable to risk-sharing contracts operating under section 1876 effective the date of enactment of the BBA. This prohibition does not apply to enrollee premium payments made to M+C plans, which are authorized under section 1854.

The regulations provide clarification on the applicability of the prohibition of State premium taxes. The BBA does not

define the term ''State,'' but elsewhere in the Medicare statute (1861(x), referring to 210(h) of the Act), the term ''State'' is defined to include the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa. The regulations include this definition of State for purposes of the scope of the premium tax prohibition.

The BBA is also silent as to whether the prohibition of premium taxes includes county taxes or taxes by other governmental entities within a State. The Federal Employees Health Benefits Program (FEHBP) statute, on the other hand, has more specific language on the applicability of the exemption from premium taxes. The FEHBP statute specifically extends the prohibition to ''any political subdivision or other governmental authority'' of a State (5 U.S.C. 8909(f)(1)).

The BBA conference report does not provide any clarification on this issue. However, a July 31, 1997 summary of the provisions of the BBA prepared by the Senate Finance Committee (''Summary: Health and Welfare Provisions in the Balanced Budget Act of 1997''), stated that ''[t]he current law on federal preemption of state premium taxes or fees on Federal payments from the FEHBP to health plans will be extended to Federal payments to M+C plans and other health plans receiving capitated payments from the Medicare Trust Funds.'' Although the language of the BBA prohibition is not as specific as the FEHBP language, we are clarifying in these regulations that the prohibition does apply to any political subdivision or other governmental authority within a State. We believe such an interpretation is necessary because counties and other State authorities derive their powers from the State. Thus, any prohibition of State actions contained in a Federal statute should be interpreted as prohibitions on actions at any level of State government or any State or local governmental body within a State.

The BBA does not define the phrase ''premium tax or other similar tax,'' other than by reference to the applicability of such a tax to revenue received from the Federal Government for health plan enrollees. Relying again on the FEHBP statute, we have included a provision in the regulations (§ 422.404(b) that serves to clarify the scope of what constitutes a prohibited premium tax. The FEHBP statute expressly permits States to impose taxes on the profits arising from participation as an FEHBP plan, to the extent that the tax on profits, or other taxes or fees, are general business taxes. We have included a similar exception because such taxes are not taxes applied directly and exclusively to premium revenues, and therefore should not be prohibited under section 1854(g).

The BBA premium tax prohibition does not provide for any exception to the prohibition based on the purpose of the tax. For example, some States are using a broadly applicable premium tax to fund health care coverage for individual State residents who might otherwise be uninsured (e.g., financing a State high-risk pool), or to fund a State guaranty fund that could potentially benefit enrollees of an M+C plan in the event of insolvency. Although such premium taxes do provide a social good, and may yield a direct benefit to M+C organizations and their enrollees, there are no exceptions to the premium tax prohibition included in the BBA or in these regulations. By not having allowed any exceptions, we would note that, to the extent participation in a State guaranty fund is used as means of satisfying State (or Federal) requirements for protections in the event of insolvency, M+C organizations that would otherwise have participated in the guaranty fund by paying the premium tax are likely to be required to meet alternative insolvency requirements. An M+C organization may also choose to voluntarily pay premium taxes in order to participate in such a fund.

J. Subpart J of Part 422

Subpart J of part 422 is being reserved.

K. Contracts with M+C Organizations

1. Definitions (§ 422.500)

Section 422.500 of subpart K contains definitions germane to subpart K that address provisions pertaining to contracts with M+C organizations. These definitions, for the most part, have been imported from part 417 under our authority from section 1856(b)(2). The lone exception, *Party of Interest* has been clarified in paragraph (3) to include non-profit entities.

2. General Provisions (§ 422.501)

Section 1857(a) provides that the Secretary will not permit an organization to operate as an M+C organization unless it has entered into a contract with HCFA. The statute also provides that the contract may cover more than one M+C plan.

An applicant, however, must meet certain requirements before HCFA can consider entering into a contract with it. First, in accordance with section 1855(a)(1), the applicant must be licensed (or if the state does not license such entities, hold a certificate of authority/operation) as a risk-bearing entity in the State in which it wishes to operate as an M+C organization; section 1855(a)(2), however, allows for a waiver of this requirement for Federally-waivered PSOs under certain circumstances. Second, the applicant must meet the minimum enrollment requirements specified at section 1857(b). These requirements provide that the organization must have at least 5,000 (or 1,500 if it is a Federally-waivered PSO) individuals receiving health benefits from the organization or at least 1,500 (or 500 if it is a PSO) individuals receiving benefits in a rural area. Section 1857(b)(3) gives the Secretary the authority to waive the minimum enrollment requirements for the first 3 contract years.

Third, an M+C organization must demonstrate certain administrative and managerial capabilities that we believe are essential for HCFA to examine prior to agreeing to contract with any applicant as an M+C organization. For this reason, pursuant to section 1856(b)(2) which provides for the adoption of regulations implementing section 1876, we have adopted the administration and management requirements from §§ 417.120 and 417.124 and have applied them to M+C organizations. In addition, pursuant to our authority in section 1856(b)(1) to establish standards under Part C by regulation, we will require that all M+C organizations establish a plan for complying with all applicable Federal and State standards. The compliance plan must include written policies, procedures, and standards of conduct, the designation of a compliance officer accountable to senior management of the organization, provisions for internal monitoring, auditing, accountability, and an adhered to process for reporting violations of law by the organization or their subcontractors.

Further, pursuant to our authority in section 1856(b)(1) to establish standards for M+C organizations by regulation, we are in this rule establishing an additional condition for entering into an M+C contract. Under this rule, an entity that is accepting new enrollees under a section 1876 cost contract will be ineligible to enter into an M+C contract covering the area it serves under its cost contract. Our reason for establishing this rule is to eliminate the potential for an organization to encourage higher cost enrollees to enroll under its cost contract while healthy enrollees are enrolled in its risk-based M+C plan. This rule is consistent with our longstanding policy that entities not

have both a risk and cost contract under section 1876 in the same area.

Further, we provide at § 422.501(b) that in order to be eligible to contract as an M+C organization, an applicant organization that held a prior contract terminated by HCFA under § 422.510 within the past five years.

Section 1857(c)(5) authorizes the Secretary to enter into contracts with organizations without regard to provisions of law or regulations that the Secretary determines to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, we provide in § 422.501(c) that HCFA may enter into contracts under part 422 without regard to the Federal and Departmental acquisition regulations set forth in title 48 of the CFR.

Further, section 1857(d)(1) and (2) provide for the auditing of the financial records of at least one third of M+C organizations annually, and the inclusion of specified inspection and auditing rights in M+C contracts. We have incorporated these requirements in § 422.501(d). We likewise specify related requirements that enable HCFA to do so.

Since section 1857(a) allows that an M+C contract may cover more than one M+C plan, we have added paragraph (e), ''Severability of contracts,'' through our authority in section 1856(b)(1). The contract provides 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 would be deemed to be in place when such a request is made.

National Contracting

The BBA does not specifically define or otherwise address the issue of national contracting. While we are interested in national contracting, we have not specified it in the regulations and welcome comment on this concept. One option we are considering would allow an M+C applicant to request that HCFA enter into a national contract with the applicant if the applicant holds license as a risk-bearing entity in each state where it operates or has a waiver as provided in § 422.370. The applicant M+C organization would have the option of having a uniform premium and benefit plan across the country, with one service area and a national ACR proposal.

We are considering a different concept of a national agreement with national chain organizations. This concept would apply to those chain organizations that enter into separate contracts in multiple States. The agreement would allow for the chain organization to establish a uniform policy across all of its states as to marketing, quality assurance, utilization review, claims processing, etc. HCFA would have to approve the national policy procedures. HCFA would continue to contract separately with individual, albeit related, M+C organizations affiliated through common ownership or control. We would continue to monitor operational activities for each organization in each State, but having approved national policy, our review at the State and local level would be reduced.

3. Contract Provisions (§ 422.502)

Section 422.502 of this rule sets forth the provisions and related requirements for contracts between HCFA and M+C organizations. In general, Medicare beneficiaries may not elect to enroll in an M+C plan offered by an M+C organization, and no payment will be made to the M+C organization, unless the Secretary enters into a contract with the organization. The provisions that describe this relationship between the Secretary and the M+C organization are based on Part C of title XVIII of the Act and on Medicare contract requirements derived from subparts C and L of part 417.

The provisions of the Act as added by the BBA are generally silent with regard to the specific provisions that must be included in the contract between the M+C organization and HCFA. The Act does, however, specify at section 1857(a) that the contract must provide that the organization agrees to comply with the applicable requirements, standards, and terms and conditions of payment of Part C of title XVIII of the Act. In addition, section 1857(e) provides that the contract shall contain such other terms and conditions not inconsistent with Part C of title XVIII of the Act that the Secretary may find necessary and appropriate. Included in § 422.502(a), ''Agreement to comply with regulations and instructions,'' are the following contract conditions:

- The M+C organization must agree to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments. The M+C organization agrees that it will comply with the prohibition in § 422.108 on discrimination in beneficiary enrollment.
- The M+C organization must agree to provide the basic benefits as required under § 422.101 and to the extent applicable, supplemental benefits under § 422.102.
- The M+C organization must agree to provide access to benefits as required under subpart C of part 422. All benefits covered by Medicare must be provided in a manner consistent with professionally recognized standards of health care.
- The M+C organization agrees to disclose information to beneficiaries as required under § 422.110.
- The M+C organization must agree to operate a quality assurance and performance improvement program, and to have an agreement for external quality review as required under subpart D of part 422.
- The M+C organization must agree to comply with all applicable provider requirements in subpart E of part 422, 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.
- The M+C organization will agree to comply with all requirements in subpart M governing coverage determinations, grievances, and appeals.
- The M+C organization will comply with the reporting requirements in § 422.516 and the requirements for submitting encounter data to HCFA in § 422.257.
- The M+C organization agrees that it will be paid under the contract in accordance with the payment rules under subpart F of part 422.
- The M+C organization will develop annual adjusted community rate proposals and submit all required information on premiums, benefits, cost sharing by May 1, as provided in subpart G of part 422.
- The M+C organization agree that its contract may be terminated or not renewed in accordance with subparts K and N of part 422.
- The M+C organization will agree to comply with 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 M+C MSA requirements in §§ 422.56, 422.103, and 422.262.
- The M+C organization will agree to comply with the confidentiality and enrollee accuracy requirement in § 422.118.
- The M+C organization agrees that complying with the aforementioned contract conditions is material to performance of the contract.

Contract requirements that were either not required of HMOs and CMPs

under section 1876, or have been modified to implement the M+C program follow:

- The M+C organization must possess the capabilities to communicate with HCFA electronically.
- The M+C organization is required to provide prompt payment of covered services if these services are not furnished by a provider under contract or agreement in an M+C plan's health services delivery network. Under section 1876, the prompt payment requirement was limited to noncontracting providers. Section 1857(f) duplicates this requirement and adds to it the requirement that if the Secretary determines that an M+C organization fails to pay claims promptly, the Secretary may provide for direct payment of the amounts owed providers. When this occurs, the Secretary reduces the amount of the M+C organization's monthly payment to account for payments to these providers. We explain the full implications of this requirement in the discussion below pertaining to § 422.520.
- Pursuant to our authority in section 1856(b)(1) to establish standards under Part C, we are requiring that M+C organizations maintain records for 6 years. The standard for retention of records for HMO and CMPs was 3 years. We are changing the retention period from 3 years to 6 years so as not to prematurely foreclose our ability to address fraudulent or other abusive activities.
- Pursuant to our authority at section 1856(b)(1) to establish standards under Part C, we specify requirements relating to M+C organizations providing access to facilities and records at § 422.502(e). In this section we assert that M+C organizations allow HHS, the Comptroller General, or their designees to evaluate, through inspection or other means, all aspects of medical services furnished to Medicare beneficiary enrollees, the facilities of M+C organizations, and enrollment and disenrollment records of M+C organizations. We further provide that HHS, the Comptroller General, or their designees may audit, evaluate, or inspect all facilities and records as the Secretary may deem necessary to enforce an M+C contract. HHS's, the Comptroller General's, and designee's right to inspect such facilities and records extends through 6 years from the date of the contract period or completion of any inspection or audit activity, whichever is later. Exceptions to this 6-year inspection timeframe can occur in instances when: (1) HCFA determines there is a special need to retain particular records or a group of records for a longer period and notifies the M+C organization at least 30 days before the normal disposition date, (2) 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 solution of the termination, dispute, or fraud or similar fault, or (3) 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.
- Pursuant to our authority in section 1856(b)(1) to establish standards under Part C, and the provision in section 1856(b)(2) for adopting section 1876 standards, we have included certain disclosure requirements from § 417.486 in § 422.502(f). We have also included additional disclosure requirements to reflect new reporting requirements in § 422.516.
- At § 422.502(f)(2), we add the requirement that M+C plans submit to HCFA specific information necessary to evaluate and administer the program and to enable beneficiaries to exercise informed choice in obtaining Medicare services. Section 1851(d) authorizes the Secretary to obtain this information to enable HCFA to fulfill its responsibility to develop activities to disseminate broadly information to current and prospective Medicare beneficiaries in order to promote an active, informed selection among such options.
- Pursuant to section 1851(b)(4)(B), we have specified requirements at § 422.502(b)(2)(vii) that M+C organizations offering MSA plans disclose to HCFA information that will enable HCFA to evaluate the impact of permitting enrollment in MSA plans.
- Enrollee financial protection provisions are addressed at § 422.502(g). The first item protects beneficiary enrollees from incurring liability for payment of any fee that M+C organizations are legally obligated to bear. Section 422.502(g) contains the enrollee financial protection that has applied to HMO and CMP enrollees under § 417.122 (a)(1), which was made applicable to all section 1876 contractors under § 417.407(f). The beneficiary protection at 422.502(g)(1) is designed to protect beneficiary enrollees from being held financially responsible for fees for which the M+C organization is legally liable. Under the provision, we assert that M+C organizations protect beneficiary enrollees in two ways. First, through inclusion, hold harmless language in its written agreements with the providers that comprised the M+C plan's Medicare provider network. And pursuant to our rulemaking authority at section 1856(b)(1), we also specify that M+C organizations must indemnify beneficiary enrollees for the organization's legal obligations that are derived from health care services provided to enrollee beneficiaries by providers that have not entered into a written agreement to participate in the M+C organization's Medicare provider network. The beneficiary protection at 422.502(g)(2) afford beneficiaries protection against loss of benefits for which the M+C organization is legally obligated to pay. Except in the case of PSOs that have been awarded Federal waivers (see subpart H), States have the primary responsibility under Part C for determining whether an M+C organization has sufficient reserves to assume the risk it takes on under an M+C contract. The State that licenses the entity under applicable State law determines whether an entity has sufficient financial reserves to enter into an M+C contract.

Congress has given HCFA some ongoing responsibility concerning solvency, however. In section 1857(d)(4)(A)(i), M+C organizations are required to provide the Secretary with such information ''as the Secretary may require demonstrating that the organization has a fiscally sound operation.'' Accordingly, we believe that it is appropriate, under our authority in section 1856(b)(1) to establish standards under Part C to require (in § 422.502(g)) that an entity that already has an M+C contract demonstrate to HCFA that it has protections in place ensuring that beneficiaries will not be held liable for the entity's debts. We believe that this can be seen as part of having a fiscally sound operation as provided for in section 1857(d)(4)(A)(i).

- The subsection entitled ''Requirements of Other Laws and Regulations'' at § 422.502(h) requires that contracts reflect the M+C organization's obligations under other laws, specifically, the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans with Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.
- Pursuant to our authority under section 1856(b)(1) to establish standards under Part C, paragraph (i) of § 422.502 contains requirements that apply to related entities, contractors, and subcontractors of an M+C organization. These requirements promote an M+C organization's accountability and program integrity.

The requirements in paragraph (i) recognize that organizations that are likely to apply for M+C contracts commonly enter into business

relationships with entities that they placed under contract to perform certain functions that otherwise would be the responsibility of the organization to perform including management and provision of services. This section therefore addresses these relationships and establishes requirements that the M+C organizations must adhere to in order to provide HCFA assurances that the M+C organization will be accountable for all contract requirements.

Specifically, this section gives HHS, the Comptroller General or their designee, the authority to audit, evaluate and/or inspect documents, papers, records of all of the organizations mentioned in § 422.502(i); and to obtain information from the M+C organization and other entities described here, six years following the close of a contract or audit. Paragraph (i)(3) of § 422.502 describes provisions that must be included in contracts and other written arrangements between M+C organizations and other entities described in this section.

- Section 422.502(j), which is derived from section 1857(e), states that the contract will contain other terms and conditions consistent with this part as HCFA may find necessary and appropriate.
- Under § 422.502(k), we require that all M+C contracts be severable as discussed previously.

Finally, pursuant to our authority in section 1856(b)(1) to establish standards under Part C by regulation, we are requiring in paragraphs (l) and (m) that an M+C organization request payment on document that certify the accuracy and completeness of relevant data as a condition for receiving its capitation payment and, in the case of the ACR, for retaining the portion of capitation payment associated with the ACR amount (rather than providing additional benefits). Section 422.502(b) also states that the M+C organization's CEO or CFO certify the accuracy of encounter data, and, in instances when encounter data are generated by a related entity, contractor, or subcontractor, such entity likewise certifies the accuracy of the encounter data.

In all of these cases, when an M+C organization submits the data in question to HCFA, we believe that it is making a ''claim'' for capitation payment in the amount dictated by the data submitted, or in the case of the ACR submission, a ''claim'' to retain the portion of the capitation payment that is under the ACR amount, rather than providing additional benefits. We believe it is important that when an M+C organization is claiming payment (or the right to retain payment) in a particular amount based upon information it is submitting to HCFA, it should be willing to certify the accuracy of this information. We believe that these certifications will help ensure accurate data submissions, and assist HCFA and the Office of Inspector General in anti-fraud activities.

4. Effective Date and Term of Contract (§ 422.504)

Section 1857(c) provides that each contract under section 1857 will be for a term of at least 1 year, as determined by the Secretary. This section also provides that the effective date and term of the contract will be specified in the contract, except that in no case will a contract under this section that provides for coverage under an M+C MSA plan be effective before January 1999 with respect to such coverage. Based on these provisions, § 422.504(b) of this rule provides that beginning in 2002, contracts will be for a period of 12 months beginning on January 1 and ending on December 31. We include an exception at § 422.504(d) which indicates that prior to January 1, 2002, HCFA may at its discretion approve contracts for periods longer than 12 months, that begin on a date other than January 1.

HCFA has decided not to exercise the discretion provided in section 1857(a)(1) to make contracts automatically renewable (section 1857(a)(1) provides that contracts ''may'' be automatically renewable from term to term.) Instead, we specify at § 422.504(c) that the contract may be renewed annually only if HCFA affirmatively authorizes a renewal, and the M+C organization has not given HCFA a notice of nonrenewal. We believe that this approach is consistent with HCFA's role as a prudent purchaser and is in the best interest of the tax payer, the Medicare beneficiary and the Medicare program.

Under the current 1876 risk contract program, HCFA receives applications on a continuous basis and also awards contracts on a continuous basis as soon as the review process is complete, and a decision for approval has been reached. We have decided to maintain this process for the next few years under the M+C program. The BBA, however, provides a framework that has encouraged us to consider changing this in the future. The requirements for a coordinated open enrollment policy and printed plan comparison charts and the advent of the lock-in periods starting in 2002 suggests that HCFA move toward a policy of establishing a cutoff date for awarding contracts annually. This cutoff date would be timed to ensure that all new plans are included in the printed plan comparison charts. If we established a cutoff phase, HCFA would implement this change to the application and award processes in the year 2001 in time for the first year of the lock-in. We invite comments on this issue.

5. Nonrenewal of Contract (§ 422.506)

Section 422.506(a) discusses the process that an M+C organization must follow if it decides not to renew its contract. If the M+C organization does not want to renew its contract, it must notify HCFA in writing by May 1 of the year preceding the year that the M+C organization intends to no longer contract with HCFA. In addition, the M+C organization must notify each Medicare enrollee by mail at least 90 days before the effective date of the nonrenewal. It must also notify the general public at least 90 days before the end of the current calendar year by publishing a notice in one or more of the newspapers of general circulation located in the M+C's geographic area.

We also provide that HCFA may accept a nonrenewal notice of an M+C organization's decision not to renew its contract submitted after May 1 if the M+C organization complies with the requirements concerning enrollee and public notification and acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program. The May 1 deadline is timed to coincide with the ACR submission and internal HCFA timelines that require the timely submission of information necessary for developing annual health fair/open enrollment materials that will be made available to new and already-enrolled Medicare beneficiaries. We believe that the conference committee reports make it clear that the Congress intends for Medicare beneficiaries to make informed choice based on accurate, comparative M+C plan information. The Conferees further make it clear that the Secretary must take all steps necessary to ensure that all Medicare beneficiaries are provided the information needed to make informed choices about health coverage. We assert that the date-specific deadlines by which an M+C organization must notify HCFA of its decision not to renew its contract is a necessary step that promotes and represents the best intent of the law.

Section 1857(c)(4) provides that the Secretary cannot enter into an M+C contract with an M+C organization if, within the preceding five years, that organization has had an M+C contract

that was ''terminated at the request of the organization,'' except ''in circumstances that warrant special consideration, as determined by the Secretary.'' While Congress used the word ''terminated'' rather than ''nonrenewed,'' the only way that a contract could end solely ''at the request of the organization'' would be as the result of a notice of nonrenewal of the contract. In the case of a termination by mutual consent, discussed below, this only occurs if *HCFA* agrees that a termination of the contract is in the best interests of beneficiaries. Even in the case of a termination by the M+C organization under § 422.512 (discussed below), an organization does not have the right simply to ''request'' termination of the contract. Rather, it must show HCFA noncompliance with HCFA's obligations. This has never happened under the Part 417 counterpart of this authority for an organization to terminate its contract (§ 417.494(c)). Thus, we have always interpreted similar language in section 1876 to apply when an organization *nonrenews* its contract. We therefore make this interpretation explicit in § 422.506(a)(4).

HCFA decision not to authorize renewal. 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 nonrenewal notice. Section 422.506(b)(1) provides that HCFA may decline to authorize a renewal of a contract for any of the following reasons:

- The M+C organization has not fully implemented or shown discernable progress in implementing quality improvement projects;
- The M+C organization demonstrates insufficient enrollment growth. As participation in the M+C program grows it is inevitable that some contracting entities will not enroll sufficient numbers of Medicare beneficiaries to justify the administrative costs associated with regulating meet the applicable minimum enrollment requirements at § 522.514.
- For any of the reasons listed in § 422.510(a) which would also permit HCFA to terminate the contract.
- The M+C organization has committed any of the acts in § 422.752(a) which would support the imposition of intermediate sanctions or civil money penalties under Subpart O.

We believe that these aforementioned reasons for not authorizing renewal of a contract are consistent with HCFA's intent to fulfill its role as a prudent purchaser of health care services.

Section 422.506(b)(2) provides that if HCFA decides not to authorize the renewal of a contract, HCFA gives written notice to—

- The M+C organization by mail by May 1 of the current calendar year;
- The M+C organization's enrollees at least 90 days before the end of the current calendar year; and
- The general public, 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, at least 90 days before the end of the current calendar year.

Section 422.506(b)(3) provides that HCFA give the M+C organization written notice of its right to appeal the nonrenewal decision in accordance with subpart N.

6. Modification or Termination of a Contract by Mutual Consent (§ 422.508)

We provide guidance at § 422.508(a) that allows for contract termination by mutual consent. If a contract is terminated by mutual consent, except as provided in the § 422.508(b), the M+C organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b) (2), and (3). If the contract terminated by mutual consent is replaced on the following day by a new M+C contract, the notice specified above does not need to be provided.

We have developed a mutual consent termination policy because we believe that there are circumstances under which an M+C organization may agree to a mutual termination by consent. This policy gives HCFA the option to offer this alternative to affected M+C organizations. Further, HCFA may decide that it is in the best interests of tax payers, Medicare beneficiaries and the Medicare program to agree to let an M+C organization terminate its contract midyear. Finally, we believe this policy accommodates M+C organizations that may wish to terminate their contract by mutual consent at the end of a calendar year and enter into a new 12 month contract year on January 1 during the years prior to 2002. We invite comment on this proposed policy.

In § 422.508, with some modifications, we have retained the provision for contract modification or termination by mutual consent that applies to contracts under section 1876. As under § 417.494(a), contracts may be modified or terminated at any time by written mutual consent. The two changes we have made are that (1) we have changed the obligation to provide enrollees and the public with notice of a termination to conform to the 60-day notice requirement in § 422.512(b) (2) and (3) (which retained the enrollee notice requirement in § 417.484(c)(2)); and (2) we have provided for an exception to the notice requirement for cases in which a contract being terminated by mutual consent is being replaced by a new contract on the day the termination becomes effective. We continue to require that M+C organizations notify their Medicare beneficiary enrollees of any changes that may occur pursuant to a contract modification by mutual consent within timeframes specified by HCFA.

7. Termination of a Contract by HCFA (§ 422.510)

Section 1857(c)(2) provides that the Secretary may at any time terminate an M+C organization contract if the Secretary determines that the M+C organization—

- Failed substantially to carry out the contract;
- Is carrying out the contract in a manner inconsistent with the efficient and effective administrative of Medicare Part C; or
- No longer substantially meet the applicable conditions of Medicare Part C.

In addition to repeating the above statutory language, we are implementing this language by identifying specific circumstances that we believe constitute examples of an M+C organization substantially failing to carry out either its contract, or carrying out its contract in a manner that is inconsistent with the effective and efficient administration. Specifically, we have identified the following circumstances: The M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program; the M+C organization substantially fails to comply with requirements in Subpart M relating to grievances and appeals; the M+C organization fails to provide HCFA with valid encounter data as required under § 422.257; the M+C organization fails to implement an acceptable quality assessment and performance improvement program as required under Subpart D; the M+C organization substantially fails to comply with the prompt payment requirements in § 422.520; the M+C organization substantially fails to comply with the service access requirements in § 422.112 or § 422.114; the M+C organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

Section 1857(h)(2)provides authority for the Secretary to immediately terminate a contract with an M+C organization in instances where the

Secretary determines that a delay in termination resulting from compliance with the procedures in section 1857(h)(1) discussed below would pose an imminent and serious risk to the health of enrolled Medicare beneficiaries.

We have implemented this authority as follows. First, § 422.510(a)(5) provides for termination when an 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 when the organization otherwise fails to make services available to the extent that such a risk to health exists. Second, § 422.510(b)(2) provides that a termination based on § 422.510(a)(5) takes effect immediately. Third § 422.510(c) provides that the opportunity for corrective action does not apply to a termination based upon § 422.510(a)(5). And fourth, subpart N of part 422 provides that in the case of a termination based on § 422.510(a)(5), a hearing is not provided until after the termination takes effect.

Section 1857(h)(1) specifies procedures that must be followed before a termination by HCFA can take effect (unless the exception for an imminent and serious risk to health applies, as discussed above). We specify these requirements at § 422.50(b)(1). Section 1857(h)(1)(A) requires that the M+C organization be provided with a ''reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies'' that were the basis for a decision that grounds for termination existed under section 1857(c)(2). Section 422.510(c) provides for such a corrective action opportunity, consistent with time frames specified in Subpart N, except in cases in which the termination is based upon § 422.510(a)(5), and the ''imminent and serious'' risk to health exception in section 1857(h)(2) applies.

Section 1857(h)(1)(B) requires that the Secretary provide the M+C organization with ''reasonable notice and opportunity for hearing,'' including ''the right to appeal an initial decision * * * *before* terminating the contract.'' (Emphasis added.) Section 422.510(d) implements this provision by requiring that a notice of appeal rights under Subpart N be provided when a termination notice is sent to an M+C organization. This notice would specify that the termination would not be effective until after the hearing and appeal, except in the case of a termination under § 422.510(a)(5).

Also, in instances where it is necessary for HCFA to immediately terminate its contract with an M+C organization for violations prescribed in § 422.510(a)(5), we specify in § 422.510(b)(2) that if a termination notice is sent and takes effect in the middle of the month, HCFA has the right to recover a prorated share of its payment made to the M+C organization at the beginning of the month following notice of said termination.

8. Termination of a Contract by the M+C Organization (§ 422.512)

Paragraph (a) of § 422.512 provides that the M+C organization may terminate the contract if HCFA has failed substantially to carry out the terms of the contract. The paragraph (b) through (d) establishes requirements for giving notice, specifies when the termination is effective, and establishes when HCFA's liability for payment to the M+C organization ends. Paragraph (e) states that organizations that terminate their contract with HCFA cannot enter into an agreement with the Secretary for five years unless there are circumstances that warrant special consideration.

9. Minimum Enrollment Requirements (§ 422.514)

The newly-created section 1857(b) of the Act specifies that HCFA may not enter into a contract with an M+C organization unless the organization has at least 5,000 enrollees (or 1,500 if it is a PSO), or at least 1,500 enrollees (or 500 if it is a PSO) if the organization primarily serves individuals residing outside of urbanized areas. We specify these requirements in § 422.514(a).

Section 1857(b) refers to individuals ''who are receiving health benefits through the organization.'' We considered interpreting receiving health ''benefits'' to mean more than simply receiving health *services.* A hospital or doctor can furnish health services on a fee-for-service basis, or an organization can *administer* health benefits offered by an employer without actually providing ''benefits'' in the form of covered costs. We also recognize that some new organizations, both federally waivered PSOs and new state licensed entities, will apply to enter the M+C program. Thus, such an interpretation would allow some new entities to achieve the minimum enrollment requirement without having any or very little enrollment.

The minimum enrollment requirement is an indicator that the organization applying for an M+C contract can handle risk and capitated payments and also is able to effectively manage a health care delivery system including the enrollment and disenrollment of beneficiaries and the timely payment of claims, provide quality assurance, and have systems to handle grievances and appeals. While having experience with risk based payments indicates the organization can handle risk, it does not provide any assurance that the organization can manage all the contractual requirements of an M+C organization.

We realize that through the waiver process for federally waivered PSOs and the application process for all new entities we require reasonable assurance that the organization will be able to manage their contract. We do not want to add an additional barrier to entry for those organizations that have gone through the waiver process or state licensure but are still start-up organizations.

We have decided to require that the minimum enrollment requirement can only be met counting enrollees in the particular organization. This will show the organization can handle risk and manage their system.

Section 1857(b)(2) contains the statement that the term ''covered lives'' should be substituted for ''individuals'' in applying the minimum enrollment rule to MSA plans. As such, we will count covered lives for MSAs for purposes of meeting the minimum enrollment requirements.

As stated earlier, section 1857(b)(3) allows M+C organizations to request a waiver of minimum enrollment requirements during the first 3 contract years. Therefore, under § 422.514(b) HCFA may waive the minimum enrollment requirement for 1 year to those organization that need a waiver provided such organizations satisfactorily demonstrate: prior experience with risk-based payment arrangements; the ability to bear financial risk under the M+C contract; and marketing and enrollment activities necessary to meet enrollment requirements specified at § 422.514 (a)(1) and (a)(2). Both HCFA actuaries and the National Association of Insurance Commissioners recommend against entering into an contract with a applicant who does not project reaching 500 members within a short timeframe. HCFA will monitor closely the progress of organizations in meeting at least this goal during the first contract year.

If the organization does not meet the applicable minimum enrollment requirement by the end of its first year of operation we may waive the requirements for an additional year if the organization meets the requirement specified in § 422.514(b)(2):

- Requests an additional minimum enrollment waiver at least 120 days before the end of the year;
- Continues to demonstrate an ability to meet its contractual obligations and bear financial risk; and,
- Demonstrates an acceptable marketing and enrollment process. The organization's enrollment projections for the second year of the waiver will become its enrollment standard.

In paragraph § 422.514(b)(3) we state that we will only approve a third and final waiver year if the organization has achieved the transitional enrollment standard that the organization projected in their marketing and enrollment plan required to receive a waiver for their second year.

Finally, if an organization does not achieve the minimum enrollment requirement and is not operating with a minimum enrollment waiver, HCFA may elect not to renew the M+C organization's contract, we specify this at § 422.514(c).

10. Reporting Requirements (§ 422.516)

This M+C regulation contains a number of sections that specify information requirements for M+C organizations. This information is to be provided from organizations to HCFA (see §§ 422.64, 422.502, and 422.512), from HCFA to beneficiaries (see § 422.64), and from the organizations to the beneficiaries (see §§ 422.80 and 422.110).

The following listing summarizes all the information required to be disclosed either to HCFA, to beneficiaries, or to both:

- Benefits
- Premiums
- Service area
- Quality and Performance: Outcomes, HEDIS, Disenrollment, satisfaction
- Supplemental benefits
- Access: Number, mix, and distribution of providers
- Out of area coverage
- Emergency care coverage
- Supplemental premiums
- Prior authorization rules
- Grievances and appeals procedures and data
- Quality assurance program
- Utilization controls
- Compensation methods
- Financial reports
- Encounter data
- Claims
- Enrollment

These represent an extensive amount of information to be disclosed both to HCFA and to beneficiaries. M+C organizations need to be particularly aware of the many requirements to disclose information to beneficiaries as seen in §§ 422.80 and 422.110. They will have to develop management information systems that meet these disclosure requirements. As it is, these sections specify the basic requirements as to information to be disclosed. HCFA will provide more detailed policy guidance on specific contents required for each of these data elements. These additional requirements will be developed with input from the public, such as plans, consumer groups, etc.

M+C organizations also need to take into consideration in the development of these management information systems, that they will soon have to meet the requirements of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996. This act will result in regulations for data standards that effect all components of the health care system. The act will specify standards for the following types of transactions: claims, enrollment and disenrollment, eligibility, payments and remittances, premiums, first report of injury, claim status, referral, providers, patient identifiers, health plan identifiers, and code sets. The organizations will also need to be in compliance with year 2000 changes.

Furthermore, M+C organizations will need to address the confidentiality and privacy provisions of these regulations and related regulations, meet the validation requirements associated with several of the data sets incorporated into this regulation, e.g, encounter data will need to be validated, and be capable of electronically transmitting this information to HCFA in the future, when such is so specified.

Section 1857(d) contains several provisions involving the financial records and financial status of M+C organizations. As discussed above, paragraphs (1) and (2) of section 1857(d) provide for auditing and inspection of M+C organizations' financial records. The paragraph (4) in section 1857(d) specifically requires that organizations ''in accordance with regulations of the Secretary, report to the Secretary financial information,'' which ''shall include'' such information as the Secretary may require demonstrating that the organization has a fiscally sound operation. Under our authority at section 1856(b)(2) to adopt section 1876 standards, we have decided to implement this authority in part by requiring that M+C organizations comply with financial reporting requirements currently set forth in § 417.126. These requirements are set forth in § 422.516(a) and (b). We believe that requirements specified in section 1857(d)(1), which require HCFA to conduct annual audits of the financial records of M+C organizations, compel M+C organizations to provide all required information described at § 422.516(a) and (b). Included in these requirements are—

- Requirement that M+C organizations develop and maintain a system for reporting information to HCFA, its enrollees and the general public, information described elsewhere in the regulation.
- A requirement that each M+C organization report to HCFA a description of significant business transactions.
- A requirement that each M+C organization submit combined financial statements to HCFA on a timely basis, as defined by HCFA.
- A requirement that for any employees' health benefits plan that includes an M+C organization in its offering, the M+C organization must furnish, upon request, the information the organization 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).
- A requirement that the organization notify HCFA regarding any loans or other special financial arrangements.
- A requirement that each M+C organization must make financial information available to enrollees upon request.

11. Prompt Payment Requirements (§ 422.520)

Under § 422.520, contracts with M+C organizations must specify that the M+C organization agrees to provide prompt payment of claims that have been submitted by providers for services and supplies rendered to Medicare enrollees when these services and supplies are not furnished by an organization-contracted provider. While this requirement closely follows requirements already in place for section 1876 contractors, (including provisions pertaining to interest to be paid if timely payment is not made), section 1857(f) extends similar prompt payment requirements to claims submitted by Medicare beneficiaries enrolled in M+C private fee-for-service plans. Section 422.520(a) contains this new section 1857(f) requirement, as well as the requirement that applies to non-contracting providers. Further, pursuant to our authority under section 1856(b)(1) to establish standards under Part C, we require organizations to act upon (either approve or deny, not

necessarily pay) all claims within 60 calendar days from the date of request. These claims include the remaining 5 percent of the clean claims not paid within 30 days as well as all other claims.

In addition, pursuant to our authority in section 1856(b)(1) to establish standards under Part C, we are requiring in § 422.520(b) that contracts or other written agreements between M+C organizations and providers and suppliers contain a ''prompt payment'' provision, the terms of which are developed and agreed to by the M+C organization and the relevant provider.

Section 1857(f)(2) also contains another new provision that specifies that if the Secretary determines that the organization fails to make payments promptly to non-contracting providers and suppliers as required under section 1857(f)(1) (and § 422.520(a)), the Secretary may provide for direct payments to affected providers and suppliers. We articulate these requirements in § 422.520(c).

Special Rules for RFB Societies

Enrollment restriction rules may be imposed by religious fraternal benefit society M+C organizations, provided the restriction of enrollment is consistent with the requirements identified in section 1859(e) of the Act. The RFB M+C organizations must still meet the requirements for financial solvency. Moreover, the Secretary may adjust the M+C organization's payment to account for the unique actuarial characteristics of the individuals enrolled in the RFB M+C organization. We specify these requirements in § 422.250(a).

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract

This interim final rule applies to M+C organizations the provisions concerning the effect of change of ownership or leasing facilities during the term of the contract that are currently set forth with regard to HMOs and CMPs in subpart M of part 417 to M+C organizations. This is accomplished by designating §§ 417.520 through 417.523 as §§ 422.550 through 422.533 in a new subpart L in part 422 and making certain nomenclature changes. (A cross-reference to subpart L of part 422 is included in subpart M of part 417 in order that these provision may continue to apply to Medicare contracts with HMOs and CMPs under section 1876.) We also revise redesignated § 422.550 (formerly § 417.520) to add that an M+C organization that has Medicare contract in effect and is considering or negotiating a change in ownership must provide to HCFA updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization. We also add this requirement to redesignated § 422.552 (formerly § 417.522), which contains requirements relating to novation agreements.

M. Subpart M—Grievances, Organization Determinations, and Appeals (§§ 422.560 Through 622)

1. Introduction

Subpart M of part 422 implements sections 1852(f) and (g), which set forth the procedures M+C organizations must follow with regard to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f), an M+C organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its M+C plans. Section 1852(g) addresses the procedural requirements concerning coverage (''organization'') determinations and reconsiderations and other appeals. As discussed in detail below, only disputes concerning ''organization determinations'' are subject to the reconsideration and other appeal requirements under section 1852(g). In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f). For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review.

For the grievance, organization determination, and appeal requirements, an M+C organization must establish procedures that satisfy these requirements with respect to each M+C plan that it offers. These requirements generally are the same for each type of M+C plan—including M+C non-network MSA plans and M+C PFFS plans.

The grievance, organization determination, and appeal requirements for M+C organizations that are set forth in this interim final rule are largely based on the existing rules for managed care organizations under part 417, Subpart Q, Beneficiary Appeals. This is in accord with section 1856(b)(2), which directs that the M+C standards be based on the analogous standards established under section 1876, as long as they are consistent with the requirements in part C. Moreover, we note that to some extent the statutory requirements themselves reflect policies contained in the existing part 417 requirements. For example, the requirements under section 1852(g)(3) concerning expedited organization determinations and reconsiderations essentially incorporate the expedited review procedures that were issued in HCFA's April 30, 1997 final rule with comment (62 FR 23368). (That final rule established expedited review processes for organization and reconsidered determinations, and clarified that the definition of an organization determination includes discontinuations of service.)

Thus, the significant differences between the grievance and appeal requirements that apply under the M+C program and the existing requirements in subpart Q of part 417 are: (1) changes that are explicitly mandated under the statute, such as the requirement under section 1852(g)(4) that HCFA contract with an independent outside entity to review coverage denials; and (2) changes that implement statutory intent, such as the reduced timeframe for reconsiderations, which is consistent with both the discretion provided under section 1852(g)(2)(A) and Congress' expectations as stated in the BBA conference report. (As discussed below, the conference report states that the Conferees ''* * * assume that the Secretary will address the issue of [reconsideration] timeframes in the Part C regulations'' and intend that the Secretary adopt timeframes that are shorter than those in existing regulations. See H.R. Rep. No. 105–217, pg. 605 (1997).) The only other substantive changes contained in these requirements are the incorporation into the regulations of several limited policy clarifications that have been issued by HCFA as implementing instructions pursuant to our April 30, 1997 final rule. These changes are discussed in detail below.

In addition to these limited substantive changes, we have also taken the opportunity to make numerous editorial and organizational changes in adopting the part 417 regulation language on beneficiary appeals for

purposes of the M+C program. For example, we have added material that summarizes the rights of M+C enrollees, and we have established distinct sections that clearly explain the timeframe and notice requirements for standard and expedited organization determinations. These types of changes do not affect the rights of beneficiaries or the responsibilities of M+C organizations with regard to grievances, organization determinations, and appeals, but we believe they can help to ensure that these rights and responsibilities are more clearly understood within the managed care community.

2. General Provisions (§§ 422.560–522.562)

Subpart M begins with an introductory section (§ 422.560) that simply sets out the statutory basis and scope for the requirements that follow. Although this material is generally shorter and more concise than the similar provisions of subpart Q in part 417, we are now specifying under § 422.560(b) that the rules concerning notice of noncoverage on inpatient hospital care and immediate peer review organization (PRO) review procedures for noncoverage determinations fall within the scope of the M+C subpart M requirements.

Section 422.561 then sets forth several definitions for terms used in the subpart. Note that some definitions previously located in subpart Q of part 417 (such as ''ALJ'') have now been included in § 400.200, rather than in part 422, since they constitute definitions that apply for all Medicare and Medicaid purposes. Terms included here that are not defined in existing part 417 include ''appeal,'' ''authorized representative,'' ''enrollee,'' ''grievance,'' and ''physician.'' For the most part, these definitions are self-explanatory; they do not impose any new requirements on M+C organizations. For example, we clarify that an ''authorized representative'' is an individual authorized by an enrollee to act on his or her behalf in obtaining an organization determination, or in dealing with any levels of the appeal process, subject to the Social Security regulations in 20 CFR part 404, subpart R. We also specify that, for purposes of subpart M, the term ''enrollee'' includes an enrollee's authorized representative. Together, these definitions should clarify that the rights of enrollees with respect to grievance and appeal procedures can consistently be exercised for them by their authorized representatives, except where specifically proscribed in the regulations. We also establish that ''physician'' is defined according to section 1861(r), which is the standard definition for both original Medicare and the M+C program.

Section 422.562, General Provisions, provides an overview of the rights and responsibilities of M+C organizations and M+C enrollees with respect to grievances, organization determinations, and appeals. The responsibilities of M+C organizations, under § 422.562(a), essentially parallel those in existing § 417.604(a). We have added a provision stating that if an M+C organization delegates any of its responsibilities under subpart M to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the applicable grievance and appeal requirements are still met. This concept is explicitly stated in section 1852(f) concerning grievance procedures, and we believe it is equally germane for purposes of organization determinations and appeals. An M+C organization's responsibility for functions that it delegates is also established under the contract requirements set forth in § 422.502(i). (Although we do not encourage M+C organizations to delegate their grievance, organization determination or appeal responsibilities, we recognize that particularly for an M+C non-network MSA plan or an M+C PFFS plan, an organization offering such a plan may choose to delegate some of these responsibilities to local entities that can meet the applicable subpart M requirements.)

Section 422.562(b) explains the basic rights of M+C enrollees under subpart M and provides regulatory references to the sections that fully explain the relevant rights. This section does not establish any rights beyond those now available under the part 417 rules, but consolidates general information about enrollees' rights into a central location in the regulations.

Like the part 417 regulations, the general provisions section concludes with brief sections addressing the applicability of requirements in subpart M and the applicability of other regulations under title II of the Act.

3. Grievance Procedures (§ 422.564)

As noted above, section 1852(f) requires that each M+C organization provide ''meaningful procedures for hearing and resolving grievances.'' There is no explicit indication in the statute of what constitutes a grievance; however, given the provision in section 1856(b)(2) for basing Part C standards on standards under section 1876, we have retained the meaning of grievance used in part 417. We have defined this term in § 422.561 as any complaint or dispute other than one that involves an ''organization determination'' (as described under § 422.566(b)).

An enrollee might file a grievance if, for example, the enrollee received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, as specified under §§ 422.570(d)(2)(ii) and 422.584(d)(2)(ii), grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to comply with an enrollee's request to expedite an organization determination or a reconsideration. Under § 422.564(a), we are requiring that an M+C organization must resolve grievances in a timely manner and that procedures for doing so must comply with any guidelines established by HCFA. This guidance would include forthcoming instructions, rulemaking, and requirements built into HCFA's Quality Improvement System for Managed Care (QISMC). (See section II.D of this preamble for more information about QISMC.) Section 422.564(b) then clarifies that grievance procedures are separate and distinct from appeal procedures, which address organization determinations. We also clarify under § 422.564(c) that the PRO complaint process under section 1154(a)(14) addresses quality issues, but is separate and distinct from the M+C organization's grievance procedures.

Although we have not in the past outlined detailed requirements for a plan's grievance procedures, we considered doing so in this interim final rule as a means of implementing the requirement under section 1852(f) for meaningful grievance procedures. Accordingly, we consulted with the managed care industry as well as beneficiary advocacy groups, reviewed comments we received from the public, and looked to recent standards in this area, such as those developed by the National Association of Insurance Commissioners (NAIC). (NAIC has developed and adopted a Model Grievance Act setting forth standards for grievance procedures that include timeframes for the resolution of quality-related issues.) We also recognize that section 1852(c)(2)(C) requires organizations to provide data on the number of grievances and their disposition in the aggregate upon an enrollee's request, and we believe timely processing of grievances is necessary to assist in consistent data reporting. Thus, we considered requiring certain timeframes for

addressing grievances and contemplated further clarification of the definition of a grievance.

However, due to limited time for rulemaking, input we received from the public opposing mandated grievance procedures, and our understanding that extensive research is underway concerning State grievance requirements (the results of which should be available in the very near future), we have decided not to prescribe specific timeframes for grievances in this rule and instead to consider doing so through proposed rulemaking. We plan to address such issues through a future proposed rule. At this time, we welcome comments on the necessary elements of a meaningful grievance procedure, including recommended timeframes, the types of issues that should be considered grievances, an expedited grievance process, independent review of grievances, reconsideration of grievances, and the type of notification enrollees should receive concerning the outcome of their grievance.

4. Organization Determinations (§§ 422.566 Through 422.576)

Section 1852(g) requires an M+C organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations. These rights are similar to those available to beneficiaries under original Medicare, except that under the M+C program the initial level of review is typically conducted by the organization itself rather than by a PRO, intermediary, or carrier.

(For the convenience of the reader, we are presenting below a chart offering a sequential overview of the available procedures and related timeframes associated with service-related organization determinations and appeals. This chart is for illustrative purposes only, and certain details (such as when extensions are permissible and timeframes for requests for payment) have been omitted for ease of presentation. For a full description of the applicable requirements, please consult the preamble material that follows and the regulations set forth in subpart M of part 422. Although the chart reflects the maximum allowable timeframes available to an M+C organization under the M+C regulations (for service requests), we emphasize that the primary applicable requirement, as discussed in detail below, is that an M+C organization make a determination as expeditiously as the enrollee's health condition requires. In addition, note that maximum timeframes for an M+C organization to make a payment-related determination are somewhat longer than for service-related determinations, as is also discussed below.)

BILLING CODE 4120–01–P

M+C ORGANIZATION DETERMINATION AND APPEAL PROCESS FOR SERVICE-RELATED REQUESTS

M+C Organization

Organization Determinations
- Standard (NTE 14 days*)
- Expedited (NTE 72 hours*)

Reconsideration by the M+C Organization
- Standard (NTE 30 days*)
- Expedited (NTE 72 hours*)

Reconsideration by Independent Entity
- Timeframes identical to those for M+C organizations**

Administrative Law Judge Hearing

Departmental Appeals Board Review

Judicial Review

* For all service-related requests, an M+C organization must render determinations "as expeditiously as the enrollee's health condition requires," but not to exceed (NTE) the timeframes noted above.

** As discussed below, the timeframe requirements for standard and expedited reconsiderations by the independent entity will be established through contract.

BILLING CODE 4120–01–C

In accordance with section 1852(g)(1), § 422.566 begins by specifying that an M+C organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. We note that under section 1852(g)(1), the issues that must be addressed through an organization determination include an enrollee's entitlement to ''receive a health service *under this section*.'' (Emphasis added.) Section 1852(a) describes basic benefits that M+C organizations must offer, as well as supplemental benefits that organizations may offer. Supplemental benefits may either be provided to all enrollees on a mandatory basis (with the Secretary's approval) or provided at the enrollee's option. In both cases, the enrollee pays for supplemental benefits. Disputes involving supplemental benefits that are mandatory for all enrollees in a plan will be organization determinations and subject to the appeal process, as similar benefits were under part 417. We believe, however, that optional supplemental benefits should also be included in the meaning of ''health services under [section 1852]'' and disputes involving these types of benefits should be the subject of organization determinations and the appeal process. This policy, which is incorporated into § 422.566(a), represents a departure from existing part 417 requirements, where disputes concerning optional supplemental benefits are not the subject of organization determinations and must be resolved only through grievance procedures. Section 422.566(b) then lists actions that are organization determinations, consistent with existing § 417.606(a) (except for new language to reflect the inclusion of optional supplemental benefits and the explicit mention of payment for post-stabilization care, along with payment for emergency or urgently needed services, which appear already in § 422.606(a)).

Section 422.568 includes the standard timeframe and notice requirements for organization determinations. Note that this section, in conjunction with §§ 422.570 and 422.572, reflect a major reorganization of the requirements in existing §§ 417.608 and 417.609. This reorganization was necessary both to help clarify the different timeframe and notice requirements that apply for expedited determinations as well as to facilitate the addition of several new BBA requirements (which are discussed below).

The primary substantive change in § 422.568 is the requirement under § 422.568(a) that an M+C organization must make a determination with respect to an enrollee's request for service as expeditiously as the enrollee's health status requires, and in no case later than 14 calendar days after the organization receives the request. As discussed in detail below in section II.M.6 of this preamble, this new requirement emphasizes making determinations consistent with an enrollee's health needs, while also providing for a reduction in the maximum time allowed to make a determination from 60 days, as reflected in § 417.608(a), to 14 days. In conjunction with the reduced timeframe for making an organization determination, we are also providing that 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 include written justification for the extension in the case file. The length of the extension period is consistent with the extensions currently allowed under part 417 for expedited organization determinations.

We note that the maximum timeframes for both organization determinations and for reconsiderations are now reckoned in ''calendar days,'' as opposed to ''working days,'' in order to be unambiguous and consistent with the statute. In addition, under § 422.568(b), we have specified that timeframes for requests for organization determinations on payment issues are identical to the ''prompt payment'' requirements set forth under § 422.520. Thus, for issues relating to payment, the requirements are as follows: (1) For ''clean claims,'' an M+C organization must make a determination regarding the claim within HCFA's current ''clean claim'' rules, that is, 95 percent of clean claims must be paid within 30 calendar days after receipt of the request for payment. (As defined in § 422.500, ''clean claims'' are claims that have no defect, impropriety, lack of any required substantiating documentation, or particular circumstances requiring special treatment that prevents timely payment.) (2) For all other claims, an M+C organization must make a determination regarding the claim within 60 calendar days after receipt of the request for payment.

Consistent with section 1852(g)(1)(B), § 422.568(c) and (d) require that an M+C organization issue written notification for all denials, including the specific reasons for the denial in understandable language, information regarding the enrollee's right to either an expedited or standard reconsideration, and a description of both the expedited and standard review processes, as well as the rest of the appeal process.

Sections 422.570 and 422.572 set forth the requirements for M+C organizations with respect to expedited determinations. Section 1852(g)(3)(A) specifically allows either an enrollee or a physician to request an expedited organization determination or reconsideration, regardless of whether the physician is affiliated with the M+C organization. We have reflected this provision in §§ 422.570(a) (for expedited organization determinations) and 422.584(a) (for expedited reconsiderations). We have also addressed the issue of the circumstances under which a physician can request expedited review for an enrollee. HCFA currently allows any physician to request an expedited organization determination without being appointed as an enrollee's authorized representative. In contrast, HCFA requires that a physician be an enrollee's authorized representative in order for the physician to request an expedited reconsideration on the enrollee's behalf. We have made this distinction because, in the context of an organization determination, we regard the physician as a provider who is requesting a service for his or her patient. In the context of a reconsideration, on the other hand, we believe the physician is serving as the enrollee's representative in the first level of the appeal process.

We have decided to continue this current policy, and have reflected in § 422.570(a) that any physician can request an expedited organization determination, while § 422.584(a) provides that a physician who requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative. We would also like to make it clear that, in any case in which a physician is only supporting an enrollee's request for expedited review, the physician does not need to be the enrollee's authorized representative.

As mentioned above, the requirements for expedited organization determinations and the like requirements for expedited reconsiderations were the subject of HCFA's April 30, 1997 final rule. Section 1852(g)(3) is modeled to a large extent on our existing requirements. For example, section 1852(g)(3)(B)(ii)

explicitly states that an M+C organization must expedite its determination (or its reconsideration of a determination) if a physician has requested the expedited review and has indicated, either orally or in writing, that the application of a standard timeframe for a determination (or reconsideration) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This new statutory provision reflects the current provisions in part 417. Sections 417.609(c)(4) and 417.617(c)(4) require that an HMO or CMP grant a physician's request for expedited review; however, they do not require that the physician make any statements about the enrollee's health, as the physician must under section 1852(g)(3)(B)(ii). In effect, the statute now requires that an M+C organization must expedite a determination at the physician's request, that is, providing that the physician's request indicates the possibility of serious jeopardy to the enrollee.

Section 422.570(b)(2) specifies that a physician may provide written or oral support for a request for expedition, and under § 422.570(c)(2)(ii), we clarify that when requests for expedited organization determinations are made or supported by a physician, the M+C organization must grant the request if the physician indicates that the enrollee's health could be jeopardized. In any case in which a physician has not initiated the request, but supports it, we regard the physician as having joined in the request and, in effect, as being a co-requestor. (We note that in a case when an enrollee submitted a request for an expedited organization determination but did not know that physician support could automatically expedite a determination, an enrollee or a physician may submit a subsequent request, including the physician's statement of support, for an expedited organization or reconsidered determination.)

These sections also incorporate several details necessary to clarify current policy, such as the provision in § 422.568(d)(1) that an M+C organization automatically transfer a denied request for an expedited organization determination to the standard 14-day timeframe described in § 422.568(a), and the requirement under § 422.570(d)(2)(ii) that an M+C organization inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite. We also require under § 422.570(c)(1) that an organization establish an efficient and convenient means for individuals to submit oral or written requests for expedited organization determinations and document any oral requests. Generally, in accordance with the provisions of § 422.570(b)(1), we would expect that such requests would be submitted directly to the M+C organization. However, because we recognize that some organizations may already have established or may wish to establish other convenient procedures for accepting oral and written requests for expedited review, we clarify under § 422.570(b)(1) that procedures may involve submitting a request to another entity responsible for making the determination, as ''directed by the M+C organization.''

Under section 1852(g)(3)(B)(iii), an M+C organization must notify the enrollee (and the physician involved, as appropriate) of an expedited determination. The requirement to notify the physician is similar to one in § 417.609(c)(3), which requires of an HMO or CMP ''notification of the enrollee, and the physician as appropriate.'' This requirement is set forth in § 422.572(a). Section 1852(g)(3)(B)(iii) also requires that the M+C organization notify the enrollee and physician of an expedited determination under time limits established by the Secretary, but not later than 72 hours after receiving the request (or receiving the information necessary to make the determination), or such longer period as the Secretary may permit in specified cases. Under this authority, we are able to retain in § 422.572(a) the existing 72-hour timeframe for expedited review that appears in § 417.609(c)(3). Also, we have exercised our discretion to allow in § 422.572(b) an M+C organization to extend the 72-hour deadline for expedited review by up to 14 calendar days if the enrollee requests the extension or if the organization finds that additional information is needed and the delay is in the interest of the enrollee.

Thus, the authority in section 1852(g)(3)(B) has allowed us to retain the recently promulgated regulations on expedited determinations with only a few clarifications and minor technical changes (for example, we have changed the 10 working day extension in § 417.609(c)(3) to 14 calendar days, to be consistent with how we are counting days under the other section 1852 provisions). We have added to the regulation an example of the type of reason for which an extension may be granted, and we have specified that an M+C organization must notify an enrollee of a determination as expeditiously as the enrollee's health care needs require but no later than upon expiration of the extension.

We have also added a provision in both §§ 422.570(f) and 422.584(f) to prohibit an M+C organization from taking or threatening to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited organization determination or reconsideration. Since publication of our April 30, 1997 final rule, several national organizations (including the American Medical Association and the American Association of Retired Persons) have expressed strong support for a general prohibition that would prevent retaliation against physicians who act on behalf of or in support of enrollees to expedite reviews. Moreover, we believe that this prohibition complements the anti-gag rules incorporated into subpart E of this interim final rule.

Section 422.574 identifies the parties to an organization determination. The statute does not specify who can ask for an organization determination involving the rights of an M+C enrollee to certain health services. Section 1852(g) does specify that an M+C organization must reconsider a determination upon the request of the enrollee, and either the enrollee or a physician can request an expedited reconsideration. The enrollee specifically has the right to appeal a reconsidered determination under section 1852(g)(5), a provision that is almost identical to the appeal provision in section 1876(c)(5)(B) for HMO and CMP enrollees.

We are interpreting these provisions in the same manner as we interpreted them in part 417 to include not just the enrollee, but also to allow other parties to exercise those rights. Section 417.610 lists as parties to an organization determination not just the enrollee, but certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and the broad category of any other entity determined to have an appealable interest in the proceeding. These parties can continue to have an interest in the proceedings throughout each level of an appeal. We have retained this provision in § 422.574, except that we have modified § 417.610(d) to include any *provider* or entity determined to have an appealable interest. We have also specifically excluded the M+C organization, since we believe that this entity constitutes the decision maker, and as such is not a party to an organization determination.

5. Reconsiderations by an M+C Organization (§§ 422.578 Through 422.590)

If a decision regarding a request for payment or service is unfavorable (in whole or in part) to the enrollee, the enrollee or any other party to an organization determination as listed in § 422.574 who is dissatisfied with the organization determination may request that the M+C organization reconsider the decision. Reconsiderations represent the first step in the appeal process. The reconsideration process encompasses both standard and expedited reconsiderations, as described under §§ 422.582 and 422.584. The timeframe and notice requirements for reconsiderations are set forth under § 422.590.

One important distinction between organization determinations and reconsiderations is that an M+C organization issues a reconsidered determination only if the reconsideration is entirely favorable to the enrollee. As discussed in detail below, § 422.590(a)(1) now requires that with respect to standard reconsiderations concerning requests for service, an M+C organization must issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the request for reconsideration. (As with organization determinations, we are also providing under § 422.590(a) that 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.) Under § 422.590(b)(1), for standard reconsiderations involving requests for payment, the M+C organization must issue any fully favorable determination no later than 60 calendar days from the date it receives the request for the reconsideration. In the case of expedited reconsiderations (which involve only requests for services), § 422.590(d)(1) requires that an M+C organization issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 72 hours after it receives the request for expedited reconsideration, again with the possibility of a 14-day extension as described in § 422.590(d)(2). If, however, the M+C organization's reconsideration results in an affirmation, in whole or in part, of its original adverse organization determination, this decision is automatically subject to further review by an independent entity contracted by HCFA. (Again, the timeframe within which an M+C organization must reconsider a standard or expedited case has been tied to the enrollee's health needs for service requests, subject to either a 30-day or 72-hour maximum (with a possible 14-day extension), while the timeframe remains at 60 days for reconsideration requests involving payment.)

Section 1852(g)(4) of the Act requires HCFA to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm, in whole or in part, an M+C organization's denial of coverage. Thus, unless an organization completely reverses its coverage denial, the M+C organization must prepare a written explanation and refer the case to the independent review entity for a new and impartial determination concerning the payment or service at issue. This requirement is consistent with existing policy. Under § 417.620, an HMO or CMP that recommends partial or complete affirmation of its adverse determination must prepare a written explanation and send the entire case to HCFA, so that HCFA can make the reconsidered determination. We have in the past contracted with an independent outside entity, the Center for Health Dispute Resolution (CHDR), to perform this function.

For standard requests for services, § 422.590(a)(2) requires that the M+C organization send the case to the independent review entity as expeditiously as the enrollee's health requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or the date of an expiration of an extension). For standard requests for payment, § 422.590(b)(2) allows the M+C organization 60 calendar days from the date it receives the request to send the case to the independent review entity. In instances involving expedited requests for reconsideration, § 422.590(d)(5) requires that the M+C organization forward its decision to the independent entity as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation of the adverse organization determination.

Section 1852(g)(2)(B) requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by ''a physician with appropriate expertise in the field of medicine which necessitates treatment.'' We have interpreted this requirement in § 422.590(g)(2) to refer to a physician with an expertise in the field of medicine that is appropriate for the services at issue. The statute also requires that the physician be one other than the physician involved in the initial determination. We believe this requirement is implicit in the provision in § 422.590(g)(1) that the reconsideration be conducted by a person not involved in making the organization determination.

For the most part, the procedures outlined above are consistent with the existing part 417 requirements and are carried over into subpart M of part 422—all significant discretionary changes (such as the timeframe reductions) as well as statutory requirements (such as required physician review of certain coverage denials) are discussed in this preamble. We also are implementing several changes in the reconsideration requirements that are analogous to those described for organization determinations, such as the requirement under § 422.584(d)(1) that an M+C organization automatically transfer a denied request for an expedited reconsideration to the standard 30-day timeframe described in § 422.590(a). In addition, § 422.590(e) requires that if an M+C organization refers a case to the independent entity, it must concurrently notify the enrollee of that action.

6. Reduction of Timeframes for Standard Organization Determinations and Reconsidered Determinations

As noted above, section 1852(g)(1)(A) requires that M+C organizations make organization determinations ''on a timely basis.'' For standard (non-expedited) reconsiderations, section 1852(g)(2)(A) specifies that a decision must be made no later than 60 days after the enrollee's request, but the Act provides the Secretary with discretion to reduce the timeframe. Again, the BBA conference report (H.R. Rep. No. 105–217, at pg. 605 (1997)) indicates Congress' understanding that HCFA was developing proposed regulations that would reduce existing timeframes and that these efforts could instead be incorporated into the regulations implementing the M+C program. Consequently, we have decided to exercise such discretion and to reduce the timeframes within which M+C organizations must render both standard organization and reconsidered determinations involving requests for service.

In researching this issue, we found widespread support for reducing timeframes for standard determinations in both medical journals and reports

from other independent entities. For example, the Physician Payment Review Commission's (PPRC) 1996 Annual Report to Congress listed ''the timeliness of the process, especially for pre-service denials'' as one of the areas requiring improvement in the current appeal process. PPRC reported that ''[c]onsiderable delays are built into the [appeal] process.'' Likewise, the Medicare Rights Center (MRC) recently recommended that HCFA require health plans to make non-expedited organization determinations within 10 days of receiving the request. The MRC also recommended that HCFA require health plans to make non-expedited reconsiderations within 20 days.

The 60-day timeframes in part 417 for organization and reconsidered determinations were based on the original fee-for-service Medicare appeal process. However, this process is mostly retrospective. In coordinated care plans, preservice requests for organization determinations exceed the number of retrospective requests. Reduced timeframes often are of critical importance—particularly when an individual is awaiting prior authorization for a service. Therefore, we believe there is a compelling need to reduce the current timeframe of 60 days for determinations regarding the provision of services in M+C organizations.

Options Considered

In developing this rule, we consulted with beneficiary advocacy groups and the managed care industry concerning several policy options, and reviewed comments received from the public. The groups agreed that the current 60-day timeframe to issue organization and reconsidered determinations was too long. A representative of HCFA's independent contractor, the Center for Health Dispute Resolution (CHDR), also agreed that 60 days was too long for processing determinations.

Beneficiary advocacy groups indicated that the timeframe for rendering standard service-related organization determinations and reconsiderations should be no more than a total of 20–30 days. Advocates reported (and our research supports) that many States require determinations within 30 days. Additionally, beneficiary advocates indicated strong support for the judgment of the United States District Court for the District of Arizona in *Grijalva, et al.* v. *Shalala* (Civ. 93–711, 1997). That case involved the appeal rights of Medicare beneficiaries who were members of HMOs and had their requests for services denied. The court's judgement in *Grijalva* prescribes various procedures to be used for beneficiary appeals in Medicare managed care programs, including the requirement that the HMO make a decision within 5 days, with an opportunity for a 60-day extension if there are exceptional circumstances.

Representatives of the managed care industry recommended that we adopt the National Committee for Quality Assurance's (NCQA) standard of 10 working days (or 14 calendar days) for organization determinations—with an opportunity for an extension. It was also noted that decisions on reconsiderations often take more time than organization determinations. The industry representatives agreed that, in many cases, plans process reconsiderations in less than 30 days, but that often times, additional time is needed to gather information (e.g., medical records). The industry representatives noted that in some instances, allowing extra time to collect information is advantageous to the beneficiary.

Based on all of this information, we are implementing revised requirements from those in part 417 for an M+C organization when it issues standard organization determinations or reconsiderations. These revised requirements include a reduction in the maximum timeframes from 60 days to 14 days for standard organization determinations involving requests for service, and from 60 days to 30 days for standard reconsiderations involving requests for service. (In both cases, 14-day extensions would be permissible under certain circumstances, as discussed above.) More important, §§ 422.568 and 422.590 establish for the first time the requirement that M+C organizations make both their organization and reconsidered determinations as expeditiously as the enrollee's health condition requires. We believe that this emphasis on the health needs of the individual enrollee is consistent with the statutory requirement that determinations be made on a timely basis. Thus, the fact that an organization makes a determination on a service-related issue within 14 days does not necessarily constitute compliance with the regulations if there is evidence that an earlier determination was necessary to prevent harm to the enrollee's health.

7. Reconsiderations by an Independent Entity (§§ 422.592 and 422.594)

Section 1852(g)(4) requires the Secretary to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. HCFA has held such a contract for services from an independent review entity for 9 years. Section 422.592 reiterates the statutory requirement. It also articulates the principle that the independent entity must conduct reviews as expeditiously as the enrollee's health requires, but not to exceed the deadlines specified in its contract with HCFA.

For standard reconsiderations, the contractor historically has been able to process most cases within 30 days. We will require the contractor to meet the standard articulated for M+C organizations at section 422.590; that is, subject to considerations of medical exigency, the contractor must process standard reconsiderations within 30 days, with the possibility of an extension. As part of our new requirement to collect and report information regarding beneficiary appeals, we will monitor all exceptions to deadlines and reasons for delay. In cases in which the delay is due to the failure of the M+C organization to supply the contractor with requested information in a timely manner, we will generally instruct the contractor to find in the beneficiary's favor on any issue that it cannot decide without the information in question. (When an M+C organization has conducted a reconsideration, it presumably will have already collected all the relevant documents and other information needed to make the decision. However, our experience demonstrates that the independent reviewer must sometimes request additional material in order to have a complete record of the dispute.)

For expedited cases, we will require the contractor to make a decision as quickly as the enrollee's condition requires, or within 72 hours (with the possibility of an extension under certain circumstances), in accordance with the expedited reconsideration requirements for M+C organizations under § 422.590(d). As with standard reconsiderations, we will monitor cases that exceed this deadline along with the reasons for the delay. If any delay is due to the failure of the M+C organization to supply the contractor with requested information in a timely manner, we will generally instruct the contractor to find in the beneficiary's favor on any issue that it cannot decide without the information in question.

In order to provide more guidance to both our contractor and the M+C organizations with which we will contract, we will work with them and other interested parties to develop common guidelines for identifying those cases that require immediate attention due to the enrollee's health condition.

These guidelines will build upon, but not be limited to, the criteria that M+C organizations must use to evaluate whether a case should be expedited, currently contained in § 422.570(c)(2). We will issue this information as part of forthcoming manual instructions.

8. Administrative Law Judge (ALJ) Hearings, Departmental Appeals Board (DAB) Hearings, and Judicial Review (§§ 422.600 Through 422.612)

If the independent reviewer's reconsidered determination is not fully favorable to the enrollee, any of the parties listed in § 422.574 has a right to request a hearing before an ALJ of the Social Security Administration if the amount remaining in controversy is $100 or more. (Note that the M+C organization does not have a right to request a hearing before the ALJ.) If the ALJ hearing does not result in a fully favorable determination, any party (including the M+C organization) may request that the Appeals Council of the DAB review the ALJ decision. Following the administrative review process, any party (including the M+C organization) is entitled to judicial review of the final determination if the amount remaining in controversy is $1,000 or more. In establishing the requirements for M+C organizations, we have clarified and adopted the existing requirements in part 417, with one exception. That is, consistent with section 1852(g)(5), we require under § 422.612(a) that a party who wishes to request judicial review of an ALJ's decision must notify the other parties involved.

9. Effectuation of a Reconsidered Determination or Decision (§ 422.618)

Based on public reaction to our April 30, 1997 final rule, we believe there may be a need for explicit regulatory requirements concerning an M+C organization's effectuation of (that is, an organization's compliance with) an appeal determination or decision. Therefore, we are including at § 422.618 (and referencing at § 422.590(a)(1) and (b)(1)) several requirements that constitute a restatement of HCFA's longstanding policy in this regard (with a corresponding timeframe reduction from 60 to 30 days in the case of service-related reconsiderations). (See sections 2405.4 and 2405.5 of the HMO/CMP Manual Transmittal 6, issued in March, 1991.) Specifically, § 422.618(a)(1) requires that if, on reconsideration of a request for service, an M+C organization reverses its adverse organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health 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)). For reconsideration of requests for payment, § 422.618(a)(2) requires that if an M+C organization reverses its adverse 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. Similarly, under § 422.618(b), if an M+C organization's adverse organization determination is reversed in whole or in part by the independent entity's reconsideration 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 the M+C organization receives notice reversing its organization determination. The M+C organization must also inform the independent, outside entity that it has effectuated the decision.

10. Noncoverage of Inpatient Hospital Care—Notice and PRO Review (§§ 422.620 and 422.622)

Under § 422.620, we are largely incorporating the existing requirements under § 417.440(f) concerning notice of noncoverage of inpatient hospital care. Section 417.440(f) requires that if an enrollee in an HMO or CMP is a hospital inpatient, the enrollee remains entitled to inpatient care until he or she receives notice that the care is no longer covered. We have revised this provision, however, to make it clear that inpatient services only continue to be covered until there is a notice of noncoverage in situations in which the hospital admission was authorized in the first instance by the M+C organization or in which the admission constituted emergency or urgently needed care, as described in §§ 422.2 and 422.112(b). This clarification is warranted in light of the fact that an M+C organization offering an M+C non-network MSA or private fee-for-service plan has the right to deny coverage retroactively for a hospital stay involving nonemergency or nonurgently needed care on the grounds that it was not medically necessary. Also, this would make it clear that an M+C organization does not have to make payment under an MSA plan if the deductible has not been satisfied.

Section 422.622 explains our requirements with respect to an enrollee's right to PRO review of a determination by an M+C organization or a hospital that inpatient care is no longer necessary.

Under existing § 417.605, Medicare managed care enrollees have two protections available to them when they believe they are being discharged prematurely from a hospital—immediate PRO Review or an HMO or CMP's internal expedited appeal process. Under § 417.604(b), enrollees may elect one appeal right or the other; exercising one right eliminates the right to the other.

We believe that the PRO review process offers significant advantages to enrollees, most significantly the protection from financial liability for a continued hospital stay until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. Additionally, PROs generally communicate directly with the Medicare enrollee (or authorized representative) during the review, conduct their reviews of an alleged premature discharge within 3 days, and use nurses and physicians to conduct the reviews. In contrast, enrollees who file for an expedited review with the managed care organization are not protected from financial liability during an appeal. The HMO or CMP has 72 hours to conduct the review. If the organization is unable to issue a fully favorable decision to the enrollee, the case file will be forwarded to the independent contractor.

In developing the M+C requirements with respect to this issue, we considered whether the regulations should require enrollees of M+C organizations to exercise their right to immediate PRO review. We consulted with representatives of both the managed care industry and beneficiary advocates. The groups with which we consulted indicated that the immediate PRO review process appears to be a better option for the enrollee. As noted previously, PRO review provides financial protection, direct communication between the PRO and the enrollee, and a decision that is generally rendered more quickly than a managed care plan's determination. However, we were not certain whether we should limit beneficiaries to one option. Particularly in the event that an enrollee misses the deadline for filing with the PRO, we believe that the enrollee should retain the option of filing an expedited appeal with the M+C organization.

Based on this review, we have concluded that the appropriate course is to draft the M+C requirements so as to make it clear that it is in the best interest of an M+C enrollee to request PRO review if the individual believes that he

or she is being discharged from a hospital prematurely. Thus, § 422.622(a)(1) specifies that: ''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. * * * An enrollee who requests immediate PRO review may remain in the hospital without further financial liability [subject to the provisions of § 422.622(c)]'' (until PRO review is completed). Section 422.622(a)(2) then provides that an enrollee who fails to make a timely request for PRO review still has the option of requesting an expedited reconsideration from the M+C organization, although the financial liability protections associated with the PRO review process do not apply. We believe that this regulatory construction makes it clear that enrollees are expected, for their own benefit, to avail themselves of the PRO review process, but does not eliminate the fall-back option of the M+C organization's expedited review process for those enrollees who fail to request PRO review on a timely basis.

We have made further revisions to the language in § 417.605 to adapt this provision to the new M+C MSA and private fee-for-service plan options. As discussed above in connection with the notice of non-coverage requirement in § 422.620, under these plan options, an M+C organization may not be aware that an enrollee has been hospitalized, and has the right to deny coverage of such a hospitalization on the grounds that the stay was not medically necessary. Also, in the case of an enrollee in an M+C MSA plan, the individual may not have reached the deductible under the plan, and therefore payment for medically necessary hospital services shall be applied to the deductible. We thus have made it clear in § 422.622(c)(1) that if an M+C organization did not authorize coverage of a hospital admission, and notifies the enrollee that a continued stay is not covered, the organization is not required to pay for services while the enrollee pursues an appeal with a PRO (that is, unless and until it is determined on appeal that the hospital stay should have been covered under the M+C plan). We have qualified this statement to provide that the M+C organization is obligated to pay for continued services if the enrollee was hospitalized in order to receive emergency services or urgently needed care as described in §§ 422.2 and 422.112(b), since these services do not require prior authorization.

In cases in which the *hospital* makes a determination that hospital services are no longer needed, section 1154(e)(4)(B) of the Act expressly precludes the hospital from charging a Medicare beneficiary for services during the period that a PRO is reviewing an appeal under section 1154(e). We have reflected this statutory provision in § 422.622(c)(2).

11. Conclusion

In developing the organization determination, appeal and grievance requirements for M+C organizations, we have undertaken a broad review of the existing Medicare managed care requirements. We have consulted with representatives of beneficiary advocacy groups and the managed care industry concerning several policy options. We believe that we have included in this interim final rule those improvements that were practical within the short timeframe allotted for rulemaking. In addition to the changes made in this rule, we intend to publish a notice of proposed rulemaking in the near future to implement a variety of other improvements in the M+C dispute resolution process.

Therefore, we welcome comments, concerns, and ideas on all issues discussed in this interim final rule, as well as on the overall organizational changes incorporated into these regulations. In particular, as noted above, we would appreciate comments on whether HCFA should specify requirements (such as timeframes) for meaningful grievance procedures. We also are seeking additional comments on establishing effective and efficient parameters as to when a reduction in services (for example, a reduction in prescription dosage, skilled nursing facility coverage, home health care or outpatient visits) constitutes a denial that gives rise to an obligation to provide written notice. Comments are also welcome on whether notification requirements should apply in all instances of service discontinuations, as opposed to only when an enrollee indicates that he or she disagrees with such a discontinuation, as provided under § 422.566(b)(4). Finally, we would appreciate input on categories of meaningful data elements for reporting plan-level grievances and appeals. We believe such comments can assist with our data collection and reporting efforts (as required by the BBA) and in promoting consistency at the plan level in data collection and reporting. We welcome all suggestions for other improvements to the M+C grievance, organization determination and appeal processes.

N. Medicare Contract Appeals

Subpart N of this interim final rule sets forth procedures for making and reviewing the following contract determinations: (1) A determination that an entity is not qualified to enter into a contract with HCFA under Part C of title XVIII of the Act; (2) a determination to terminate a contract with an M+C organization; and (3) a determination not to authorize a renewal of a contract with an M+C organization. Pursuant to at section 1856(b)(2), which provides for the adoption of standards under section 1876 to implement analagous provisions in the new Part C, the procedures set forth in subpart N of part 422 are for the most part modeled after the contract appeal procedures currently in place with regard to HMO and CMP contracts under section 1876, which are set forth at 42 CFR part 417 subpart R. We describe below the provisions of new subpart N of part 422 that are not identical to 42 CFR part 417.

Section 422.641 sets forth the contract determinations that are subject to the reconsideration and appeals procedures in subpart N.

Section 422.644(a) specifies that when HCFA makes a contract determination, it provides the M+C organizations written notice specifying reasons for the determination and M+C organization rights pursuant to a reconsideration.

Under, § 422.644(d) a HCFA notice that it has decided not to authorize an M+C organization contract renewal is sent to the M+C organization by May 1 of the current contract year. (Note that while this notice informs an M+C organizations of its right to appeal a decision not to authorize a renewal, a contract will not be renewed unless an affirmative notice *authorizing* renewal is sent by HCFA. *See* § 422.506(b)(2).) The May 1 deadline specified above should afford HCFA enough time to consider any M+C organization's request for reconsideration and still afford adequate time for HCFA to ensure the accuracy of its printed and electronic material utilized in the annual health fair.

If HCFA decides to terminate a contract under § 422.644(c) for reasons other than those specified at 422.510(a)(5) it must provide notice to the M+C organization by mail at least 90 days before the intended date of the termination. Consistent with section 1857(h)(2), which provides for immediate termination where there is an ''imminent and serious risk'' to enrollee health and pursuant to our rulemaking authority at section 1856(b)(1), in § 422.644(c) we also provide a separate notice timeframe for immediate terminations discussed in

§ 422.510(a)(5). See section K of this preamble. Pursuant to violations described in § 422.510(a)(5), HCFA will notify the M+C organization in writing that its contract has been terminated effective the date of the termination decision by HCFA. We believe that in instances where the life and physical well being of beneficiaries is in jeopardy, HCFA must have the ability to immediately sever its relationship with an M+C organization in order to protect beneficiaries and to safeguard taxpayer confidence in HCFA's administration of the Medicare program.

Section 422.646 states that initial contract determinations are final and binding unless the determination is reconsidered in a manner consistent with applicable requirements described in § 422.648. In § 422.650(b) we have shortened the deadline for filing a request for reconsideration to 15 days from the sixty days allowed for HMOs and CMPs under § 417.650(b), and have eliminated the provision made in § 417.650(c) for a deadline extension for good cause. We believe the time frames afforded under § 422.650 still provide M+C organizations sufficient time to prepare a request for reconsideration of the contract determination at issue, should the organization decide to do so.

As in the case of the deadline for requesting reconsideration, and based on our rulemaking authority at section 1856(b)(1), in § 422.662(b), we have shortened the 60 day time period for requesting a hearing under § 417.662(b) to 15 days. We also have again eliminated ''good cause'' extension authority that was found in § 417.662(c).

Like § 417.664(a), § 422.664(a) provides that the effective date of a determination to terminate a contract will be postponed until after a final decision is rendered on any M+C organization appeal. Section 422.664(b) also follows § 417.664(b) in providing that a request for a hearing will *not* postpone a decision not to authorize a contract renewal unless HCFA finds an extension of the contract past its expiration date consistent with the purposes of Part C. There are two significant differences between § 417.664 and § 422.664, however. First, as discussed below, § 417.664 provides that in the case of a termination only, the general rule is that the termination will be postponed until after an additional post-hearing decision level of review required under section 1857(h)(1)(B). Second, § 422.664(c) implements the ''imminent and serious risk to health'' exception in section 1857(h)(2), under which a termination can take effect immediately, and will not be postponed while an appeal is pursued. Specifically, when a contract termination decision is based upon § 422.510(a)(5), discussed in section K above, the termination is effective immediately. While the M+C organization still has the right to appeal the termination, this appeal will not prevent the termination from taking effect.

In § 422.670, pursuant to our rulemaking authority at section 1856(b)(1), we have added a requirement that the hearing officer establish a time and place for the hearing within 30 days of the date of their receipt of the request for a hearing. Again, this time constraint has been added because we believe it is necessary to impose time-weighted discipline on the reconsideration process that strengthens HCFA's enforcement capabilities while simultaneously enhancing beneficiary protections. Changing the time frame from the open-ended language provided under § 417.670 to the 30-day time frame provided at § 422.670 accomplishes these goals.

In § 422.692, we provide in the case of termination decisions only for an appeal from the hearing decision, as required under section 1857(h)(2) before a termination can take effect. We have provided for review of a hearing officer's decision by the Administrator, under similar procedures to those used for the Administrator's review of decisions of the Provider Reimbursement Review Board pursuant to § 405.1875.

O. Intermediate Sanctions

The M+C organization actions subject to intermediate sanctions and civil money penalties are substantially the same as those established at § 417.500 for section 1876 contracting plans. However, there are some exceptions. Since the 50/50 enrollment requirement has been dropped, so have the accompanying intermediate sanctions.

The BBA also contains additional sanction authority not found in § 417.500, which we are implementing in subpart O. First, the BBA retains and modifies new section 1876 intermediate sanction and civil money penalty authority originally enacted in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This authority has not been implemented in § 417.500. Under this new authority (in section 1876(i)(1) for HMOs and CMPs and in section 1857(g)(3) for the M+C program), intermediate sanctions and civil money penalties can be imposed on the same grounds upon which a contract could be terminated. *See* discussion of contract termination in sections K. and N. above. Under the section 1876 provision, the procedures now found in section 1857(h)(1), discussed in section N. above, applied to the new HIPAA sanction authority, and had to be followed before sanctions based upon this new HIPAA authority could be imposed. Under the BBA, however, sanctions based on the grounds for termination in section 1857(c)(2) can be imposed on the same terms as the sanctions in § 417.500. *See* section 1857(g)(3). As discussed above in section K., in § 422.510(a)(4) through (a)(11), we have identified specific M+C organization behaviors that we believe meet one of the broad grounds for termination in section 1857(c)(2). Under the authority in section 1857(g)(3) to impose sanctions where the grounds in section 1857(c)(2) exist, intermediate sanctions can be imposed for any of the violations identified in § 422.510(a), and we so provide in § 422.752(b).

Finally, private fee for service plans are subject to intermediate sanctions if they fail to enforce the balance billing limit that applies to charges to plan members by contracting providers. See discussion of these provisions in section IV. of this preamble.

The process for imposing all of the M+C intermediate sanctions will largely be the same as established under § 417.500. Under this process, when HCFA determines that a sanctionable violation has occurred, it notifies the M+C organization that enrollment and marketing must be suspended (or, alternatively, in the case of some violations, payment for new enrollees will be suspended) in 15 days, unless the organization provides evidence that HCFA's determination is incorrect. There is an exception to this 15 day delay in the effective date of the sanctions if HCFA determines that the M+C organization's conduct poses a serious threat to an enrollee's health and safety. *See* § 422.756(d)(2). In addition to or in place of these intermediate sanctions, civil money penalties may be imposed for the same underlying violations. For any of the violations that were previously set forth in § 417.500, and are now in § 422.752(a), the Office of Inspector General imposes civil money penalties in accordance with 42 CFR part 1003. In the case of the new HIPAA sanction authority discussed above, HCFA imposes civil money penalties, with the exception of a determination under § 422.510(a)(4), based upon fraudulent behavior by an M+C organization. In this latter case, OIG imposes civil money penalties.

P. Technical and Conforming Changes

This interim final rule makes a number of technical and conforming changes to part 422 subpart H (which was established by an interim final rule published on April 14, 1998 (63 FR 18124) and amended by an interim final rule published on May 7, 1998 (63 FR 25360) For example, we remove the definition of ''health care provider'' from subpart H. We do this because this rule establishes a definition of ''provider'' in subpart A of part 422 for purposes of the entire part that is exactly the same as the definition of ''health care provider'' appearing in subpart H. Further, as a conforming change, we then change ''health care provider'' wherever it appears in subpart H to ''provider.''

In addition to the additions and revisions to part 422 of our regulations discussed throughout this document, this interim final rule also makes a number of technical and conforming changes to the following parts of 42 CFR: 400, 410, 411, and 417. These changes, which are generally in the form of redesignations and nomenclature changes, are made in order to bring our regulations into conformity with the provisions of the section 4001 through 4006 of the BBA.

We have also made a conforming change to 42 CFR part 403 ''Special Programs and Projects,'' with regard to Medicare supplemental policies. As Medicare does not cover the total cost of providing medical care, approximately 75 percent of Medicare beneficiaries purchase or have available through their own, or a spouse's employment or former employment, some type of private supplemental health insurance coverage. This kind of insurance helps to pay for expenses, services, and supplies that Medicare either does not cover or does not pay in full such as coinsurance or deductible charges, prescription drugs, and some long term care services. This coverage is ordinarily referred to as Medicare supplemental (Medigap) insurance. The BBA, in section 4003, provides that an M+C plan is not considered a Medicare supplementary policy. Therefore, we are revising § 403.205 to specify that a Medicare supplemental policy does not include a M+C plan. We are aware of other provisions in that statute affecting the Medigap area, but those are included or will be covered under the National Association of Insurance Commissioners (NAIC) Model Standards in line with existing § 403.210. NAIC works with us to annually update the Model Standards with regard to changes to the Medicare supplemental insurance area.

Q. Transition Information for Current Medicare Program

Section 4002 of the BBA included a number of provisions that were effective upon enactment for eligible organizations with section 1876 contracts or section 1833 agreements or that would alter the requirements for those contractors that remained in force following the implementation of the M+C program. The provisions that were effective upon enactment were conveyed to current contractors through operational policy letters (OPLs) numbered 61, 63, and 65 and available to the public on HCFA's Internet homepage. Most of the provisions convey automatically with the publication of the Part C regulations, either contained in the newly-established part 422 or contained in conforming changes to part 417, while others simply created operational impacts during the transition year of 1998.

The BBA in section 4002(a) immediately changed the required enrollment composition of 50 percent Medicare and Medicaid, and 50 percent commercial under section 1876 to: (1) Consider only Medicare members for 50 percent of the enrollment, and (2) permit waiver of the requirement when it is ''in the public interest.'' All enrollment composition requirements for Medicare contractors are eliminated beginning with contract periods on or after January 1, 1999.

The BBA in section 4002(j) changed the definition of a health care prepayment plan (HCPP) to mean: (1) An organization that is Union or Employer sponsored; or (2) an organization that does not provide, or arrange for the provision of any inpatient hospital services. Current HCPPs must meet this definition on January 1, 1999 and new 1998 applicants must meet the definition as of the effective date of the HCPP agreement. Also, as of January 1, 1999, HCPPs are not required to meet Medigap requirements.

The BBA also affected section 1876 cost contracts. Upon enactment of the BBA (August 5, 1997), the Secretary may not enter into new section 1876 cost contracts, except for current HCPPs that converted to section 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2002.

III. Medicare+Choice MSA Plans

A. Background

As noted above, among the type of M+C options available under section 1851(a)(2) of the Act is an M+C MSA plan, that is, a combination of a high deductible M+C insurance plan and a contribution to an M+C MSA. Section 1859(b)(3)(A) of the Act defines an MSA plan as an M+C plan that:

- Provides reimbursement for at least all Medicare-covered items and services (except hospice services) after an enrollee incurs countable expenses equal to the amount of the plan's annual deductible.
- Counts for purposes of the annual deductible at least all amounts that would have been payable under original Medicare if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.
- After the annual deductible is reached, provides a level of reimbursement equal to at least the lesser of actual expenses or the amount that would have been paid under original Medicare if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

Eligible individuals may enroll in M+C MSA plans effective January 1, 1999. Section 1859(b)(3)(B) sets the maximum annual deductible under an M+C MSA plan for 1999 at $6,000, with changes for future years to be based on the national per capita M+C growth percentage established under section 1853(c)(6). (See section II.F of this preamble.) In this interim final rule, we are seeking comment regarding establishing, pursuant to our general authority under section 1856(b)(1), a minimum deductible under an M+C MSA plan. As discussed below, one possibility would be to establish a minimum deductible equal to the projected actuarial value of the average per capita copayment under original Medicare, rounded to the nearest $50.

Section 4006 of the BBA adds new section 138 of the Internal Revenue Code of 1986 containing Internal Revenue Service (IRS) rules concerning M+C MSAs. In general, an M+C MSA is a tax-exempt trust created solely for the purpose of paying the qualified medical expenses of the account holder. The account may be established only in connection with an M+C MSA plan, and must consist only of contributions from HCFA under the M+C program or of

transfers from another M+C MSA, if an enrollee has set up more than one M+C MSA. Section 138 also sets forth IRS rules concerning the distribution of MSA funds and tax penalties associated with the distribution of funds from an M+C MSA for purposes other than paying the qualified medical expenses of the account holder. (These provisions are discussed below in section III.J of this preamble.)

In establishing the M+C MSA option, Congress specified under section 1851(b)(4) of the Act that the opportunity to enroll in an M+C MSA plan was available on a demonstration basis to up to 390,000 enrollees through December 31, 2002. The Secretary is charged with regularly evaluating the impact of permitting enrollment in M+C MSA plans and with submitting a report to Congress by March 1, 2002, concerning the effects of the M+C MSA program and whether it should be extended beyond 2002.

The introduction of M+C MSAs builds upon the private market MSA demonstration program now available to small employers and the self-employed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Like the HIPAA demonstration, the BBA conference report (H.R. 105–217, pg. 585) indicates that the introduction of M+C MSAs is premised on the need for beneficiaries to play a greater role in the health care purchasing decision. M+C MSAs offer beneficiaries incentives to ensure that the health care resources they need are allocated in an efficient manner. This increased consumer control is believed to have potential for discouraging the overutilization of health services.

In implementing the BBA provisions concerning the M+C MSA demonstration, our primary objective is to allow a true test of the potential benefits of the MSA concept to the Medicare program and its beneficiaries. Thus, as with other parts of the M+C regulations, an underlying design principle has been to preserve as much flexibility as possible for organizations and providers in terms of service delivery arrangements, while still building in the protections intended under the BBA for M+C MSA enrollees and the Medicare trust fund. For the convenience of the reader, all portions of the M+C regulations that specifically concern M+C MSA plans and accounts are discussed below in this preamble; however, the M+C MSA regulations do not constitute a separate subpart of new part 422. This is because, except as noted below, the general M+C requirements throughout part 422 apply equally to M+C organizations that offer M+C MSA plans; thus it would be redundant to repeat all applicable requirements in a separate M+C MSA subpart.

B. General Provisions (Subpart A)

Sections 422.2 and 422.4 set forth several definitions for terms connected with M+C MSA plans, including ''M+C MSA,'' ''M+C MSA plan,'' and ''MSA trustee.'' As noted in section II.D of this preamble, we also distinguish between a ''network'' and a ''non-network'' M+C MSA plan. The definitions consist of general meanings for these terms as used in the BBA and do not impose specific requirements. Thus, the definition for an MSA references the applicable requirements of sections 138 and 220 of the Internal Revenue Code, and the M+C MSA plan definition references the applicable requirements of new part 422.

The theory behind the new M+C MSA option is that a beneficiary will pay a lower monthly premium for a ''catastrophic'' insurance policy with a high deductible, and use the money deposited in his or her M+C MSA account to cover expenses during the extended period prior to this high deductible being reached. This concept is reinforced by the fact that Congress excluded from eligibility for M+C MSA plans individuals with ''first dollar'' health care coverage (such as, Medicaid-eligible individuals'—see discussion below), who would not be required to incur expenses during the significant period of time expected to transpire before the high M+C MSA plan deductible is met. This is also the reason that Congress amended the Medigap statute to preclude insurers from selling policies to enrollees in M+C MSA plans that would cover costs incurred before the high deductible is met. Indeed, the legislative history expressly refers to ''[p]rohibit[ing] the sale of certain [Medigap] policies to a person electing a *high deductible* plan,'' meaning an MSA plan. (H.R. Rep. No. 105–217, pg. 654 (1997). Emphasis added).

Although Congress did not include a minimum deductible amount, we believe that the statutory scheme, and the above-quoted reference to a ''high deductible plan'' in the Conference report, clearly *imply* that MSA plans would have a higher deductible than other plans. As noted above, we are seeking comment on providing for a minimum deductible based on the actuarial value of the average per capita cost-sharing under original Medicare rounded to the nearest $50. For 1999, this amount is $1,000. (Clearly, any deductible *lower* than the actuarial value of what original Medicare beneficiaries pay is *not* a ''high'' deductible.) We believe that a minimum deductible amount could ensure that M+C MSA plans comport with the ''high deductible'' design envisioned by Congress, without inappropriately limiting organizations' flexibility in designing M+C MSA plans. Without such a deductible, however, we are concerned that an organization could purport to offer an ''M+C network MSA plan'' that had such a low deductible that it would be impossible to distinguish from a coordinated care plan, although the plan would not be subject to the rules that Congress intended be applied to coordinated care plans. Therefore, in deciding whether to institute a minimum deductible for M+C MSA plans, we intend to examine any evidence that such abuses may be taking place, in addition to our review of public comments on the issue.

The only other general requirement concerning M+C MSA plans is the incorporation under § 422.4(a)(2) of the statutory provision (section 1851(a)(2)(B)) that one of the available alternatives under the M+C program is the combination of an M+C MSA plan with a contribution into an M+C MSA. Consistent with the statute, any State-licensed risk-bearing entity could offer an M+C MSA plan, whether it is an HMO offering an ''M+C network MSA plan'' under which beneficiaries are limited to a limited network of providers for covered services after the deductible is met, or an indemnity plan covering services on a fee-for-service basis after the deductible is met.

C. Eligibility, Election and Enrollment Rules (Subpart B)

1. Eligibility and Enrollment (§ 422.56)

Any individual who is entitled to Medicare under Part A, is enrolled under Part B, and is not otherwise prohibited (such as an ESRD patient), is eligible to enroll in an M+C plan. However, the statute places several limitations on eligibility to enroll in an M+C MSA plan. These limitations are set forth at § 422.56 of the regulations. Section 422.56(a) indicates that M+C MSA plans are established on a demonstration basis and incorporates the statutory provisions of section 1851(b)(4), that is:

- No more than 390,000 individuals may enroll in M+C MSA plans.
- No individual may enroll on or after January 1, 2003, unless the enrollment is a continuation of an enrollment already in effect as of that date.
- No individual may enroll or continue enrollment for any year unless

he or she can provide assurances of residing in the United States for at least 183 days during that year.

The 390,000 limit represents approximately 1 percent of the Medicare population. We do not intend to apply any State or regional limits on enrollment in M+C MSA plans, although we will monitor the number of enrollees on an ongoing basis. We believe it is unlikely that the number of applications for M+C MSAs will reach 390,000 in the first enrollment period, November, 1998. If necessary, however, we will accept applications for enrollment in M+C MSA plans on a first-come, first-served basis, with the first 390,000 applicants being allowed to enroll. We will notify organizations offering M+C MSA plans directly should the enrollment cap be reached.

The only restrictions on enrollment in M+C MSA plans under § 422.56(b) and (c) are those directly contemplated under section 1851(b)(2) and (3) of the statute. Specifically, § 422.56(b) states that an individual who is enrolled in a Federal Employee Health Benefits Program (FEHBP) plan, or is eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD), may not enroll in an M+C MSA plan. The statute provides that the restriction on FEHBP enrollment may be eliminated if the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies to ensure that the enrollment of FEHBP participants will not result in increased expenditures for health benefit plans. We intend to apply this same test for the enrollment restrictions that apply to VA and DoD-eligible individuals. In addition, § 422.56(c) incorporates the statutory prohibition under section 1851(b)(3) on enrollment in M+C MSA plans by individuals who are eligible for Medicare cost-sharing under Medicaid State plans.

Section 422.56(d) sets forth several additional restrictions on enrollment in M+C MSA plans that we believe are clearly consistent with statutory intent. These restrictions are discussed in detail below in section III.D.2 of this preamble, in the discussion of supplemental benefits under an M+C MSA plan.

2. Election (§ 422.62)

Section 1851(e) of the Act establishes general rules concerning the time periods when a beneficiary may elect to enroll in an M+C plan, with special rules for M+C MSA plans set forth at section 1851(e)(5). Based on these provisions, § 422.62(d) specifies that an individual may elect an MSA plan only during one of the following periods;

- An initial election period, that is, the 7-month period beginning 3 months before the individual is first entitled to parts A and B of Medicare.
- The annual coordinated election period in November of each year.

Unlike for other M+C plans, an individual may discontinue election of an M+C MSA plan only during the annual coordinated election period. Thus, effective January 1, 1999, enrollees in M+C MSA plans are ''locked in'' for 1 year, or for the remainder of the calendar year for elections during an initial election period that take effect other than on January 1. This lock-in rule contrasts sharply with the rules for other types of M+C plans, which provide for continuous open enrollment and disenrollment through December 31, 2001.

There are two exceptions to this lock-in rule. First, as specified under section 1851(e)(5)(C) and codified at § 422.62(d)(2)(ii), an individual who elects an M+C MSA plan during an annual election period in November of a given year, and has never before elected an M+C MSA plan, may revoke that election by submitting to the organization offering the plan a signed request or by filing the appropriate disenrollment form by December 15 of that year. In addition, we are providing at § 422.58(d)(2) that an individual may disenroll from an M+C MSA plan during the special election periods prompted by circumstances such as termination of the plan, change in the individual's place in residence, etc., as spelled out under § 422.62(b). As discussed in detail in section II.B of this preamble, section 1851(e)(4) provides that these special election periods are to take effect on January 1, 2002, in concert with the initial effective date for the lock-in rules for M+C plans other than MSA plans. Given that the lock-in rule for M+C MSA plans takes effect on January 1, 1999, we believe it is appropriate that the protections afforded by the special election period should be applicable at that time to individuals who elect M+C MSA plans.

3. Information About the M+C Program (§ 422.64)

Section 1851(d) and § 422.64 address the requirement that M+C organizations must provide the information that HCFA needs to help beneficiaries make informed decisions with respect to their available choices for Medicare coverage. The only M+C MSA-specific requirement involved here (also applicable for M+C private fee-for-service plans) is that the description of an M+C MSA plan's benefits should include differences in cost-sharing, premiums, and balance billing, as compared to other types of M+C plans (see § 422.64(c)(7)(iv)). We believe that the purpose of this requirement is to make sure that beneficiaries are aware of the fundamental differences between M+C MSA or private fee-for-service plans and other types of M+C plans, rather than to present detailed information concerning the benefits, premiums, and copayments for all other *specific* M+C plans in the area. For compliance purposes, then we intend to evaluate the information submitted by organizations for MSA plans in these terms. We note that we would apply the same standard in determining compliance with the requirement of § 422.110(b)(2)(ii) concerning an organization's responsibility to disclose to its enrollees a description of the benefits available under other types of plans.

D. Benefits (Subpart C)

1. Basic Benefits Under an M+C MSA Plan (§ 422.102)

Section 422.102 incorporates the statutory requirements for M+C MSA plans defined under section 1859(b)(3) of the Act, as outlined above. Thus, § 422.102(a) specifies that an MSA organization offering an MSA plan must make available to an enrollee, or provide reimbursement for, at least all Medicare-covered services (except for hospice services) after the enrollee's countable expenses reach the plan's annual deductible. We note that section 1859(b)(3)(A)(i) only uses the phrase ''provides reimbursement for'' the covered services, but the intent of the statute clearly includes situations where a network M+C MSA plan would either furnish the services directly or arrange for provision of the services. We believe that the phrase ''make available to the enrollee'' accounts for either of these situations.

Section 422.102(b) then indicates that countable expenses must include the lesser of actual costs or all the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation. In accordance with section 1859(b)(3)(A)(ii) of the statute, under each MSA plan, an organization would have the discretion to define what it considers countable expenses, subject to the statutory threshold of the Medicare

payable amount. We would envision that M+C organizations offering MSA plans could provide that countable expenses would include a considerably broader range of services than does Medicare, including expenses for services that often would constitute supplemental health care benefits under other M+C plans, such as prescription drugs, dental services, or preventative care services. (As discussed below, section 1852(a)(3)(B)(ii) prohibits an M+C MSA plan from providing most supplemental health care benefits before an individual reaches the annual deductible. However, counting the expenses for such services towards the annual deductible is permissible.) An M+C organization could also choose to provide that countable expenses under an M+C MSA plan would include a provider's full charges, rather than just the amount payable under the Medicare payment rate schedules.

Section 422.102(c) provides that after the deductible is met, an M+C MSA plan pays the lesser of 100 percent of either the actual expense of the services or of the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation. As discussed below in section III.F., M+C balance billing protections do not apply in this situation. Thus, unless explicitly included in the terms of the M+C MSA plan, any amounts billed in excess of 100 percent of this Medicare allowed amount would be the responsibility of the enrollee. In this provision, we have interpreted the language in section 1859(b)(3)(A)(iii)(II) referring to the ''amounts that would be paid (without regard to any deductibles and coinsurance) under parts A and B'' to mean the amount that would be paid if there *were no* beneficiary liability provided for in the form of deductibles and coinsurance—in other words, the full amount of the Medicare rate. We have put this a different way in § 422.102(c), providing that the amount in question *includes* the amounts that the beneficiary would pay in deductibles and coinsurance. We considered interpreting ''without regard to any deductibles and coinsurance amounts'' to mean without *counting* the amounts original Medicare beneficiaries would pay in deductibles and coinsurance. We decided, however, that after a deductible of up to $6000, and with balance billing permitted, M+C MSA plans should be required to pay the full Medicare payment rate once the deductible is met. Again, an organization would be free to offer expanded benefits under an M+C MSA plan beyond the minimum requirements after the deductible is met, including supplemental benefits that it could not offer before the deductible is met.

Section 422.103(d), concerning the annual deductible, is based on section 1859(b)(3)(B). As the statute specifies, the maximum annual deductible for an MSA plan for contract year 1999 is $6,000. In subsequent contract years, the maximum deductible may not exceed the maximum deductible for the previous contract year increased by the national per capita M+C growth percentage for the year. In calculating the maximum deductible for future years, HCFA will round the amount to the nearest multiple of $50.

Another issue we examined in developing the regulations concerning the annual deductible for M+C MSA plans was whether to establish specific requirements on deductibles for individuals who enroll in M+C MSA plans effective other than on January 1 of a given year, that is, individuals who turn 65 and make midyear elections of an M+C MSA plan within their initial enrollment periods. Our primary alternatives on this issue were to: (1) require all M+C MSA plans to ''prorate'' the deductible, that is, reduce the amount of the deductible for midyear enrollees in proportion to the amount of the calendar year remaining or (2) allow insurers the flexibility to decide for themselves how to deal with partial year enrollees. Although the prorating alternative would reduce the cost-sharing burden on beneficiaries during the first partial year, and thus possibly make it more likely that an individual whose initial election period occurs late in the year would choose an M+C MSA plan, this option has several drawbacks. Few if any insurance carriers now prorate their deductibles for midyear enrollees, and we are reluctant to implement such an approach unilaterally, particularly since we have no evidence that the costs of implementing a prorated system would be exceeded by the benefits to beneficiaries in terms of reduced risk. Such a requirement could limit interest in establishing M+C MSA plans, if insurers believed that they could be placed at risk of the enrollment of individuals with low prorated deductibles who anticipate high cost short-term health care needs.

Instead, we decided to allow insurers to decide for their M+C MSA plans how to deal with partial year enrollees. This should foster flexible approaches to this situation, with organizations making decisions based on their perceptions of the cost of implementation and the benefits to them in terms of attracting prospective enrollees. For example, an organization's plans could include a ''carry-over'' procedure. Under such a procedure, bills incurred during a specified period of one calendar year could be carried over to the following year and applied to the next year's deductible.

2. Supplemental Benefits (§§ 422.102 and 422.103)

Section 422.102 addresses the general M+C rules on supplemental benefits. Unlike other M+C plans, MSA plans are not permitted to include any mandatory supplemental benefits and are limited in terms of the optional supplementary benefits that can be offered. In accordance with section 1852(a)(3)(B)(ii), § 422.103(a) specifies that an M+C MSA plan generally may not provide supplemental benefits that cover expenses that count toward the annual deductible. In addition, section 4003(b) of the BBA added new section 1882 to the Act to prohibit the sale of most supplementary health insurance policies to individuals enrolled in M+C MSA plans. The only exceptions to this rule are spelled out in section 1882(u)(2)(B). These exceptions apply both for purposes of the prohibition on selling freestanding supplementary health insurance (or ''Medigap'' insurance), and for purposes of ''optional supplemental benefits'' offered under M+C MSA plans. These exceptions are reflected in § 422.103(a)(2). Under § 422.103(a)(2), the only types of policies that an enrollee in an M+C MSA plan may purchase that cover expenses that may count toward the annual deductible are as follows:

- A policy that provides coverage for accidents, disability, dental care, vision care, or long-term care.
- A policy in which substantially all coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, or liabilities relating to use or ownership of property.
- A policy that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) for hospitalization. (Note that the fact that an organization offering an M+C MSA plan permits a particular expense to count toward the plan's annual deductible does not necessarily mean that such expenses are considered ''qualified medical expenses'' by the IRS.)

The above restrictions on optional supplemental benefits and Medigap

coverage under section 1882, combined with Congress' explicit exclusion of individuals with ''first dollar'' health coverage under government programs (Medicaid, VA benefits, and FEHBP benefits—see section 1851(b)(2) and (3) and discussion above), make it clear that Congress intended that individuals enrolled in M+C MSA plans would be required to use the money in their M+C MSA accounts to pay for services until the ''high deductible'' under the plan is met. While Congress addressed government programs under which expenses during the deductible would be covered, and prohibited the *sale* of *new* private supplemental insurance that would cover such deductible amounts (whether an optional supplemental benefit offered under an M+C MSA plan, or a freestanding ''Medigap'' policy), some categories of individuals with first dollar coverage that would cover expenses that would count toward an M+C MSA plan deductible would remain eligible to enroll in M+C MSA plans absent a regulatory prohibition.

We believe that it would give effect to clear congressional intent to expand the categories of individuals ineligible to enroll in M+C MSA plans to include the additional categories that Congress neglected to include. For example, while Congress prohibited the *sale* of private insurance covering expenses that count toward an M+C MSA deductible, it did not address individuals who may already *have* such coverage, including those who have first dollar Medigap coverage through their employer. In addition, individuals who have elected hospice coverage are also eligible for first dollar Medicare payment, without any qualification in the case of MSA plans. (See section 1853(h)(2)(A).) This is also inconsistent with Congress' intended design for the M+C MSA option. Pursuant to our authority under section 1856(b)(1) to establish M+C standards by regulation, we accordingly are providing in § 422.56(d) that individuals with such health benefits are ineligible to elect an MSA plan.

As mentioned above, M+C MSA plans may not provide any supplemental benefits, except those exempted, covering expenses that count towards the annual deductible. Once the deductible is reached, however, there are no limitations on the supplemental benefits a plan may offer, as long as the plan satisfies the requirements concerning making available basic part A and B Medicare services. We believe that a market may emerge for supplemental insurance policies in connection with M+C MSA high deductible insurance policies. We considered the possibility of establishing one or more sample benefit plans for use in conjunction with M+C MSA plans, similar to the limited number of standardized Medigap plans that are now offered. Although we are not doing so at this time, we welcome comments on the need for such uniform plans.

E. Quality Assurance (Subpart D)

Like for other M+C plans, an organization offering an MSA plan must have an ongoing quality assessment and performance improvement program for the services furnished to M+C enrollees under the plan. As discussed in detail above, the quality assurance requirements that apply to an M+C MSA plan depend on whether the plan is a network model plan, that is, a plan that provides benefits either through contracting providers or under arrangements made by the plan, or a non-network plan. Consistent with section 1852(e)(2) of the Act, a network model M+C MSA plan must meet requirements similar to those that apply to all other M+C coordinated care plans (with the exception of the achievement of minimum performance levels); the statute and regulations establish different requirements for non-network M+C MSA plans. See section II.D of this preamble, and § 422.152 of the regulations, for more information on this subject. Also, see section II.D. of the preamble and § 422.154 for information on the external review requirements that apply to network M+C MSA plans. Under § 422.154(b)(1), the external review requirements do not apply to non-network M+C MSA plans.

F. Relationships Between Plans and Participating Physicians (Subpart E)

For the most part, subpart E of new part 422 does not establish any requirements that are specific to MSA plans. However, § 422.214, ''Special rules for services furnished by noncontract providers,'' does have implications for enrollees in MSA plans. The provisions of this section are based on section 1852(k) of the Act, beginning with the requirement under section 1852(k)(1) that for enrollees in M+C coordinated care plans, a physician that does not have a contract with the plan must accept as payment in full an amount no greater than the amount the physician could collect if the individual were under the fee-for-service Medicare program, including any applicable deductibles, coinsurance, or balance billing permitted by the plan. (See section 1848(g) concerning the Medicare fee-for-service rules on limiting charges.) Section 1852(k)(2) then establishes balance billing limits for M+C private fee-for-service plans, as discussed in detail in section IV of this preamble and § 422.216; however, the statute contains no balance billing protections for enrollees in M+C MSA plans.

It is clear from the legislative history of the provisions imposing balance billing limits that the omission of any limits under M+C MSA plans was not inadvertent. Page 609 of the Conference Report (H.R. Rep. No. 105–217) refers to the House bill, which included across the board limits on what could be collected. The Senate amendment is described as including a ''[similar provision except that it *excepts from the requirement* * * * a[ ] fee-for-service plan as well as *an MSA plan*.'' The ''conference agreement'' is then described as ''including] the Senate provision with an amendment to provide for application of the provision to Medicare+Choice *fee for service plans*. * * *'' Thus, Congress clearly indicates that it provided for a balance billing limit for M+C coordinated care plans and private fee-for-service plans (albeit a different limit), but *not* for M+C MSA plans. On page 611, the Conference Report expressly states that the House bill provided that an ''MSA plan * * * would not be subject to the * * * limitations on balance billing.'' The conference agreement indicates that it ''includes'' this ''House bill'' position. In light of the absence of any statutory provision for a limit on balance billing under M+C MSA plans, and these clear statements of congressional intent that there be no such limits, we have not provided for any limits on balance billing under M+C MSA plans in these regulations.

G. Payments Under MSA Plans (Subpart F)

Section 1853 describes the method to be used to calculate the annual M+C capitation rate for a given payment area (see section II.F of this preamble and § 422.254). We apply the same methodology in determining the annual capitated rate associated with each M+C MSA plan enrollee. Thus, for calendar year 1999, the capitated rate will continue to be adjusted for the age, gender, Medicaid-eligibility, disability, institutional status, and employment of the individual beneficiary, with risk adjustment scheduled to begin on January 1, 2000, as also discussed in detail in section II.F of this preamble.

The special rules concerning the allocation of the M+C capitated amount for individuals enrolled in M+C MSA plans are set forth at section 1853. In

general, HCFA will allocate the capitated amount associated with each M+C MSA enrollee as follows:

- On a lump-sum basis at the beginning of the calendar year, pay into a beneficiary's M+C MSA an amount equal to the difference between the annual M+C capitation rate for the county in which the beneficiary resides and the M+C MSA premium filed by the organization offering the MSA plan (this premium is uniform for all enrollees under a single M+C MSA plan.) This results in a uniform amount being deposited in an M+C MSA plan enrollee's M+C medical savings account(s) in a given county, since the uniform premium amount will be subtracted from the uniform county-wide capitation rate for every enrollee in that county.
- On a monthly basis, pay to the M+C organization an amount equal to one-twelfth of the difference, either positive or negative, between the annual M+C capitation payment for the individual and the amount deposited in the individual's M+C MSA.

Section 422.262 contains the regulations concerning the allocation of Medicare trust funds for enrollees in M+C MSA plans. First, under § 422.262(a), an enrollee must establish an M+C MSA with a qualified trustee or custodian. An enrollee may establish more than one account, consistent with section 1853(e)(2)(B) of the Act, but must designate the particular account to which payments by HCFA are to be made. As specified under § 422.262(b), a trustee can be a bank, insurance company, or anyone approved by the IRS to be a trustee of Individual Retirement Accounts. Section 422.262(b) also requires that M+C MSA trustees must register with HCFA, agree to comply with IRS rules concerning MSAs, and provide organizational information that HCFA may require.

The specific requirements concerning the amount that HCFA pays into an individual's M+C MSA are spelled out at § 422.262(c). We calculate the payment by first comparing the monthly premium for the M+C MSA plan to the county-wide capitation rate under § 422.252 that is used in making payments to M+C organizations under other types of M+C plans (final payment to M+C organizations is based on this county-wide capitation rate, adjusted by demographic factors). If the monthly premium is less than the monthly capitation rate for the county, HCFA deposits into the individual's M+C MSA a lump sum equal to the annual difference between these two amounts, that is, the monthly difference multiplied by 12, or by the number of months remaining in the calendar year when the individual becomes covered under the M+C MSA plan.

The lump-sum payment is made in the first month of coverage under the M+C MSA plan, but HCFA makes no payment until the individual has not established an M+C MSA before the beginning of the month. Should an individual's coverage under an M+C MSA plan end before the end of a calendar year, HCFA will recover the excess portion of the lump-sum deposit attributable to the remaining months of that year.

In summary, Medicare's contributions to an individual's M+C MSA are equal to the difference between the unadjusted county-wide capitation rate for the county in which the enrollee lives and the premium filed by the individual's high deductible M+C MSA plan. For example, if the annual Medicare payment rate for a county is $6,000 ($500 per month), and the annual premium for an M+C MSA insurance plan is $4800 ($400 multiplied by 12), HCFA would deposit $1,200, in January, into the M+C MSA of each plan enrollee residing in that county. It would pay to the insurer (generally divided into 12 equal monthly payments) the difference between the demographically adjusted M+C payment amount for that individual and the MSA contribution. (See the example below.) The annual payment by HCFA represents the only permissible deposit into the individuals's M+C MSA, with the exceptions of transfers from another M+C MSA established by the same individual or interest or income that accrues to the account.

Example of Payments Under an M+C MSA Plan

Monthly premium for an M+C MSA plan	$400
Monthly M+C county-wide capitation rate	500
Monthly demographically adjusted M+C payment for an individual beneficiary:	
Individual A (65-year old beneficiary)	450
Individual B (85-year old beneficiary)	700

A. Annual contribution to enrollee's M+C MSA =
(M+C county-wide capitation rate − M+C MSA plan monthly premium) × 12. ($500 − $400) × 12 = $1,200

B. Monthly payment to an M+C organization under an M+C MSA plan for an enrollee =
Demographically adjusted M+C payment rate for an enrollee − Monthly contribution to the enrollee's M+C MSA plan
Individual A: $450 − $100 = $300
Individual B: $700 − $100 = $600

In theory, payments to the plan for an individual enrollee could be positive or negative, depending on the relationship between a plan's premium and the capitation rate for a given county. If, in the example above, the M+C MSA plan premium were only $25 (rather than $400), the monthly contribution to an enrollee's M+C MSA would be $475 ($500 − $25 = $475). For the 65-year old beneficiary (Individual A), the resultant payment to the plan would be a negative $25 ($450 − $475 = (−$25)). Given that organizations offering M+C MSA plans likely will carefully assess payment ranges and demographic factors within their market areas before proposing a premium, we believe that a negative payment would be rare, but not impossible.)

H. Premiums (Subpart G)

Section 1854 establishes the requirements for determination of the premiums charged to enrollees by M+C organizations. Like other M+C organizations, organizations offering M+C MSA plans in general must submit by May 1 of each year information concerning enrollment capacity and premiums. For M+C MSA plans, the information to be submitted includes the monthly M+C MSA plan premium for basic benefits and the amount of any beneficiary premium for supplementary benefits. These requirements are set forth under section 1854(a)(3) of the act and § 422.306(c) of the regulations.

Unlike for M+C coordinated care plans, section 1854(a)(5) Act expressly exempts M+C MSA plan premiums from review and approval by the Secretary. Section 1854(b)(1)(B) merely states that for M+C MSA plans, the monthly amount of the premium charged to an enrollee equals the M+C monthly supplemental beneficiary premium, if any. Although this provision effectively

precludes an organization offering an M+C MSA plan from charging an additional premium to an enrollee for basic Medicare benefits paid for through the capitated payment made by HCFA, the plan is free to set the basic and supplemental premium at whatever levels the market place will bear.

The only statutory limitation placed on an M+C MSA plan's ability to establish premiums is the ''uniform premium'' requirement of section 1854(c). The effect of this provision is that the monthly basic and supplementary premiums may not vary among individuals enrolled in an M+C MSA plan. (See the discussion of service area in section II.A. of this preamble.) Thus, insurers that want to charge different amounts for different benefits, according to geographic areas for example, could do so only by establishing multiple M+C MSA plans. Within a plan, however, payments into the M+C MSAs of individuals residing in the same county will be uniform; payments to the plans will vary for each individual.

I. Other M+C Requirements

The remaining requirements under subpart 422 have few if any implications specific to M+C MSA plans. For example, the organizational and financial requirements, provisions on compliance with State law, contracting rules, and grievance and appeal requirements generally apply in equal measure to MSA plans as to other types of plans. More accurately, perhaps, these requirements primarily apply to the M+C organization, rather than the plan; thus, an organization offering any type of M+C plan must meet the applicable requirements.

One issue that may require clarification, however, involves the provision of section 1856(b)(3)(B)(i) (and § 422.402(b)) that any State standards relating to benefit requirements are superseded. We recognize that this provision means that State benefit rules will not apply (such as State laws that mandate first dollar coverage for particular benefits such as mammograms or other preventative services). Some States may not license entities to offer catastrophic coverage, and it is possible that M+C MSA plans could not be offered in that State. We welcome public comment on this issue.

The only other sections of these regulations that contain requirements that are specific to M+C MSA plans are found in Subpart K—Contracts with M+C Organizations. First, in accordance with section 1857(c)(3), § 422.504(a) specifies that the effective date for a contract providing coverage under an M+C MSA plan may be no earlier than January 1, 1999.

We note that § 422.500(b)(2) authorizes HCFA to include in a contract any requirements that we find ''necessary and appropriate'' that are not inconsistent with the M+C statute and regulations. Given the demonstration basis of M+C MSA plans under section 1851(b)(4), and the corollary requirements for an evaluation and a report to Congress, we believe it may be necessary and appropriate to require that organizations offering M+C MSA plans provide HCFA with data that will enable us to evaluate M+C MSA plans in terms of selection, use of preventive care, access, and impact on the Medicare trust fund. We are now in the process of determining what, if any, specific data will be required with respect to M+C MSA plans (beyond the encounter data to be collected with respect to all M+C plans) to facilitate HCFA's evaluation. In § 422.502(f)(2)(vii), we provide authority for HCFA to request data from M+C organizations offering MSA plans related to selection, use of preventive care, and access to services.

J. Tax Rules

As mentioned earlier, section 4006 of the BBA added new section 138 to the Internal Revenue Code (IRC) of 1986 concerning M+C MSAs. The regulations set forth in this interim final rule do not incorporate the IRC provisions on M+C MSAs. However, for the convenience of the reader, we are presenting here a brief summary of the tax rules associated with M+C MSAs. For a full explanation of the tax consequences of establishing a M+C MSA, we refer readers to sections 138 and 220 of the IRC and to the relevant IRS publications. (For more information, contact the IRS at (888) 477–2778 or through its website at www.irs.ustreas.gov.)

When an individual joins an M+C MSA plan, HCFA makes a specified contribution, as explained above, into the M+C MSA designated by the individual. No other contribution may be made into the M+C MSA, and the contribution is not included in the taxable income of the account holder. Any income earned on amounts held in the M+C MSA are not currently included in taxable income, similar to an individual retirement account.

Withdrawals from an M+C MSA are not considered taxable income if used for the ''qualified medical expenses'' of the account holder, regardless of whether the account holder is still enrolled in an M+C MSA plan at the time of the distribution. In general, ''qualified medical expenses'' are defined the same as under the IRS rules relating to itemized deductions for medical expenses. (See sections 213(d) and 220(d)(2)(A) of the IRC and IRS publication 502, Medical and Dental Expenses.) For M+C MSA purposes, however, most health-related insurance premiums do not constitute qualified medical expenses, nor do amounts paid for the medical expenses of any individual other than the account holder. Also, keep in mind that the IRS definition of qualified medical expenses encompasses a broader range of items and services than are covered by Medicare, including for example prescription drugs and dental services. Thus, items that are considered qualified medical expenses by the IRS do not necessarily constitute countable expenses toward an M+C MSA plan's annual deductible.

An enrollee in an M+C MSA plan may make withdrawals from an M+C MSA that are not used to pay for the qualified medical expenses of the account holder, but these withdrawals are included in the account holder's taxable income and may be subject to additional tax penalties under section 138(c)(2) of the IRC. The additional tax provisions do not apply to distributions following the disability (as defined in section 72(m)(7) of the IRC) or death of the account holder. Finally, under section 138(d) of the IRC a surviving spouse of an M+C MSA holder may continue the M+C MSA upon the death of the account holder, including making nontaxable withdrawals for the qualified medical expenses of the spouse or the spouse's dependents, but may not make new contributions to the M+C MSA. Again, we recommend contacting the IRS for further details.

K. Letters of Intent

In closing, we wish to solicit letters of intent from organizations that intend to offer high deductible M+C MSA insurance plans to Medicare beneficiaries and/or to serve as M+C MSA trustees or custodians. A letter of intent to offer an M+C MSA plan should include basic information about the plan, the geographic area in which the plan intends to operate, the name, address, and telephone number of a contact person, so that beneficiaries can call the plan to verify whether the plan did, in fact, submit an application and receive our approval. This letter of intent must be received no later than July 31, 1998.

For prospective M+C MSA trustees, the letter of intent must include the name of the organization, the address, a contact person and telephone number,

funds routing number, Federal tax identification number, the geographic area the trustee will serve, a public information number for publication, and attestation that the organization is a chartered bank, licensed insurance company, or other entity qualified under section 408(a)(2) or section 408(h) of the Internal Revenue Code to act as a trustee or custodian of an individual retirement account. For trustees, no further application to us will be required if the organization appears to be qualified based upon submitted information. Trustees that decide at a later date to participate will have to notify us before offering M+C MSAs.

Statements of intent should be submitted to—Health Care Financing Administration, CHPP, Attn: Cynthia Mason, Room C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244.

A letter of intent in no way commits an organization to submit an application to offer an M+C MSA plan or serve as an M+C MSA trustee, nor does it preclude the submission of an application if a letter of intent is not submitted to us. As part of our information campaign, we plan to publish and disseminate the information we receive to inform beneficiaries of the plans that may be participating in the M+C MSA plan demonstration project.

IV. M+C Private Fee-for-Service Plans

1. Background and Definition of M+C Private Fee for Service Plans (§ 422.4(a)(3))

As noted above, among the type of M+C options available under section 1851(a)(2) is an M+C private fee for service plan. An M+C private fee for service plan is an M+C plan like any other except where there are special rules and exceptions that apply to them. The effect of these special rules and exceptions is that we believe that M+C plans will function much like a traditional health insurance plan rather than a coordinated care plan nor a medical savings account. The law provides considerable flexibility in the creation of this M+C option and therefore, it is likely that M+C private fee for service plans will vary widely in how they function. Moreover, the law does not limit the premiums that an M+C organization may charge for an M+C private fee for service plan, thus making it very sensitive to market forces in its pricing, its benefits and its function.

We propose to define an M+C private fee-for-service plan as being an M+C plan that pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk, does not vary the rates for a provider based on the utilization of that provider's services, and does not restrict enrollees' choice among providers who are lawfully authorized to provide the services and agree to accept the plan's terms and conditions of payment. This is the statutory definition of M+C private fee-for-service plan at 1859(b)(2)(A). The requirements these plans must meet to contract with HCFA as an M+C private fee-for-service plan are incorporated into the relevant sections of this regulation. An M+C private fee-for-service plan must meet all of the requirements for any other M+C plan, except to the extent that there are special rules for M+C private fee-for-service plans.

2. Quality Assurance (§§ 422.152 and 422.154)

The law exempts M+C private fee for service plans and non-network MSAs from some of the quality assurance requirements of the law. Moreover, the law exempts M+C private fee for service plans and non-network MSAs from external quality review if they do not have written utilization review protocols. Specific discussion of the statute and the regulations that implement these provisions that apply to both M+C private fee for service plans and non-network MSAs are found in subpart D at sections 422.152 and 422.154. As with all other requirements for M+C organizations and M+C plans, those provisions of regulations that are not specific to coordinated care plans and MSAs also apply to M+C private fee for service plans.

3. Access to Services (§ 422.214)

In § 422.214 we implement the special requirements for access to health services that are contained in section 1852(d)(4). The law requires that the Secretary must assure that the M+C private fee-for-service plan offers sufficient access to health care. Specifically, in § 422.114(a) we require that 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 health care providers willing to furnish services under the plan. Pursuant to the specific instructions of the law, under § 422.114(a) HCFA will find that an M+C organization meets this requirement if, with respect to a particular category of provider, the plan has—

- Payment rates that are not less than the rates that apply under original Medicare for the provider in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the plan; or
- A combination of the above.

Hence, an M+C private fee-for-service plan will be found to have met the access requirements for a category of services if it has sufficient numbers of providers under direct contract in its service area or, if not, it has payment rates that are equal to or higher than the original Medicare payment for the service. This access test must be met for each category of service established by HCFA on the M+C organization application. Clearly, if an M+C private fee-for-service plan has payment rates that are no lower than Medicare, it need not address if it has a sufficient number of providers of services. However, where the plan has payment rates that are less than the Medicare payment for that type of provider, the plan must demonstrate that it has sufficient number of providers of that type under direct contract. For purposes of making this judgement of sufficiency, HCFA will use the same standards for M+C private fee-for-service plans as for coordinated care plans. We see no basis to use different standards.

In § 422.114(b) we specify that the plan must permit the enrollees to receive services from any provider that is authorized to provide the service under original Medicare. This implements that part of section 1852(d)(4) that says that the access requirements cannot be construed as restricting the persons from whom enrollees of the M+C private fee-for-service plan may obtain covered services.

4. Physician Incentive Plans (§§ 422.208 and 422.210)

In § 422.208(e) we specify that an M+C private fee-for-service plan may not use capitated payment, bonuses, or withholds in the establishment of the terms and conditions of payment. This is necessary to implement that part of the definition of an M+C private fee-for-service plan that specifies that the plan must pay without placing the provider at financial risk. We believe that these physician incentives place the physician at financial risk and thus are not permitted by the law for M+C private fee-for-service plan payments. Capitation places physicians at risk because of the uncertainty of the extent to which the beneficiary will require the physician's time and services to provide an adequate level of service. Withholds from payment place the physicians at financial risk because of the uncertainty of what the ultimate payment for the

services furnished will be. Bonuses are essentially the same as withholds. In both the case of bonuses and withholds, the physicians knows the least amount that could be paid but in both cases, they face uncertainty about what the total payment from the plan would be for the services furnished.

5. Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

In § 422.216(a) we address payment to providers. Specifically in 422.216(a)(1) we state that the M+C organization offering an M+C private-fee-for-service plan pays contract providers (including those that are deemed to have contract under § 422.216(f)) on a fee-for-service basis at a rate, determined under the plan, that does not place the provider at financial risk. This reflects the statutory definition of an M+C private fee-for-service plan.

We also specify in § 422.216(a)(1) that the payment rate includes any deductibles, coinsurance, and copayment imposed under the plan and must be the same for all providers paid pursuant to a contract whether or not the contract is signed or deemed to be in place as discussed below. This reflects our understanding of the meaning and use of these terms in common insurance use. It also reflects our belief that the plan rate (on which balance billing discussed below is based) is intended to be analogous to the Medicare allowed amount for a service, of which the deductible, coinsurance or copayment is a part. We think the deductible, and coinsurance or copayment is a part of the plan payment rate because deductibles have to be subtracted from that plan payment and because coinsurance is a percentage of the plan payment rate, thus being included within the rate by definition. We believe that the payment rate does not include balance billing because the common definition of balance billing under both original Medicare and common insurance is an amount above and beyond the payment rate established for the service. Balance billing is discussed in more detail below in (c) as a provider charge to enrollees.

As noted above, we specify in § 422.216(a)(1)(i) that a uniform payment rate must be established for a given item or service furnished under a contract, whether the contract is signed or deemed to exist (*see* discussion of deemed contracts below). In § 422.216(b)(1)(i), we also require that the plan deductible, coinsurance or copayments and other beneficiary liability be uniform for services furnished by all contracting providers, whether contracts are signed or deemed to be in place. These two requirements are closely related, since permissible enrollee liability is linked by statute to the plan's payment rate. The balance billing limitation in section 1852(k)(2)(A) that applies to M+C private fee-for-service plans is based on the plan payment rate, which has deductible, copayment and coinsurance amounts built into it. In our view, therefore, the uniform cost-sharing rule in § 422.216(b)(1)(i) follows from the uniform payment rate rule in § 422.216(a)(1)(i).

We believe that the uniform rate requirement in § 422.216(a)(1)(i) is implicit in the definition of private fee-for-service plans in section 1859(b)(2), which refers in the singular to reimbursing, hospitals physicians and other providers at ''a rate'' determined under the plan. The balance billing limit in section 1852(k)(2)(A) even more explicitly supports a uniformity rule, in referring in the singular to ''a'' prepayment ''rate'' that is established under ''a contract (including [a deemed contract]). * * *'' Section 1852(k)(2)(A) thus makes clear that Congress contemplated that a *single* ''rate'' would be established for a given service, or for a service in a given area, under ''a contract,'' and that this rate would apply under the contract, ''including'' a contract deemed ''through the operation of subsection (j)(6)'' of section 1852 (discussed below).

Even if the statute did not refer to a single rate that applies under a contract, and expressly include a deemed contract in this statement, we would exercise our authority under section 1852(b)(1) to impose a uniform rate and cost-sharing requirement. We understand from oral presentations and written comments received in response to the January 20, 1998 **Federal Register** notice (63 FR 2920), that some entities would like to establish different payment rates and enrollee cost-sharing for providers that sign contracts than those which would apply to providers deemed to have a contract. These entities indicated that they wanted to establish incentives to use the network of providers with signed contracts. We believe that it would be inconsistent with the scheme established by Congress to permit this.

Under such an approach, the M+C organization would in essence be establishing a defined and limited network of preferred providers. Congress has applied a different set of rules to plans that employ provider networks, and exempted M+C private fee-for-service plans from these requirements. Indeed, a ''preferred provider organization'' (PPO) plan and ''point of service'' option are each expressly mentioned as examples of ''coordinated care plans'' subject to the quality assurance rules that apply to network plans, including network MSA plans. We believe that permitting private fee-for-service plans to have different cost-sharing amounts for providers with signed contracts would create a ''loophole'' permitting organizations from offering network type PPO plans without complying with the quality assurance requirement that Congress intended to apply to network plans.

In § 422.216(a)(1)(ii) we specify that contracting providers must be paid on a fee-for-service basis. This is required by the definition of M+C private fee-for-service plans contained in 1859(b)(2)(A).

In § 422.216(a)(1)(iii) we specify that the M+C organization must make the payment rate available to providers that furnish items or services that may be covered under the M+C private fee-for-service plan offered by the organization. We require this to ensure that the contracting providers will be advised or be able to acquire the amount of payment for the services they furnish to plan enrollees. This is particularly important given the plan's flexibility to set and change payment rates.

In § 422.216(a)(2) we specify that the M+C organization must pay a contract provider (including one deemed to have a contract) an amount that is equal to the payment rate described above less any applicable deductible, coinsurance or copayment. The M+C plan's share of the payment is the payment rate (which includes deductible, coinsurance and copayment as discussed above) less that enrollee's cost-sharing.

In § 422.216(a)(3) we also specify that the plan pays for services of noncontract providers in accordance with § 422.100(b)(2).

Section 1852(k)(2)(B)(i) specifies that the minimum payment rate for noncontracting providers of M+C private fee-for-service plans must be the payment rate set in 1852(a)(2)(A), the same payment rate that applies when coordinated care plans pay noncontracting providers for approved services. The provisions of 1852(a)(2)(A) are set in regulations at § 422.100(b)(2) and thus that provision applies to the payment to noncontracting providers by M+C private fee-for-service plans. Thus, the plan must pay the provider at least the amount that the provider would have received under original Medicare, including any allowed balance billing amounts. The provider must accept this amount, together with allowable cost

sharing paid by the enrollee, as payment in full.

In § 422.216(b) we address provider charges to enrollees. Specifically in § 422.216(b)(1) we state that a contract provider (including one that is deemed to have a contract under paragraph (f) (discussed below) may charge the enrollee no more than the deductible, coinsurance, copayment, and balance billing amounts permitted under the plan, that the plan must have the same cost-sharing for deemed contract providers as for contract providers and that the plan may permit balance billing no greater than 15 percent of the payment rate for the service.

The provisions regarding what enrollees may be charged are based on our interpretation of section 1852(k)(2)(A)(i) that says that a provider shall accept as payment in full ''* * * an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.'' We believe that the intent of this provision is that the plan may, but is not required to, permit the provider to collect balance billing equal to but not in excess of 15 percent of the plan payment rate. We believe that the intent of the section was to permit a balance billing provision that mirrors that which currently exists section 1848(g) with respect to services paid under the Medicare fee schedule for physician services for beneficiaries who are enrolled in original Medicare.

We recognize, however, that the inclusion of the words ''balance billing otherwise permitted under the plan'' in the second parentheses in section 1852(k)(2)(A)(i) could be construed, if read literally, to permit the 115 percent limit on enrollee liability for balance billing to be applied to a payment ''rate'' that already included balance billing ''otherwise provided for'' in the plan.

This interpretation would in effect have created two balance billing amounts: one balance billing amount within the payment rate (that would be above and beyond the deductible, coinsurance and copayment) and another balance billing amount based upon the payment rate (effectively a balance billing amount as a percentage of another balance billing amount). This is a convoluted result that we do not believe was intended. In addition to producing a convoluted result, the above reading of the reference to balance billing in the second parenthetical in section 1852(k)(2)(A)(i) would permit M+C organizations to avoid the limitation on enrollee liability in section 1854(e)(4), which applies only to deductibles, coinsurance, and copayments. *See* section G. below. If an M+C organization offering a private fee-for-service plan could ''provide for'' balance billing amounts in its payment rate, such amounts would not count towards the overall limit on enrollee liability in section 1854(e)(4). This could result in unlimited enrollee liability if such unlimited ''plan'' balance billing amounts were coupled with balance billing of 115 percent of rates that include the plan balance billing.

The provision that requires that the plan establish the same cost-sharing for the services of deemed contract providers as for contract providers is discussed above in its relationship to § 422.216(a)(1).

In § 422.216(b)(1)(iii) we specify that the M+C organization must specify in the contract the deductible, coinsurance, copayment, and balance billing permitted under the plan for services furnished by a contracting provider (including a deemed contract under paragraph (f)). We believe it is important to ensure that the providers who furnish services are explicitly aware of the amounts they can collect from enrollees since there are potential penalties for violation of these limits.

In § 422.216(b)(1)(iv) we specify that an M+C organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of part 422, for failing to enforce limits on beneficiary liability that apply to contract (including deemed contract) providers. This implements section 1852(k)(2)(A)(i).

In § 422.216(b)(2) we specify that a noncontract provider may charge the enrollee no more than the cost-sharing established under the M+C private fee-for-service plan limited as specified in § 422.308(b). This requirement implements section 1852(a)(2), which applies to all M+C plans other than MSA plans, and which is referenced in section 1852(k)(2)(B)(i), which applies specifically to payments to non-contract providers under M+C private fee-for-service plans. Section 1852(a)(2) requires that M+C organizations provide for payment to non-contracting providers of an amount, representing the sum of payment from the organization and any cost-sharing provided for under the M+C plan, that is at least equal to the total dollar amount of payment that would be authorized to be paid under parts A and B, including any balance billing permitted under such parts. We have defined ''cost-sharing'' in section 422.2 as including only deductibles, copayments and coinsurance, and not balance billing amounts. Because section 1852(a)(2)(A)(i) uses the term cost-sharing, we believe that it requires that M+C organizations make payment in an amount that, when combined with deductible amounts, coinsurance or copayments provided for under the M+C plan, at least equals the amount the individual or entity would be able to collect under original Medicare, as we have provided in section § 422.216(b)(3). This means that enrollees must be held harmless against any balance billing by non-contracting providers.

While § 1852(a)(2) thus limits enrollee liability to deductible, coinsurance, and copayment amounts (and does not permit enrollee liability for balance billing in the case of non-contracting individuals or entities), it does not contain any limit on the *amount* of enrollee liability that can be imposed under a M+C private fee-for-service plan for services furnished by a non-contracting provider. While section 1854(e)(4) limits the actuarial value of cost-sharing overall, it does not limit the amount that can be charged for a particular service, except as specified elsewhere in this rule, for example limits for emergency services as established in section 422.112(b). Hence, except for limits specified elswhere in this rule, M+C organizations that offer M+C private fee-for-service plans will be able to establish cost-sharing for services of non-contracting providers without regard to a specific limit per service.

In § 422.216(c)(1) we specify that an M+C organization that offers an M+C private fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section. We also specify in § 422.216(b)(1)(iv) that if the M+C organization fails to enforce the limit as required by paragraph (c)(1) of this section, the organization is subject to intermediate sanctions under subpart O of this part. We intend to leave to the organization's discretion the means by which it will enforce the limits on charges to enrollees. However, through the ongoing monitoring of the M+C private fee-for-service plan, HCFA will review the means by which the plan is enforcing the limits on charges to enrollees by looking at the extent of complaints from enrollees and the action the M+C organization takes to resolve them, both systematically and individually.

In § 422.216(c)(2) we specify that an M+C organization that offers an M+C private fee for service plan must monitor the amount collected by non-contract 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. HCFA may impose the sanctions provided in section 1848(g)(1)(B). These are the penalties that apply to nonparticipating physicians who fail to abide by the limiting charge under original Medicare.

In § 422.216(d) we specify that the M+C organization that offers an M+C private fee-for-service plan must provide to plan enrollees an appropriate explanation of benefits that includes a clear statement of the enrollee's liability, including any liability for balance billing consistent with this section. Section 1852(k)(2)(C)(i) requires that the plan must notify the enrollee of balance billing that can be collected by the provider. We believe that it would be misleading for this notice to be limited to the balance billing that can be collected by the provider since the provider may also be able to collect deductible, coinsurance and or a copayment from the enrollee (depending upon the plan's policy) and that therefore the plan should notify the enrollee of all cost-sharing and balance billing that can be collected by the provider so that there is no confusion.

We also specify that, in its terms and conditions of payment to hospitals, the M+C organization must require a hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to $500 or more, notice that balance billing is permitted for those services and a good faith estimate of the likely amount of balance billing, based on the enrollee's presenting condition. Section 1852(k)(2)(C)(ii) requires that such a notice be furnished by a hospital for inpatient services and permits the Secretary to require such a notice for other hospital services at a tolerance to be set by the Secretary. We believe that this requirement was included in the law because of the potential for the balance billing provisions that apply to contracting providers to create quite large liability for enrollees of these plans. For example, if an M+C private fee-for-service plan permits a hospital to balance bill up to the 115 percent of plan payment rate that the law would permit, and the plan payment is $10,000 for the hospital stay, the enrollee would be liable for $1500 in balance billing in addition to the deductible, coinsurance and copayment the plan permits the hospital to collect.

We specify that the advance notice requirements applies to all services furnished by a hospital because of the trend towards furnishing services on an outpatient basis that would previously have been furnished on an inpatient basis. These services can be very expensive and we believe that the enrollee has a need to know the cost-sharing for these services in advance of receiving the services as for inpatient hospital services.

We have set the tolerance at which the hospital must provide this advance notice at $500, which is the tolerance for nonparticipating physicians to provide advance notice of the nonparticipating physician's actual charge under section 1842(m)(1) for purposes of Part B of original Medicare.

In § 422.216(e) we specify that the M+C organization must comply with the coverage decisions, appeals, and grievances procedures of subpart M. This requires that the M+C organization, offering the M+C private fee-for-service plan, make coverage determinations on all services and that it must make a determination before the service is furnished if the enrollee or provider requests it. We believe that this requirement is necessary to enforce the provisions contained in section 1852(g)(1)(A), which apply to all M+C organizations. Specifically, section 1852(g)(1)(A) requires that ''A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such services. Subject to paragraph (3), such procedures shall provide for such determinations to be made on a timely basis.'' Paragraph (3) is the expedited decision process.

We recognize that providing advance determinations of coverage has not been a common feature of commercial fee-for-service plans in the past. However, the law's use of the present tense with regard to the requirement for coverage determinations and its reference to the expedited appeals process (which is intended to obtain a quick appeal of a denial of a service not yet furnished) clearly anticipates that there will be the opportunity for an advance determination of coverage for all M+C plans. Moreover, the opportunity to acquire an advance determination of coverage is particularly important since there is no protection from retroactive denial for enrollees in an M+C private fee-for-service plan. This is a source of great risk for enrollees in M+C private fee-for service plans, who, unlike enrollees in coordinated care plans, may seek treatment from any licensed provider that agrees to accept the terms and conditions of the plan.

While the opportunity for advance determinations of coverage presents the opportunity to minimize the risk by giving the enrollee and provider the opportunity to determine whether the plan will pay for the service and the amount for which the enrollee will be liable, it does not provide protection to the enrollee that is comparable to the protection provided by original Medicare under the provisions of section 1879 (which apply to assigned claims) and under 1842(l) (which apply to unassigned physician claims). These provisions hold the beneficiary without fault when a services is denied as not medically necessary to treat illness or injury unless the beneficiary was advised by the provider in advance of the service that Medicare would not pay and the beneficiary accepted liability if Medicare did not cover the service. These provisions also permit a physician to take assignment on a claim for Medicare services to be found to be not at fault and to be paid by Medicare for the noncovered service if he can demonstrate that he did not know and could not reasonably have known that the service was not covered.

We considered and rejected imposing several requirements that would have provided Medicare beneficiaries with protection like that available under original Medicare. Specifically, we considered requiring that the M+C organization must require that contracting providers (including deemed contractors) submit claims for the services they furnish to enrollees. We also considered but rejected requiring the M+C organization to require that contracting providers (including deemed contractors) assume the responsibility for acquiring an advance determination of coverage from the plan or risk being unable to charge the enrollee if they did not notify the enrollee in advance of the service if the plan does not cover the care. This approach would have provided enrollees protection from the liability of full payment in the case of retroactive denials and would have given providers an opportunity to minimize their risk by acquiring advance approval of coverage.

However, we decided that it would be contrary to the spirit and intent of the M+C fee-for-service legislation to impose these requirements on providers and plans, since they would make the plan much more like a coordinated care plan than like a traditional fee-for-service plan. Moreover, such a construction would place the provider at financial risk, contrary to the

definition of an M+C private fee-for-service plan.

Our silence in regulations on the claims filing requirements of M+C private fee-for-service plans and the absence of any explicit mechanism for providing protection to enrollees from retroactive denials of coverage does not foreclose the possibility that an M+C private fee-for-service plan may choose to address these issues. For example, the M+C private fee-for-service plan may choose to include in its terms and conditions of payment a requirement that the provider must bill the plan for payment. Similarly, the M+C private fee-for-service plan may choose to provide some level of payment for services subject to retroactive denials as an additional benefit or as a supplemental benefit under the plan. This could be an attractive feature of the plan and a valuable benefit to enrollees.

Although we are silent on these issues, we remain concerned about the absence of protections for beneficiaries who enroll in private-fee-for-service plans. We are soliciting comments on these issues, and we are particularly interested in comments on whether to apply the protections discussed above as a requirement or how otherwise to protect the beneficiary from being financially at risk, while not creating undue burdens on providers and insurers.

In § 422.216(f) we specify that any provider that does not have a contract will be treated as having a contract in effect with the M+C organization offering the M+C private fee-for-service plan if the provider furnishing services (1) is aware that the beneficiary receiving the services is enrolled in the plan, and (2) before furnishing the services, has a reasonable opportunity to be informed about the terms and conditions of payment and coverage under the plan. Section 1852(j)(6) requires that we deem a noncontracting provider to be a contracting provider when these criteria are met. In § 422.216(f) we further specify three general criteria, each of which must be met for a provider to be deemed to have a contract with the plan and which are discussed further in § 422.216(g) and (h).

In § 422.216(f) we specify that for the deemed contract provision to apply the services must be covered under the plan and must be furnished to an enrollee of an M+C private fee-for-service plan, by a provider that does not have in effect a signed contract with the M+C organization. We also specify in § 422.216(f)(2) that the provider must have been informed of the individual's enrollment in the plan and must have been informed or given a reasonable opportunity to obtain information about the terms and conditions of payment under the plan in a manner reasonably designed to effect informed agreement. The information must include the information described in § 422.202(a)(1).

In § 422.216(g) and (h) we further clarify that the requirements of paragraph (f) of this section are met (and the noncontract provider is subject to the provisions for contracting entities) if the following conditions are met.

Enrollment information must be provided by one of the following methods or a similar method:

- Presentation of an enrollment card or other document attesting to enrollment.
- Notice of enrollment from HCFA, a Medicare intermediary or carrier, or the M+C plan itself.

We considered how best to ensure that the noncontracting provider would be advised that the enrollee is enrolled in the M+C private fee-for-service plan. However, since there is no direct contract between the provider and the M+C private fee-for-service plan, it becomes incumbent upon the enrollee to advise the provider of the enrollment. Even where the provider had previously been notified of the beneficiary's enrollment in the M+C private fee-for-service plan (e.g. at the time of a previous service), the provider cannot automatically assume that the beneficiary is enrolled in the plan and may not be able to learn the beneficiary's enrollment status prior to providing services. This occurs because, before 2002, beneficiaries can disenroll from M+C plans at any time, either voluntarily or involuntarily by moving out of the service area. After that date, the beneficiary can disenroll within the first 3 months of the year or at any time if they move out of the service area. Hence, there are very few times that a noncontracting provider can know with certainty that the beneficiary remains enrolled in the M+C private fee-for-service plan based on previous knowledge of enrollment. If the provider fails to acquire current enrollment information from the enrollee or the plan at the time of each service, we do not see how he or she can be held to have met the first test of ''deemed contract status'': knowing that the beneficiary is enrolled in the plan.

To be a deemed contractor, the provider or supplier who knows that the patient is enrolled in the plan must either have been given information on payment terms and conditions or must have had a reasonable opportunity to learn such terms and conditions of plan payment. Under that circumstance, treatment of the patient implies consent to the terms and conditions of plan payment.

To meet the requirement of having been given information on payment terms and conditions, we specify in paragraph (h)(1) that the information must have been communicated to one of the following:

- The provider of the services.
- The provider's employer or billing agent.
- A partnership of which the provider is a member.
- Any party to which the provider makes assignment or reassigns benefits.

We expanded the list of parties to whom the information must be provided beyond those of providers themselves in recognition that providers, and in particular, individual physicians and practitioners, seldom receive the insurance information that is sent to them and seldom complete and submit their own claims. By reassigning insurance benefits to other parties and by delegating the responsibility to complete and submit claims to other parties, they are, effectively, also delegating the authority to make decisions governing their payment for which they remain responsible.

We also specify in paragraph (h)(1) that the information must have been transmitted via mail, FAX, electronic mail or telephone. Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment. We specify how the information must have been provided because we have been asked if general distribution of information to the public (e.g. annual newspaper notice) is an acceptable notice to bind the provider to being considered to be a deemed contractor. We do not believe that it is reasonable for a plan to do a general public notice since the provider may not see it and has no way of relating that information to itself. However, where the plan has transmitted the information directly to the provider by mail, FAX, electronic mail or telephone, the statute's test of having been furnished the information to the provider has clearly been met.

However, the law also provides that a provider that has a reasonable opportunity to acquire the terms and conditions of plan payment must be treated as if it were a contract provider. To implement this provision of the law, we further specify in paragraph (h)(2) that a provider that does not have a contract with the plan is deemed to have a contract with the plan if the plan has an acceptable procedure under which the provider could acquire the

terms and conditions of plan payment before providing services to the enrollee. Specifically, we say that this test is met where the M+C plan has in effect a procedure under which noncontract providers are advised how to request the payment information and the plan responds to the request before the provider furnishes the service. This procedure could be the inclusion of a toll free telephone number or E-mail address on the enrollment card for the provider's use in acquiring the terms and conditions of payment. Where the plan responds to the provider's request before the service is furnished, the provider would be treated as a contract provider if the provider subsequently furnishes the service to the enrollee, regardless of whether the provider agrees to accept the terms and conditions of the plan.

The effect of these statutory provisions is that there are very few circumstances in which a provider would not be treated as if it had a contract with the plan. These would include but not be limited to the following:

- Where the beneficiary did not notify the provider of enrollment in the plan.
- Where the provider requested but was not furnished terms and conditions of payment in advance of the provision of services to a known enrollee.
- Where the plan did not have a process that provided terms and conditions of payment.

We think that in most cases, plans will ensure that there is a procedure in place for providing this information before services are furnished. We think that the most likely circumstances in which a provider will be considered to be a noncontracting provider will be in cases of emergency where the provider has not previously been mailed the terms and conditions of payment under the plan or where the provider does not know that the beneficiary is enrolled in the plan.

In § 422.216(h)(2)(iii) we specify that the plan must include the following in the terms and conditions of plan payment that it must furnish to providers of services:

- Billing procedures.
- The amount the plan will pay towards the service.
- The amount the provider is permitted to collect from the enrollee.
- The information described in § 422.202(a)(1).

V. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

The Unfunded Mandates Reform Act (Public Law 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100,000,000 or more.

Summary of the Interim Final Rule

As discussed in detail above, this rule implements the M+C program as directed by the BBA of 1997. The primary objective of the M+C program is to increase the number and types of health plan choices available to Medicare beneficiaries.

Since the implementation of section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA 82) (Public law 97–248), the Medicare program has offered beneficiaries a prepaid capitated option through HMOs and CMPs paid on a full risk basis. Enrollment by Medicare beneficiaries in Medicare managed care risk plans has grown to over 4.5 million enrollees. The number of plans increased 31 percent in CY 1995, 36 percent in CY 1996, and 31 percent in CY 1997. With the implementation of the M+C program, we expect that the rate of growth of beneficiaries enrolling in capitated plans will continue.

The M+C program authorizes HCFA to contract with several new types of entities not previously available to Medicare beneficiaries such as provider sponsored organizations, preferred provider organizations, entities offering an ''MSA plan'' and a contribution into an M+C medical savings account (MSA), and M+C private fee-for-service plans. These new options will provide Medicare beneficiaries with a broad range of health insurance alternatives like those available in the private sector. Based on current growth rates and other information discussed later, we estimate that anywhere from 160 to 800 new entities may apply to contract with HCFA as M+C organizations.

By expanding choices and providing extensive educational materials through a coordinated open enrollment period, it is expected that beneficiaries will choose plans and health delivery systems that will maximize the benefits to these individuals.

The BBA also revamped the payment methodology for entities receiving capitated payments from Medicare. These payment changes were intended primarily to insure that the amounts paid to M+C organizations were fair and equitable to both the Medicare Trust Funds and to the participating organizations. Although Medicare's capitation rates had been set at 95 percent of expected costs based on actual fee-for-service costs, there is significant evidence that Medicare has paid more for enrollees in the managed care program than it would have paid in the fee-for-service program. This is due primarily to the favorable selection that these plans have experienced. The new payment rules slow the annual increase M+C organizations would have received under the old payment methodology. In addition, there has long been concern regarding the regional variation in payment rates, particularly between urban and rural counties. Because the capitated payment rates had been based upon the fee-for-service payments, the capitated rates not only included the variation in local prices, they also reflected different fee-for-service practice patterns in each region. To level out the variation in payment rates, the new methodology uses a blend of local and national rates and input price adjustments to insure the payments more closely reflect the different prices in the region while giving less weight to the different utilization rates. Finally, to insure that the new options would be

viable in all parts of the country a floor on capitated payments was introduced.

Summary of Discussion of Impact

We believe that the overall impact of this regulation should be beneficial to Medicare beneficiaries by providing them with more options to receive health care. However, although many of the provisions in this regulation are intended to assist beneficiaries by providing them with comparative information, we are concerned that the many new choices and types of plans may prove confusing even for the most knowledgeable consumers. Reductions in capitated payment amounts in what are now relatively higher payment areas may result in reduced benefits for beneficiaries. Providers (especially rural providers) should benefit from this regulation because they can contract directly with HCFA under the PSO provisions. New contracting entities will benefit as the Medicare statute has not previously permitted entities that were not state licensed HMOs or CMPs to participate in the Medicare managed care program. Providers could be negatively impacted if they contract with M+C organizations by the degree that any reduction in the rate of growth in payments to M+C organizations will be passed on to them. We also recognize that existing contractors and States may be adversely affected but cannot quantify to what degree. This impact analysis will focus on the provisions of the BBA and this regulation that significantly alter the risk program we have been administering since 1985. The major differences between the section 1876 risk program and the M+C program are:

The coordinated open enrollment and public education campaign:

New payment methodology for contracting plans

Introduction of New Contracting Entities

Provider Sponsored Organizations

Medicare Savings Account Plans

Private Fee-for-Service Plans

New Quality Standards

Our analysis will assess the impact these changes will have on Medicare beneficiaries, the Medicare Trust Funds, providers, managed care entities, and States. Whenever possible, we will use appropriate methods for assessing the impact quantitatively. However, because of the large number of unknowns—such as the prospective number of contracting organizations—this analysis relies upon many simplifying assumptions.

B. Coordinated Open Enrollment and Public Education Campaign

Section 1851 directs HCFA to hold annual coordinated open enrollment periods beginning in November 1999 (all plans will also be open to enrollment in November 1998) to allow eligible beneficiaries the opportunity to enroll in M+C organizations. It also directs HCFA to broadly disseminate information to current and prospective Medicare beneficiaries on the coverage options available in order to promote an active, informed selection among such options. At least 15 days before each annual, coordinated election period, HCFA will send to each eligible individual a notice containing information in order to assist the individual in making an election. This information describes M+C options as well as original Medicare. In addition, M+C organizations are directed to provide plan-specific information.

The public education campaign will include information on covered benefits, cost sharing and balance billing liability under the original Medicare program; election procedures; grievance and appeals rights under the original Medicare fee-for-service program and the new M+C program; information on Medigap and Medicare SELECT; and the beneficiary's right to be protected against discrimination based on health status.

The costs of the coordinated open enrollment and public education campaign will be borne primarily by the participating M+C plans. Section 4001 of the BBA added a new section 1857(e)(2) to the Social Security Act that establishes a fee requirement under which M+C organizations and section 1876 contractors must contribute their pro rata share, as determined by the HCFA, of costs related to enrollment, dissemination of information, and the counseling and assistance programs.

The annual fee will be assessed by HCFA on all participating organizations. The amount of the user fee will vary year to year as determined through the appropriations process. The BBA authorized ceiling amounts of $200 million in FY 98, $150 million in FY 99, and $100 million annually in FY 2000 and beyond. However, in FY 1998 HCFA was authorized to collect only $95 million through the appropriations process.

On December 2, 1997 HCFA gave notice of our methodology of assessing current contractors for their pro rata share of the expenses associated with the CY 1998 information campaign. To determine each organization's share, we divided the total amount appropriated for the information campaign by the total projected revenues for the first 9 months of CY 98. The resulting percentage was deducted from the payments to contracting organizations.

We explored several alternatives to this methodology. One option was to assess each organization on a per capita basis (by number of Medicare enrollees). Another option was to assess each organization on the percentage of revenue they received from capitated Medicare payments, but have a cap on the highest amount any organization would pay.

We rejected both of these methodologies as not consistent with the goals of the BBA. One of the primary effects of the reformed payment methodology of the BBA was to even out variation between high and low payment areas. By charging a per capita amount, those organizations that are located in areas that have a high payment rate would pay a reduced percentage of their revenue. Or put another way, we deemed that if an organization received a higher payment per person, it should pay a correspondingly higher user fee for its share of the education campaign. We also decided not to put a cap on the assessment any organization would receive based on the premise that only large organizations would receive the benefit of a cap and smaller organizations would have to pay more to make up the difference. This did not seem fair or consistent with our intention of encouraging the creation of new contracting entities and spurring competition in areas with lower payment rates.

As stated in the interim final rule (M+C Program: Collection of User Fees from M+C Plan and Risk-Sharing Contractors (42 CFR 417.470–417.472)), we will establish a fee percentage rate and collect the fees over nine consecutive months beginning with January until the assessment limit has been reached. The following table illustrates the method by which we will calculate the fee percentage rate, provides the rate for FY 1998, and sets forth projections for FY 1999–2002.

TABLE 1.—COLLECTION OF CONTRIBUTIONS FROM ORGANIZATIONS FOR COSTS RELATING TO INFORMATION DISSEMINATION

	Projected fiscal year total medicare payment to organizations (in millions of dollars) [1]	Projected medicare payment to organizations per month (in millions of dollars) [2]	Projected medicare payment to organizations over 9 months (in millions of dollars) [3]	Authorized assessment amount (in millions of dollars) [4]	Fee amount secretary is directed to collect (in millions of dollars) [5]	percentage of projected 9-month payment
FY 1998	30,000	2,465	22,181	200	95	.428
FY 1999	38,000	3,167	28,500	150	150	.526
FY 2000	47,000	3,917	35,250	100	100	.284
FY 2001	63,000	5,250	47,250	100	100	.212
FY 2002	64,000	5,333	48,000	100	100	.208

[1] Source: Congressional Budget Office, The Economic and Budget Outlook: Fiscal Year 1999–2008. January 1998.
[2] Projected total fiscal year payment divided by 12 (months).
[3] Projected monthly payment amount multiplied by 9 (months).
[4] New Section 1857(e)(2)(D) of the Social Security Act, as added by the BBA (Public Law 105–33).
[5] For purposes of these projections, we have assumed that Congress will include the full amount authorized under the BBA.

As noted in the interim final rule published on December 2, 1997, we believe that assessing the fees to reflect an organization's pro rata share of the expenses associated with the information campaign will require the deduction of only a very small percentage of any organization's total annual Medicare payments. For example, in FY 1998 the percentage fee assessment is 0.428 percent—less than one-half of one percent. In subsequent fiscal years the fees as a percentage of Medicare payments will likely represent an even smaller percentage of the Medicare payments as the number of eligible organizations increase and the existing organizations experience enrollment growth.

Information Campaign

In general, we believe that this investment in new forms of information dissemination should be beneficial to Medicare beneficiaries, contracting organizations, and the Medicare program. By providing extensive educational materials, it is expected that beneficiaries will choose organizations and health delivery systems that will maximize the benefits for them. Finally, while organizations face an assessment fee to support information campaign activities, it comprises a very small proportion of their revenue from the Medicare program and could serve to enhance their marketing efforts and to save marketing expenditures.

HCFA's information dissemination activities provided for under this regulation encompass a variety of interventions, including mailings of standardized, comparative information about coverage options, an Internet web site with such information, and a toll-free telephone line for beneficiary inquiries. In addition, the regulation provides for information dissemination activities to be undertaken by M+C organizations, including mailings to Medicare enrollees of plan-specific information and the provision of additional information upon request by Medicare eligible individuals.

In order for market competition to work effectively, consumers must have information about their choices in order to make good decisions. The information dissemination efforts provided for under this regulation will give Medicare beneficiaries information about the Medicare market, enabling them to compare fee-for-service coverage to managed care coverage, as well as coverage under different M+C organizations.

The Medicare program and managed care arrangements are inherently complex subjects, and it is challenging to communicate information that is meaningful and accurate. Many studies have shown that Medicare beneficiaries' level of understanding of how the Medicare program works today is very low (GAO, 1996) and this lack of understanding could be compounded by the introduction of a new array of choices if beneficiaries lack sufficient information or lack the skills or understanding necessary to use available information.

For example, studies have found that many individuals who disenrolled from Medicare risk HMOs misunderstood the nature of the plan, such as the lock-in feature. (OIG, 1997; GAO, 1996; IOM, 1996). As Medicare beneficiaries become better informed about the Medicare program generally and their options under M+C specifically, they will be able to make more informed decisions about meeting their health care needs, leading to fewer disenrollments based on misunderstandings. Disenrollment can be costly for plans. In 1996, a GHAA study estimated that disenrollment costs plans close to $1,300 per Medicare disenrollee. (GHAA, 1996)

While enhancing beneficiary choice is positive and providing beneficiaries with information on their choices is necessary, we are concerned that Medicare beneficiaries, especially in areas where several M+C organizations are operating, may experience information overload. Beneficiaries may have great difficulty in understanding the different types of plans available to them in their area or understanding the different benefit packages plans may offer. Beneficiaries will be required to assess their health needs in relation to the benefits being offered and they may well have to choose among a wide array of different benefit packages. These will be difficult choices and some beneficiaries may not choose the option best suited to their individual needs.

We believe important secondary effects may ensue as well. To date, plans have competed primarily on the basis of price and benefits. Broad dissemination of plan-specific information, including quality measures, should encourage competition among organizations based on quality factors, in addition to price and benefits. As Medicare beneficiaries become more familiar with health plans, their expectations of plan performance and quality services will increase. Enhanced beneficiary awareness will provide an incentive to plans to improve in areas that beneficiaries demonstrate are important to their decision making, such as the availability of certain providers and positive customer service experiences.

Moreover, beneficiaries will be better health care consumers in general if they understand their rights under managed

care and how to make a plan work for them. As Medicare enrollees receive more information and become more active decision makers on plan options, we believe they will also become more informed and active decision makers with respect to meeting their personal medical needs. More informed and active decision making on the part of enrollees will, in turn, facilitate plans' efforts to manage the delivery of appropriate, high quality health care services.

In addition, it should be noted that the information campaign is designed to reach all Medicare beneficiaries, and it is likely that, to the extent that this encourages growth in the M+C program, organizations will be well positioned to take advantage of the expanding market. Since the number of organizations and total revenues over which the BBA fee collections will be spread is likely to continue to rise with increased participation in the M+C program in future years, we believe the regulatory impact of the selected option for imposition of fees on M+C organizations will not be significant. Moreover, M+C organizations will benefit from the increased visibility they will receive through the focused information campaign each open enrollment season.

Aside from the benefits of the public education campaign there are benefits derived from the coordinated open enrollment for contracting organizations, beneficiaries, and to a lesser degree the Medicare Trust Funds, as discussed below.

Coordinated Open Enrollment and Beneficiary Lock-In

We anticipate that the transition into a coordinated open enrollment period and the beneficiary lock-in will be beneficial to M+C organizations in their efforts to attract and retain Medicare enrollees. It also will allow them to maximize their visibility as beneficiaries focus on information about plans during a single, coordinated period. An annual open enrollment period may present a challenge for start-up organizations that did not have the benefit of adding enrollment during continuous open enrollment periods available before 2002. However, the M+C beneficiary lock-in will provide a more stable enrollment base for all participating organizations.

Current contractors have conveyed that continuous open enrollment, which was prevalent prior to passage of the BBA, provided an incentive for beneficiaries that exhaust extra benefits offered by one HMO/CMP to switch to another HMO/CMP or back to traditional fee-for-service Medicare. This behavior provides a disincentive for M+C organizations to offer extra benefits, and we anticipate that M+C organizations will be more likely to offer extra benefits if concerns about enrollees disenrolling upon exhausting a benefit are diminished.

Moreover, as the lock-in is phased in, organizations offering M+C plans will operate within a framework that supports their efforts to manage the delivery of health care services. For example, if beneficiaries are not moving in and out of a plan, the M+C organization offering the plan will be better able to track a beneficiary's utilization of services over time. The lock-in will encourage plans to invest more in preventive health services or screening of new enrollees, because it increases the likelihood that the plan will retain its members long enough to benefit from eventual savings due to reduced morbidity. (PPRC, 1996)

We also note that M+C organizations will have to address the potential staffing and administrative requirements associated with a lock-in and a compressed enrollment period, such as how to staff appropriately to handle inquiries during the open enrollment period, how to process new enrollees when enrollment begins, and how to conduct initial physical histories and review medications for new enrollees. Therefore, there will be added burdens on the M+C organizations as they experience administrative and clinical burdens in implementing the lock-in. M+C organizations may have to hire temporary staff and this would be a cost to them (PPRC, 1996)

Although beneficiaries will have less flexibility with a lock-in period, they will also benefit from a coordinated open enrollment period because it provides a framework conducive to informed decision making. Similar to the experience of many individuals in the private sector, beneficiaries will receive extensive information each year, allowing them to compare all options simultaneously. By receiving standardized, comparative information during an annual, coordinated period, beneficiaries will find it easier to make appropriate choices among competing plans and between these plans and traditional Medicare fee-for-service. An annual coordinated open enrollment period will maximize the opportunity for all beneficiaries to make decisions that best meet their own needs.

Some beneficiaries may be more reluctant to enroll in an M+C organization if they must remain enrolled for extended length of time. The Office of Inspector General surveyed a two-stage random sample of 4,065 enrollees and disenrollees from 40 Medicare risk HMOs to compare their responses and to gain greater insight into HMO issues. The majority of beneficiaries surveyed stated that their most important reason for joining an HMO was their desire for more affordable health care. Only 17 percent of beneficiaries said they would be more hesitant to join an HMO if they did not have the option to disenroll at will. (OIG 1998) (see Table 2).

TABLE 2.—EFFECT OF MANDATORY ONE-YEAR ENROLLMENT—1996

[In percent]

	All	Enrollees	Disenrollees
If beneficiary had to stay in HMO for one year, the effect on the enrollment decision would be:			
—more likely to join	34	34	22
—less likely to join	17	16	33
—no effect on decision	49	49	45

Source: U.S. Department of Health and Human Services, Office of the Inspector General, Beneficiary Perspectives of Risk HMOs 1996, OEI–06–95–00430 (March 1998).

Beneficiaries retain the protection of the right to disenroll where the M+C organization's misrepresentation or the beneficiary's misunderstanding results in an enrollment that should not have occurred. In addition, the year-long opportunity for newly eligible aged individuals to disenroll and return to original Medicare is a particularly valuable protection for many beneficiaries who may be just beginning to understand the implications of new

options. (Newly eligible disabled beneficiaries are not afforded this option.) Beneficiary protections are enhanced by guaranteed issue of Medigap policies for first-time M+C enrollees who gave up supplemental coverage upon enrolling in an M+C organization and disenroll within 12 months, and for newly eligible aged beneficiaries who enroll in an M+C organization at age 65 and disenroll within twelve months of becoming eligible for Medicare.

Finally, we believe the lock-in will benefit the Medicare Trust Funds. The General Accounting Office found that the flexibility for beneficiaries to disenroll at will can cause problems for the Medicare program. (GAO, 1997) For example, beneficiaries could decide to use an M+C plan or other private plans while in relatively good health but disenroll to fee-for-service when their health care needs increased. The result could be a disproportionate number of less healthy beneficiaries in the fee-for-service sector, excess payments to HMOs, and unnecessary Medicare spending. We believe that the nine-month lock-in period will help reduce risk selection and, consequently, reduce the current problem of paying monthly premiums for beneficiaries while they are healthy but paying traditional claims when they become ill and disenroll from a managed care plan.

C. New Payment Methodology for M+C Plans

Section 1853 directs HCFA to modify the payment methodology for entities receiving capitated payments from Medicare. These payment changes are intended to: promote savings, reduce geographic variation in the rates, and stimulate the growth of new entities to serve Medicare beneficiaries in historically underserved areas. As described above, beginning in 1998, monthly county rates are the greatest of: (1) a minimum payment amount (of $367 in 1998); (2) a minimum percentage increase of 2 percent over the preceding year's payment for the area; and (3) a blend of the area-specific rate and an input-price adjusted national rate, further adjusted by a budget neutrality adjustment. The area-specific portion of the blended rates and the minimum payment amount are updated each year by the national average per capita Medicare growth rate (with specified reductions from 1998–2002).

Payment changes to M+C organizations figure prominently in reducing overall Medicare spending and postponing the depletion of the Medicare Trust Fund from 2001 to 2010. The CBO estimates that the BBA reduces Medicare spending by $116.4 billion dollars between 1998 and 2002. An estimated $22.5 billion, or almost 20 percent of total Medicare savings under the BBA, is attributable to payments to M+C organizations. Much of the savings is attributable to lower payment rates in the original Medicare program. Additionally, removal of GME and IME from the capitated payments to M+C organizations represents a redirection of $4 billion, which would be paid directly to providers. All told, the BBA payment changes are estimated to reduce annual spending increases for both the M+C program and original Medicare from 8.5 percent to about 5 percent a year between 1997 and 2002.

The new payment methodology will lessen the significant geographic variation in payments by reducing the influence of factors that cannot be explained by geographic differences in medical input prices. Under the pre-BBA methodology, capitation amounts were based on actual per capita costs for original Medicare in each enrolled's county of residence. Under the BBA formula, adjustments for input prices is specifically included in the computation of blended rates, but the influence of practice pattern differences is gradually minimized through the payment blending. Over the period 1998–2002, each county's blended payment amount is increasingly based upon a standardized rate that reflects practice patterns across the country. In this way, the new methodology attempts to achieve a more equitable distribution of payments, and will hopefully encourage plans to focus on implementation of quality-based, cost-effective treatment methods.

One of the chief considerations in restructuring the payment methodology was evidence that Medicare managed care organizations have attracted healthier and therefore less expensive enrollees than fee-for-service organizations. In its 1996 Annual Report to Congress the PPRC reported on a study of enrollees in Medicare risk plans between 1989 and 1994. This study showed that those enrolled in managed care plans cost the Medicare program only 63 percent as much as the average Medicare beneficiary during the six months preceding enrollment when both groups were enrolled in traditional Medicare. In contrast, persons who disenrolled and returned to traditional fee-for-service Medicare cost the program 160 percent as much as the average beneficiary in the six months following disenrollment. In its December, 1997 study, the Congressional Budget Office estimated that Medicare paid 6–8 percent more for enrollees in risk-based HMOs than it would have paid for those enrollees under fee-for-service Medicare. Although prior law did set Medicare capitation rates 5 percent below fee-for-service payments under original Medicare, this reduction was not enough to compensate for favorable risk selection. The new methodology mandated by the BBA requires risk adjustment beginning in the year 2000.

Medicare managed care enrollment has grown steadily in recent years. However, most of the growth has been concentrated in urban areas. Between December of 1990 and December of 1997, enrollment in risk contracts grew from 3.3 percent of Medicare beneficiaries to 14.0 percent. Twenty-four percent of beneficiaries residing in large urban areas with a population of 1 million or more were enrolled in a Medicare risk plan in June of 1997. Twelve percent of beneficiaries residing in areas adjacent to large urban areas and smaller metropolitan areas, and less than 3 percent of Medicare beneficiaries residing in rural areas, were enrolled in a Medicare risk plan. Approximately thirty-three percent of Medicare beneficiaries reside in an area that is not served by any Medicare managed care organization.

We assessed the impact of the payment methodology by first considering the overall impact and then considering the impact of changes in payment on specific entities. The potential overall impacts of changes in payment are: reductions in spending; redistribution of payments; increases in enrollment in M+C plans; changes in the distribution of enrollment in M+C plans; and the creation of a more competitive market offering a wider range of choices for Medicare beneficiaries.

We have identified the types of entities and individuals that will be directly affected by changes in payment. They include: beneficiaries, M+C organizations offering coordinated care plans (including current Medicare managed care contractors), and M+C organizations offering private fee-for-service plans or MSA plans, States, providers, and the Medicare Trust Funds.

One clear impact of the revised payment methodology is decreased spending relative to estimates of spending under prior law. In its BBA analysis, CBO estimated that changes in payments to managed care plans save $22.5 billion between 1998–2002. As stated earlier, these savings contribute significantly toward efforts to extend the long-term solvency of the Medicare Part

A Trust Fund. Table 3 provides more recent alternative projections of $30 billion in savings between 1998–2003. (HCFA Office of the Actuary, 3/98.)

TABLE 3.—PROJECTED IMPACT DUE TO CHANGES IN PAYMENT METHODOLOGY

Fiscal year	Savings (in billions of dollars)
1998	0.3
1999	0.7
2000	4.4
2001	6.6
2002	8.1
2003	9.2

*Includes risk adjustment.
Source: HCFA Office of the Actuary, 3/98.

As noted above, projected savings due to the change in the M+C payment methodology are also tied in part to the overall savings in Medicare created by BBA changes in payments to Medicare fee-for-service providers. Specifically, since the National Per Capita M+C growth factor (NGP) is defined as the ''projected per capita rate of growth in Medicare expenditures'' reduced by the BBA's specified percentage reduction, the NGP will include the impact of reductions and/or slower increases to provider payments in the original Medicare program.

Another factor that affects the amount of savings is the minimum payment amount and the minimum percentage increase. Because the payment methodology does not allow for reduction of the floor and minimum payment increases, budget neutrality, which is achieved by reducing or increasing the blended rates, may not be achieved in all years where the computation requires a reduction in the blended rates. This situation occurred in the calculation of the 1998 and 1999 rates, when no county received the blended rate because the budget neutrality adjustment brought all rates to an amount below the amount of the minimum 2 percent increase. See discussion in Section II.F. above.

It is clear that one aspect of the new payment methodology, the floor, actually increases spending compared to prior law. CBO estimates that increasing payments to the floor counties will cost $2.2 billion more than expected under previous law over the 5-year period of 1998–2002. However, increasing payment to floor counties meets important policy objectives in that by reducing payment disparities it is hoped that more choices will become available in under-penetrated areas.

The payment methodology has removed some of the variation in payment rates by increasing payment rates in lower payment counties through use of a minimum payment amount. In the future, blending will further reduce variation by reducing the influence of local fee-for-service costs in the blended rates. Table 4 shows the impact of the payment methodology by location. The floor rate increased payments significantly in rural areas and in some urban counties as well.

TABLE 4.—AVERAGE AND RANGE OF MEDICARE COUNTY PAYMENT RATES, BY LOCATION, 1997–1998

	1997 Average	1998 Average	1997 Range (Low:High)	1998 Range (Low:High)
All Counties	470	484	221:767	367:783
Central Urban	546	557	349:767	367:783
Other Urban	440	452	256:728	367:742
Urban Fringe	394	413	231:693	367:707
Other Rural	371	397	221:647	367:660

Source: MEDPAC, March 1998 Report to Congress: Medicare Payment Policy.

A further change in the methodology is the graduate medical education (GME) carve-out. While the removal of GME does not generate savings for the Medicare trust fund or Medicare GME, it does reduce capitation rates in counties that historically received GME payments (except in counties where the minimum payment amounts apply). In general, GME carve-outs disproportionately affect urban managed care organizations because urban counties house more teaching hospitals. Table 5 shows the 1995 GME percentages in urban and rural counties.

TABLE 5.—ESTIMATED GRADUATE MEDICAL EDUCATION PAYMENT REDUCTIONS AS A PROPORTION OF MEDICARE RISK PAYMENT RATES BY URBAN AND RURAL LOCATION (PERCENTAGE), 1995

Location	GME percentage
All Counties	3.4
Urban Counties	3.8
Central Urban	5.3
Other Urban	3.1
Rural Counties	2.1
Urban Fringe	2.2
Other Rural	1.9

Source: PPRC, 1997 Annual Report to Congress, Chapter 3, p. 62.

We anticipate that these changes to the variations payment will affect the enrollment distribution of M+C enrollees.

The methodology has already increased capitation levels in rural areas now receiving the payment floor, in some counties significantly. HCFA's Office of the Actuary currently predicts that the blended rates will begin in CY 2000, which should increase rates in some rural areas that received the 2 percent increase in 1998 and 1999. In fact, to the extent that blended rates are eventually applied under the budget neutrality rules, the blended rate will gradually elevate payments to counties that have an area-specific payment that is below the national average as adjusted for input prices.

The improved incentives in rural counties should prompt M+C organizations to contract in these areas. Greater participation of managed care plans in rural counties should spur increases in M+C enrollment in the long run. CBO expects an incremental gain of 3 percent market share for coordinated care plans by 2002. This growth occurs, for the most part, in non-urban areas. It

is expected that higher payments in rural areas will encourage M+C organizations to offer plans in these areas. In particular, PSOs were included as an M+C option in part because of the belief that rural providers might organize M+C organizations in their areas which, because of their smaller population bases, generally have not been as attractive to managed care plans for commercial or Medicare business.

Table 6 provides a profile of the distribution of risk contractors and enrollment prior to passage of the BBA.

TABLE 6.—DISTRIBUTION OF MEDICARE RISK ENROLLMENT, AND RISK CONTRACTORS

Location	Percent of beneficiaries in risk plans (6/97)	Percent of counties offering 0 risk plans (6/97)	Percent of counties offering 1 risk plan (6/97)	Percent of counties offering 2–4 risk plans (6/97)	Percent of counties offering more than 5 risk plans (6/97)
Urban (MSA of 1 million or more)	24	0	2	19	79
Other Urban (surrounding counties or smaller MSA)	11.8	27	12	34	27
Fringe Urban (rural areas bordering MSA)	2.6	71	18	11	1
Other rural areas	1.1	91	6	3	0

Source: MEDPAC 1997 Chartbook.

It is expected that as more M+C organizations enter the Medicare market, competitive pressures will increase. As the payment changes are implemented and geographic variation in payment levels is reduced, the profitability of M+C organizations will be driven less by where they deliver services, and more by how well they deliver services. An organization's success will depend on the quality of services offered, the extent and clarity of an organization's communications with beneficiaries, the ability of a plan to effectively manage the provision of care to Medicare beneficiaries, and the satisfaction levels of Medicare enrollees in a plan, as well as the benefits offered and the premiums charged. These competitive forces should provide increased access to high quality services under capitated plans for Medicare beneficiaries.

For beneficiaries in rural areas we believe the overall impact of these changes should make participation in the M+C program a more viable option. Conversely, as payment rates become less robust in urban areas and margins decrease, some coordinated care plans may choose to reduce benefits, or increase premiums. Reductions in benefits or increases in premiums would have a negative impact on beneficiaries.

We should also note here that oftentimes we look at payment as a driving force in the Medicare program as a whole. While the increased payment to rural counties should on its face provide an incentive for organizations to offer their services and products in rural areas, that may not always be the case. That is, some may assume that when Medicare pays coordinated care plans considerably more than the average per capita fee-for-service cost in a geographic area, as it does in many of the payment floor counties, this would cause organizations to rush to enter into contracts in these areas. However, plans may decide that the smaller pool of potential enrollees (and hence the smaller pool over which to spread risk) do not justify either their added financial risk or the proportionally larger start up and marketing costs associated with launching a plan in a rural area.

We believe and Congress intended that these increases for rural counties would stimulate the growth of capitated plans in these areas. However, there still is a large degree of uncertainty over the actual effects of the BBA changes for rural areas. In the end only M+C organizations can really determine if the payment levels justify their costs.

D. Introduction of New Contracting Entities

In general, we believe that new entities will be formed to serve the Medicare market. As discussed above, the new payment methodology and the availability of PSO and MSA plans should stimulate the private sector's development of entities to compete for Medicare beneficiaries. While estimates of the development of new entities are somewhat speculative, the following are our best estimates based on currently available information, enrollment projections, informal surveys and discussions with industry representatives.

Provider Sponsored Organizations: The Congressional Budget Office projects that PSO enrollment will reach a 3 percent share of Medicare beneficiaries, or about 1 million beneficiaries, by 2002 and that a significant portion of the PSO enrollment will be in rural areas (CBO, 1997).

Currently, there are approximately 5.5 million beneficiaries enrolled in 307 Medicare risk products, which is an average of approximately 8,000 enrollees per Medicare risk plan. We believe that CBO's projections, presented in the following table, represent a good estimate of the approximate number of new PSO plans that will be established. Some industry analysts have projected a higher level of certified PSOs than projected by CBO. While we believe it is highly unlikely that as many as 25 PSOs will be certified by the end of 1998, we believe that CBO's projections for 1999 and thereafter are reasonable.

Enrollment estimate	Year	New PSOs
100,000	1998	25
400,000	1999	50
600,000	2000	75
800,000	2001	100
1,000,000	2002	125

Source of enrollment estimate: CBO, 1997.

As a secondary impact, the M+C program could result in expanded availability of PSOs, particularly in rural areas. That is, PSOs that are successful in their Medicare contracts may decide to expand into the commercial market. In turn, if commercial payers learn of their success in serving the Medicare population, they may have more confidence in the ability of PSOs to assume and manage risk and may, therefore, be more interested in contracting with them.

Private Fee-For-Service Plans: The Congressional Budget Office projected that no Medicare beneficiaries will enroll in private fee-for-service plans, and no reliable estimates for the number of likely private fee-for-service market entrants are available. However, we have received some expressions of

interest from insurance carriers and others regarding how these plans will work and whether there is an opportunity to serve Medicare beneficiaries. If offered, we would expect them to be most attractive to wealthier beneficiaries because of their anticipated higher premiums and other out-of-pocket costs. While private fee-for-service plan providers are allowed to engage in limited balance billing, there is no statutory limit on premiums that a plan may charge beneficiaries.

Medical Savings Account Plans: The Congressional Budget Office estimated that 390,000 Medicare beneficiaries will enroll in M+C MSA plans by 2000. This is the statutory limit for the total number of beneficiaries that can enroll in the MSA demonstration. While there are no reliable estimates on the number of organizations that will offer M+C MSAs, we expect that many organizations offering MSA plans in the commercial marketplace will offer MSA plans in the Medicare market as well.

According to a recent General Accounting Office study, 57 carriers, including three HMOs, offered MSA plans in the commercial market as of the summer of 1997. Blue Cross & Blue Shield plans represented almost one-third of the plans offered in the market. At that time, an additional fifteen carriers and eight HMOs indicated an interest in offering MSA plans. However, commercial enrollment in MSA plans has been considerably lower than had been anticipated. While the demonstration project under the Health Insurance Portability and Accountability Act allowed for 750,000 MSAs to be sold, as of June 30, 1997, only 17,145 individuals had enrolled in these new products, according to the Internal Revenue Service.

The GAO found that the complexities surrounding the tax implications of an MSA product, increased time necessary to explain the product to customers, and lower commissions to brokers/agents for selling a high deductible product have contributed to the low number of plans sold. However, some of these complexities may be mitigated under the BBA, as beneficiaries are barred from contributing their own money to the medical savings account, and they will receive extensive information about MSA plans as part of the annual information campaign on their M+C options.

Impact of New Contracting Entities

Beneficiaries may benefit from competitive pressures on M+C organizations to compete on such factors as reduced premiums, extra benefits, and quality. However, the difference between out-of-pocket costs under managed care plans and the traditional fee-for-service program may decrease as M+C payments moderate. Under the Medicare risk program, beneficiaries enrolled in risk HMOs generally have had lower out-of-pocket costs than beneficiaries in the traditional Medicare fee-for-service sector. For example, a recent study by the American Association of Retired Persons projected that beneficiaries enrolled in a Medicare managed care plan will spend an average of 16 percent of their annual income, or $1,775, on out-of-pocket health care costs, in 1997. This is compared to the estimated out-of-pocket expenses for Medicare fee-for-service beneficiaries, which were projected on average to be 21 percent of their annual income, or $2,454, on out-of-pocket costs. (AARP, 1997).

We also anticipate that many providers will have new opportunities to serve Medicare beneficiaries, such as through provider sponsored organizations or through strategic partnerships with other coordinated care plans seeking to enter new markets. As M+C enrollment grows, providers will find it increasingly important to their business to participate in an M+C network as many of their patients will be locked into these networks. In turn, we believe M+C organizations will seek to contract with providers that are capable of serving both their commercial and Medicare populations.

Finally, the M+C program will most affect those states in which the greatest market opportunities for newly created M+C organizations exist. Oversight and licensing responsibilities will likely increase for such states as newly created M+C organizations, such as PSOs, seek to serve the Medicare market. The BBA increases the workload for States only to the extent that new organizations will begin operating in the State. It is likely that States will also have to monitor the compliance of PSOs that have a waiver of State licensure in the case of quality and consumer protection standards. This constitutes an additional workload of partial monitoring of plans that are not subject to State solvency requirements.

Many states will be confronted with issues on licensing of PSOs, whether by bringing such entities under existing HMO laws and regulations or establishing separate PSO licensing provisions. In a recent report, the National Association of Insurance Commissioners reported that ten states have already enacted state-level PSO regulation (NAIC, 1997), and the National Council for State Legislatures reports that thirteen states currently are considering PSO legislation.

States will also have to integrate PSOs into their state guaranty fund or other mechanism for protecting beneficiaries against insolvent plans. While this will not be a new function, it is expected to increase the amount of regulatory oversight necessary due to new market entrants and could place burdens on a state's ability to protect consumers if PSOs become insolvent.

Finally, the preemption of state mandated benefit and provider participation laws will lead to mandated benefits being applied to a smaller number of State residents. However, states may still enforce any laws relating to cost-sharing for a benefit included in an M+C contract as well as any laws restricting balance billing practices by providers. Moreover, we believe that few states will be impacted by the BBA's prohibition on state imposition of premium taxes on payments to Medicare risk contracts/M+C organizations. While almost all states impose premium taxes on insurers generally (and nineteen states have specific premium tax schedules for HMOs), it is our understanding that most states have not subjected Medicare revenue to a premium tax and that many states specifically exempt Medicare payments to HMOs from any premium tax.

E. New Quality Standards

Each M+C organization must have arrangements for an ongoing quality assessment and performance improvement program for health care services it provides to Medicare beneficiaries enrolled in the M+C plans. The quality assurance program for an M+C organization must, among other things: (1) stress health outcomes and provide for the collection, analysis, and reporting of data to permit measurement of outcomes and other indices of the quality of M+C organizations and organizations; (2) include measures of consumer satisfaction; (3) provide the Secretary with such access to information collected as appropriate to monitor and ensure the quality of care; (3) provide review by physicians and other health care professionals of the process followed in the provision of health care services; (4) provide for the establishment of written protocols for utilization review, based on current standards of medical practice; (5) have mechanisms to detect both underutilization and overutilization of services; (6) take action to improve quality and assess the effectiveness of that action through systematic follow-up; and (7) make available information

on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options.

An M+C organization is deemed to have met the quality assessment and performance improvement requirements if the organization is accredited (and periodically reaccredited) at a level acceptable to the Secretary by a national, private accrediting organization approved by the Secretary. Deemed M+C organizations must meet certain requirements, including submitting to surveys to validate its accreditation organization's process and authorizing its accreditation organization to release to HCFA a copy of its most current accreditation survey and any information related to the survey as required by HCFA.

Accrediting organizations will have to meet certain requirements in order to receive approval as well as ongoing requirements to maintain its approved status.

The quality assurance and performance improvement requirements under this regulation provide that each M+C organization achieve minimum performance levels on standardized quality measures. They also require that organizations conduct performance improvement projects that achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical services that can be expected to affect health outcomes and member satisfaction. This approach to ensuring quality reflects the expansion in recent years of the problem-focused approach that was prevalent in the past to include a focus on systematic quality improvement as well.

We believe that the quality assessment and performance improvement requirements under this regulation will not impose significantly new burdens on most M+C organizations.

First, as discussed in detail in section III D of this preamble, requirements under this regulation build on a variety of HCFA and State Medicaid agency efforts to promote the assessment and improvement of quality in plans contracting with Medicare and Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with state and federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system to reduce duplicative or conflicting efforts and that has an emphasis on demonstrable and measurable improvement.
- Initiatives to improve accountability by requiring uniform collection and reporting of data to allow assessment of plan performance and to facilitate comparisons among plans, such as the Health Plan Employer Data and Information Set (HEDIS 3.0).
- Projects to enhance the role of Medicare Peer Review Organizations (PROs) in evaluating and improving managed care plan quality, including the development and testing of a minimum set of performance evaluation measures and quality improvement projects developed through collaboration between PROs and the managed care industry.

Second, we anticipate that many new M+C organizations will be offered by organizations currently participating as Medicare risk contractors. While we acknowledge that many organizations have not developed the capacity to fully meet the pre-BBA requirements, we believe that this regulation does not create substantially new demands for building new administrative and information systems necessary to meet the quality assessment and performance improvement requirements for M+C products, as such organizations already are subject to similar requirements as section 1857 contractors. Moreover, we will build into the contract process a gradual phase-in of the number of focus areas for which a plan must demonstrate improvement to allow sufficient time for a plan to implement and conduct well-designed improvement projects.

Third, we anticipate that many organizations seeking to offer M+C products will have had to invest in administrative and information systems to meet the requirements of other purchasers and State regulators, diminishing burdens this regulation might otherwise have imposed. This is true even for provider-sponsored organizations that seek a federal waiver from state solvency requirements, as such entities are still subject to other state requirements, including a state's quality assessment and improvement requirements.

We have built on efforts in other sectors in developing these quality assessment and performance improvement requirements in order to minimize the burden that these activities place on plans. (GAO, September 1996; NCQA, 1997), such as:

- Many employers and cooperative group purchasing groups and some States already require that organizations be accredited by the National Committee on Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, the American Healthcare Accreditational Commission, or other independent bodies.
- Many also require that organizations report their performance on HEDIS, FACCT, or other measures and conduct enrolled surveys using the CAHPS or other instruments. For example, NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. (NCQA, 1997)
- States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

Another important mechanism in avoiding duplication of effort and unnecessary administrative burdens with respect to internal quality assurance requirements is the ''deemed'' status afforded organizations for each standard that is accredited by a national, private accrediting organization.

Fourth, we have worked closely with private-sector leaders in health plan performance and quality measurement to avoid duplication of effort and promote standardization in measurement approaches. (GAO, September 1996) For example, we convened advisory groups of managed care organizations, State and Federal purchasers and regulators, beneficiary advocates, and experts in mental health and substance abuse services and relied heavily on the insight and expertise of these groups in refining standards and guidelines.

Fifth, measuring and reporting plan- and provider-specific information will allow plans and networks to compare themselves to competitors, track their own performance over time, and so drive their own internal quality improvement programs. (Palmer, 1997). Moreover, plans will have added incentives to initiate performance improvement projects that will lead to more cost-effective delivery of health care services, such as influenza immunization outreach efforts which lead to lower complications and treatment of influenza-related conditions or improving access to primary care to reduce inappropriately frequent use of the emergency room by enrollees. This regulation allows plans the freedom to select its own particular topics for measurement and improvement so that each plan can conduct projects relating to aspects of care and services that are significant for its own population.

Although the quality standards under this regulation are not substantially

different from requirements already in place, we recognize that some M+C organizations may need to invest in administrative and/or information systems necessary to comply with the existing as well as the M+C standards. Additionally, while some plans may be tempted to invest their resources into the areas in which they must measure and demonstrate improved performance at the expense of other parallel quality initiatives, we have designed the quality assessment and performance improvement requirements under this regulation to be as flexible as possible and encourage plans to work with HCFA in developing long-range goals for projects.

Our role in overseeing compliance with the quality standards interrelates with our efforts to sponsor an annual information campaign that coincides with the open enrollment period for M+C organizations and is an important augmentation to those efforts. These efforts are designed to ensure that all organizations in the M+C program have the organizational structure and operational capacity to provide quality health care to Medicare beneficiaries and to ensure that beneficiaries have accurate information on quality to guide their health plan selections.

F. Conclusion

We expect that this rule overall will have a positive impact on the Medicare program, Medicare beneficiaries, providers, rural providers and suppliers, and entities that have not previously contracted with us. However, some current managed care contractors will experience a decrease in the capitated payments they otherwise would have received without passage of the BBA, possibly resulting in reduced benefits for Medicare enrollees. States will also have to develop mechanisms to license new risk bearing entities known as provider sponsored organizations after 3-year waivers.

VI. Collection of Information Requirements

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The Agency cannot reasonably comply with the normal clearance procedures because of the statutory requirement, as set forth in section 1856 of Balanced Budget Act of 1997, to implement these requirements on June 1, 1998.

HCFA is requesting OMB review and approval of this collection within 11 working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within 10 working days of publication of this document in the **Federal Register**.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

Application Requirements (§ 422.6)

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 an application, in the form and manner required by HCFA, including all of the requirements set forth in § 422.6.

In order to contract with us under the M+C program, organizations are required to complete an application to demonstrate their capability of carrying out the requirements of the Medicare program. Completing an application requires the capability of organizations to adhere to Medicare program guidelines and demonstrate to HCFA by in-house documentation that such capability exists. In prior years, applicants were required to complete applications forms (HCFA 901–903) to obtain a Medicare contract under section 1876 of the program. The application having OMB clearance #0938–0470 estimated that approximately 100 hours would be required to complete an application. We believe the new applications are quite similar and therefore estimate that 100 hours will be required to complete an application under the Medicare + Choice program. We project approximately 100 applications a year requiring 10,000 hours of time by all applicants on an annual basis.

Eligibility To Elect an M+C Plan (§ 422.50)

A beneficiary must complete and sign an election form and gives information required for enrollment.

The burden associated with this requirement is the time it takes for a beneficiary to complete an enrollment form. The enrollment form varies for each organization, but similar identifying information is collected. It is estimated that it will take 2,000,000 beneficiaries (based on 2,012,025 enrollments in calendar year 1997) 10 minutes for an annual burden of 20,000,000 minutes = 333,000 hours.

Continuation of Enrollment (§ 422.54)

An M+C organization that wishes to offer a continuation of enrollment option must submit their marketing materials to HCFA for approval, which meet the requirements set forth in this section, that describe the option and the M+C organization's assurances of access to services as set forth in this section and, an M+C organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule.

The burden associated with this requirement is captured below in § 422.64.

Election Process (§ 422.60)

The election 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 HCFA and the M+C organization.

The burden associated with this requirement is captured above in the § 422.50 discussion.

The M+C organization must file and retain M+C plan election forms for the period specified in HCFA instructions, and submit beneficiary M+C plan and optional supplemental benefit elections to HCFA.

The burden associated with this requirement is the time required for each organization to perform record

keeping on each application filed. It is estimated that it will take each organization 5 minutes for each of 2,000,000 beneficiaries (based on 2,012,025 enrollments in calendar year 1997). The total annual burden is estimated at 10,000,000 minutes = 167,000 hours. On average, M+C organizational level burden is 167,000/450 (100 new/350 current) = 371 annual hours. In addition, it is estimated to take each M+C organization 4 hours per month to electronically submit a subset of beneficiary M+C plan and optional supplemental benefit election information to HCFA, for a total annual burden of 21,600 hours.

The M+C organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by HCFA that meets the requirements set forth in this section.

The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. The annual total burden is estimated at 2,000,000 minutes = 33,000 hours. On average, M+C organizational level burden is 33,000/450 (100 new/350 current) = 73 annual hours.

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 must transmit the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

The burden associated with electronic submission of information to HCFA is estimated at 1 second per application processed, for an annual burden of 2,000,000 minutes = 33,000 hours. On average, M+C organizational level burden is 33,000/450 (100 new/350 current) = 73 annual hours.

Election of Coverage Under an M+C Plan (§ 422.62)

Except as provided in paragraph (d)(2)(ii) of § 422.62, an individual may disenroll from an M+C MSA plan only during an annual election period or the special election period described in paragraph (b) of this section. However, an individual who elects an M+C MSA plan during an annual election period and had 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 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.

The burden associated with this requirement is the time required for each beneficiary to complete a disenrollment form. It is estimated that about 5 percent of the maximum number of beneficiaries permitted to choose an MSA (390,000) would disenroll (19,500) and each disenrollment form would take 4 minutes to complete, for an annual burden of 78,000 minutes = 1,300 hours.

Information About the M+C Program (§ 422.64)

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 that meets the general and content requirements set forth in § 422.6, 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.

The burden associated with this requirement is the time required for the organization to provide the information to HCFA. It is estimated that it will take 450 (100 new/350 current) organizations 12 hours for an annual burden of 5,400 hours. In addition, it is estimated that on an annual basis it will take 4 hours for an estimated 50 organizations to modify and submit their revised materials to HCFA for review for a annual burden of 200 hours.

Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

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.

An individual who wishes to disenroll from an M+C plan may do so by (1) electing a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by HCFA, (2) submitting a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by HCFA or, (3) filing the appropriate disenrollment form through other mechanisms as determined by HCFA.

The burden associated with electing a different plan is included in 422.50. The burden associated with disenrolling is the time to complete a disenrollment form. It is estimated that 720,000 disenrollments (based on the number of disenrollments in calendar 1997) will take 2 minutes each for an annual burden of 1,440,000 minutes = 2,400 hours. On average, M+C organizational level burden is 2,400/450 (100 new/350 current) = 5 annual hours.

The M+C organization must submit each disenrollment notice to HCFA promptly.

The burden associated with electronic submission of information to HCFA is estimated at 1 second per disenrollment processed, for an annual burden of 1,200 minutes = 20 hours.

On average, M+C organizational level burden is 1,200/450 (100 new/350 current) = 3 annual hours.

In the case of a plan where lock-in applies, the M+C organization must provide the enrollee with a statement explaining that he or she remains enrolled until the effective date of disenrollments, and 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.

The burden associated with each organization providing the beneficiary prompt written notice of disenrollment and lock-in, produced by an automated system, is estimated at 1 minute per disenrollment processed, for an annual burden of 720,000 minutes = 1,200 hours. On average, M+C organizational level burden is 1,200/450 (100 new/350 current) = 3 annual hours.

The M+C organization must file and retain disenrollment requests for the period specified in HCFA instructions.

The burden associated for each disenrollment request is the time required for each organization to perform recordkeeping on each disenrollment request filed. It is estimated that it will take 5 minutes for 720,000 disenrollments processed for an annual burden of 3,600,0000 minutes = 60,000 hours. On average, M+C organizational level burden is 6,000/450 (100 new/350 current) = 13 annual hours.

Disenrollment by the M+C Organization (§ 422.74)

If the disenrollment is for any of the reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(3) of § 422.74, 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. The notice must be mailed to the individual before submission of the disenrollment notice to HCFA and include an explanation of the individual's right to a hearing under the

M+C organization's grievance procedures.

There is a burden associated with the requirement for the organization to notify the beneficiary about an involuntary disenrollment, and to separately notify the beneficiary of the effective date of the disenrollment. It is estimated that less than 100 such notices will be issued and that each notice will take 1 minute for an annual burden of less than 100 minutes = or less than 1.5 hours.

A M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums if the M+C organization sends a written notice of nonpayment to the enrollee within 20 days of the date that the delinquent charges were due stating that nonpayment of premiums will not automatically result in disenrollment and information about the lock-in requirements of the M+C plan.

There is a burden associated with the requirement for the organization to notify the beneficiary and it is estimated that less than 500 of these requests occur annually at 1 minute per notification, resulting in an estimated burden of 500 minutes, or approximately 80 hours.

A 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. 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. And, a M+C organization must submit documentation related to the proposed disenrollment and any information submitted by the beneficiary, to HCFA for review to determine whether the M+C organization has met the disenrollment requirements.

The burden associated with this requirement is the time for the organization to document the behavior of the beneficiary and document the efforts of the organization to resolve any problems and provide information to HCFA concerning the involuntary disenrollment request. The burden reflects documentation and transmission of documentation to HCFA by the managed care plans. It is estimated that less than 100 such requests occur annually (based on estimate of regional office collection of such information), and it is estimated that each request will take 1 hour to manually collect the data and 15 minutes to transmit the data to HCFA, for a burden of 125 hours.

A M+C organization must report to the Office of the Inspector General of the DHHS any disenrollment based on fraud or abuse by the individual.

There is a burden associated with the requirement for the organization to report to the Office of the Inspector General any disenrollment based on fraud or abuse by the individual. It is estimated that only 1% of all involuntary disenrollments, or 10 involve fraud or abuse, and the reporting burden would be 1 minute each, for a total burden of less than 1 hour.

If a M+C organization 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. The notice must be sent before the effective date of the plan termination or area reduction.

The burden associated with this requirement is captured below in § 422.506.

Approval of Marketing Materials and Election Forms (§ 422.80)

At least 45 days before the date of distribution the M+C organization must submit any marketing material or election form to HCFA for review. The materials must be in a format and using standard terminology specified by HCFA, that meet the requirements specified in this section.

The burden associated with this requirement is captured above in § 422.64.

A M+C organization must notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its enrollment area.

We anticipate notification to the general public would be through a general circulation newspaper and would require 8 hours of burden per organization to modify their enrollment period bulletin and seek publication in a local newspaper, for an annual burden of 3,600 hours.

Special Rules for Point of Service Option (§ 422.105)

M+C organizations must maintain written rules on how to obtain health benefits through the POS benefit. While the maintenance of written rules is a recordkeeping requirement subject to the PRA, the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3).

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 the requirements set forth in (d)(2)(i) through (d)(2)(iv) of this section.

The burden associated with this requirement is captured above in § 422.64.

An M+C organization that offers a POS benefit must report data on the POS benefit in the form and manner prescribed by HCFA.

The special rules for M+C organizations offering a POS benefit as stipulated in § 422.105 requires that M+C organizations provide to HCFA POS data relating to the utilization of the POS benefit by plan members. This is not a new data requirement since M+C organizations that offer a POS benefit would need to have this data in the normal course of business in order to pay POS claims. We estimate that providing this data to HCFA would require 1 hour per quarterly submission. Thus, the annual burden would be 1 hour $\times$ 4 = 4 hours per MCO in providing the required POS data.

Disclosure Requirements (§ 422.111)

An M+C organization must disclose the information specified in § 422.64 and in paragraph (b) of § 422.111 to each enrollee eligible for or electing an M+C plan it offers. The information must be in clear, accurate, and standardized form, and provided at the time of enrollment and at least annually thereafter. The burden associated with this requirement is captured above in § 422.64.

If an M+C organization intends to change its rules for an M+C plan, it must submit the changes for HCFA review under the procedures of § 422.80. The burden associated with this requirement is reflected in § 422.80 above.

The plan must also give notice to all enrollees 30 days before the intended effective date of the changes. The burden associated with this requirement is reflected above in § 422.80.

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.

HCFA has no basis to calculate the burden impact imposed by these requirements. Therefore, we explicitly seek comment on the impact of this notification requirement.

Access to Services (§ 422.112)

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 inform beneficiaries of their right to maintain access to specialists and 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.

The requirements imposed by this section would be pursuant to an administrative action and therefore are exempt from the PRA as defined in 5 CFR 1320.4.

An M+C plan seeking a service area expansion must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served. The burden associated with meeting this requirement is captured above in 422.6.

An M+C plan must demonstrate to HCFA that its providers are credentialed through the process set forth at § 422.204(a). The burden associated with meeting this requirement is captured above in 422.6.

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/or monitor them on an ongoing basis; and (3) establishment 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.

Plans must also; (1) establish written standards for the timeliness of access to care and member services that meet or exceed standards established by HCFA, (2) continuously monitor and document the timely access to care and member services within a plan's provider network to ensure compliance with these standards, and take corrective action as necessary, (3) establish written policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations, and (4) ensure that providers consider and document beneficiary input into the provider's proposed treatment plan.

Plans must maintain written procedures to ensure that; (1) 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, 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; appropriate and confidential exchange of information among provider network components, (2) written 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 (4) documentation demonstrating that systems to address barriers to enrollee compliance with prescribed treatments or regimens.

HCFA's believes these requirements are reasonable and customary business practices and the burden associated with these requirements is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). Therefore, we are assigning one token hour of burden for these requirements. HCFA invites comment on the burden estimate associated with these requirements.

Confidentiality and Accuracy of Enrollee Records (§ 422.118)

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish and maintain procedures set forth in (a) through (c) of this section.

While the maintenance of health records is a recordkeeping requirement subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3), and assigning 1 token hour of burden for this requirement. We solicit comment on the burden associated with this requirement.

Information on Advance Directives (§ 422.128)

Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in 43 CFR part 489 subpart I.

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.

An M+C organization must provide written information to those individuals with respect to the requirement set forth in this section.

These requirements are identical to the requirements currently approved under OMB# 0938–0610, with an expiration date of July, 31, 1999. Since the currently approved requirements encompass a larger universe of provider types then just managed care organizations it is difficult to estimate the burden on the M+C organizational level. However, the per beneficiary encounter burden is estimated to be 3 minutes. In the near future, HCFA will revise this collection to capture this new provider type and resubmit the collection to OMB for approval.

Protection Against Liability and Loss of Benefits (§ 422.132)

Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization. The burden associated with demonstrating this requirement is captured below under § 422.306.

Each M+C organization must have an insolvency protection plan that provides for continuation of benefits. Each plan must submit a insolvency plan to HCFA for approval. The reporting requirements are similar to the insolvency plan reporting requirements submitted by 1876 plans. The burden associated with completing and submitting an insolvency plan is estimated to be 40 hours per plan on an annual basis. Therefore, the total annual burden associated with this requirement is 18,000 hours (40 hours x 450 plans (100 new/350 current)). In the near future, HCFA will revise this collection to capture this new provider type and resubmit the collection to OMB for approval.

Quality Assessment and Performance Improvement Program (§ 422.152)

The organization offering the plan must measure performance under the

plan, using standard measures required by HCFA, and report its performance to HCFA.

All Medicare+Choice organizations and an organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan will be required to measure performance under their plans, using standard measures required by HCFA, and report their performance to HCFA. Reporting will be required annually. The standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938–0701. The currently approved annual per plan burden is estimated to be 400.53 hours. Therefore, the total burden associated with this requirement is 180,239 hours (400.53 hours × 450 plans (100 new/350 current)). In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

The organization must report the status and results of each performance improvement project to HCFA as requested.

All Medicare+Choice organizations offering coordinated care plans will be required to undertake performance improvement projects relative to those plans. Each organization must report the status and results of each project to HCFA as requested. We expect that, in any given year, each organization will complete two projects, and will have two others underway, relative to each plan. We expect that we will request the status and results of each organization's projects annually. We estimate that it will take an organization 5 hours to prepare its report for each project. Therefore, we estimate that the total annual hours involved per plan to be 20 and an overall annual burden for all plans of 9,000 hours.

For all types of plans that it offers, an organization must: (1) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program, (2) Ensure that the information it receives from providers of services is reliable and complete, and (3) Make all collected information available to HCFA.

All M+C organizations must maintain a health information system, and must make all collected information available to HCFA. The requirement guarantees our access to organization information: it does not impose an obligation for routine organization submission of information. At this time, we do not anticipate requesting information other than that relating to the standard measures and performance improvement projects discussed above.

External Review (§ 422.154)

Except as provided in paragraph (c) of § 422.154, each M+C organization must, for each M+C plan it operates, have an agreement that meets the provisions of this section, with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in 42 CFR part 466 of this chapter.

Most M+C organizations must have an agreement with a review organization approved by HCFA to perform functions of the type described in 42 CFR part 466. A similar requirement already exists for Medicare contracting HMOs, at § 466.72. The burden estimate prepared for OMB submission #0938–0445 would also apply to the new requirement. The currently approved burden associated with this requirement on the organizational level is 10 hours every three years.

In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Compliance Deemed on the Basis of Accreditation (§ 422.156)

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).

The burden associated with this requirement is captured below in § 422.158.

Accreditation Organizations (§ 422.157)

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 information required in paragraphs (c)(1)(i) through (c)(1)(v) of § 422.157, (2) Within 30 days of a change in HCFA requirements, submit to HCFA all of the information required in paragraphs (c)(2)(i) through (c)(2)(iii) of § 422.157, (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, and (5) Within 10 days of HCFA's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations. The burden associated with this requirement is captured below in § 422.158.

Procedures for Approval of Accreditation as a Basis for Deeming Compliance (§ 422.158)

A private, national accreditation organization applying for approval must furnish to HCFA all of the information and materials referenced in this section. However, when reapplying for approval, the organization need furnish only the particular information and materials requested by HCFA.

The BBA allows HCFA to deem that a M+C organization meets certain Medicare requirements if that organization is accredited by an accreditation organization approved by HCFA. We expect that four national accreditation organizations will eventually be approved. The application and oversight procedures that we have developed for deeming in the managed care arena mirror those already in place in the fee-for-service arena as currently approved under OMB # 0938–0690. Therefore, much of the burden estimate prepared for the fee-for-service deeming regulations in 42 CFR part 488, Subpart A, would also apply here. The initial application burden associated with obtaining deeming authority is 96 hours every six years. Since we anticipate that four organizations will apply, the total burden is 386 hours over a six year period. The ongoing burden of supplying HCFA with data on the status of its deemed facilities is estimated to be 48 annual hours per deeming organization for a total annual burden of 192 hours. In the near future HCFA will resubmit this collection to OMB for approval of deeming in the managed care arena use.

Participation Procedures (§ 422.202)

An M+C organization that operates a coordinated care plan or network MSA must provide for the participation of individual health care professionals and of the management and members of groups through reasonable written 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.

The M+C organization must maintain documentation demonstrating that: (1) practice guidelines and utilization management guidelines meet the requirements of (1)(i) through (iv) of this section, (2) the guidelines have been 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, and (4) an M+C organization that operates an M+C plan through subcontracted physician groups or other subcontracted networks of health care professionals provided that the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups.

The burden associated with these requirements is the time required to maintain documentation demonstrating that the requirements have been met and, as necessary, the time necessary to communicate the guidelines to providers and enrollees. HCFA believes that these requirements are reasonable and customary business practices and the burden of meeting these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2). Therefore, we are assigning one token hour of burden to these requirements. We explicitly solicit comments on the burden associated with meeting these requirements.

Participation Contracts: Requirements and Prohibitions (§ 422.204)

An M+C organization that operates a coordinated care plan or network MSA plan that provides benefits through contracting health care professionals must provide notice to contracting professionals when the organization denies, suspends, or terminates their agreement with the professional and include (1) the reason for the action, (2) the standards and the profiling data the organization used to evaluate the professionals, (3) the numbers and mix of health care professionals needed for the organization to provide adequate access to services, and (4) the professional's right to appeal the action and the timing for requesting a hearing. This is a new requirement.

The burden associated with this requirement is the time required for organization to prepare a written notification of the denial, suspension, or termination of their agreement with the organization. In discussions with HCFA plan managers, it was predicted that .5 percent of all organizations (approximately 2 organizations) would find it necessary to take such action for about 1 percent of their contracted professionals within a single year and if the organization was already established and doing business. The range of number of contracted professionals extends from 3 contracted professionals to 67,000. Excluding outliers on both ends of the range, we estimate that an organization contracts with an average of 3,000 health care professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on known contractors (350) would be 2 organizations * 30 * 10 minutes = 600 minutes or 10 hours annually.

In addition, HCFA expects to receive approximately 100 additional applications for contracts with new entities to be processed in 1998 for 1999. For organizations creating new networks, they would probably all have at least one instance of denial the first year affecting approximately 1 percent of the number of contracting professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on new contractors would be 100 organizations * 30 * 10 minutes = 30,000 minutes or 500 hours. The total burden with current applications and expected applications for contracts would be 510 hours annually.

The number of new organizations is expected to increase by 100, on an annual basis creating an expected burden for current contracts [350(*.005(organization-rounded to the nearest whole number) *30*10)/60 =]10 hours + new contracts [100*30*10 /60 =]500 hours = 510 hours.

An M+C organization is required to notify any licensing or disciplinary bodies or other appropriate authorities when it suspends or terminates a contract with a health care professional because of deficiencies in the quality of care provided by the professional.

The burden associated with this requirement is the time required for the organization to prepare a written notification to the appropriate authorities. No exact data is available to estimate how often this situation might occur. HCFA estimates that this situation might occur in 3 percent of the M+C organizations once during an annual period. The amount of time estimated to prepare the written notification is 10 minutes. The annual burden associated with this requirement is estimated to be [450 * .03 * 1 *10/ 60] = 2.25 hours.

Interference With Health Care Professionals' Advice to Enrollees Prohibited (§ 422.206)

Section 422.206 prohibits the M+C organization from restricting the provision of treatment advice by health care professionals to enrollees. However, the prohibition against interference is not construed as requiring counseling by a professional or a referral to a service by that professional, if there is an objection based on moral and religious grounds. Section 422.206 implements a new disclosure requirement and requires M+C organizations to notify HCFA during the application process, and later to all current and prospective enrollees, through appropriate written means, if the organization has such a conscience protection policy regarding counseling in effect or if the policy is changed subsequent to the application. The expected number of M+C organizations exercising this option is not expected to exceed 10 in any given year. The amount of burden imposed in the application process, which is captured in the application burden and in the preparation of the contents of the subscriber agreement or member handbook or a subsequent written notice to enrollees is reflected above in § 422.6 and § 422.64.

Physician Incentive Plans: Requirements and Limitations (§ 422.208)

An M+C organization must conduct periodic surveys of current and former enrollees where substantial financial risk exists.

The burden associated with this requirement is captured below in § 422.210.

Disclosure of Physician Incentive Plans (§ 422.210)

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). An M+C organization must disclose annually to HCFA the physician incentive arrangements that are effective at the start of each year.

Sections 422.208 and 422.210 require disclosure of physician incentive plan information to HCFA or to States and to Medicare beneficiaries and the enrollee surveys required when plans put providers at substantial risk. This collection of information, Incentive Arrangement Form HCFA–R–201 and supporting regulations, used to monitor

physician incentive plans on an annual basis, is approved under OMB # 0938–0700. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

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.

We expect the M+CPFFS plan to provide written information to contracting providers and to make the information available via a website or toll free number to noncontracting providers who inquire. 50 M+CPFFS plans (estimate of M+CPFFS plans in out years; in first year we may have none) will be required to provide 20,000 annual responses (about 1 million providers nationwide divided by 50 M+CPFFS plans) at an estimated 5 minutes per disclosure (average of phone calls, website time, mailing time for hard copies to contracting providers) for a total annual burden of 1,667 hours per provider and an overall annual burden of 83,350 hours.

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. Specifically, an M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by non-contract 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.

M+C private fee-for-service plans must investigate and send to HCFA documentation of excessive charges by providers. It is estimated that 50 M+C private fee-for-service plans will have 10 cases per year, at 20 hours per case (to contact the enrollee who complained, acquire and review documents, contact the provider, prepare report to HCFA). Therefore, the total burden associated with this requirement is 10 cases × 20 hours = 200 annual hours per plan, for a total annual burden of 10,000 hours.

An M+C organization that offers an M+C private 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.

This requirement is akin to the Medicare EOMB or summary statement and must be furnished on a regular basis for every claim paid or denied by the M+C private fee-for-service plan. It is estimated that 3 million notices will be disseminated by M+C private fee-for-service plans. This estimate is determined by; multiply 5000 enrollees per plan by 12 (one notice per month) or 60,000, multiplied by an estimated 50 plans for a total of 3 million notices. At an estimated 3 minutes of burden per notice, the total burden is 9 million minutes or 150,000 burden hours. On a plan level the average annual burden is estimated to be 3,000 hours.

In its terms and conditions of payment to hospitals, organization the hospital is required, 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: (1) Notice that balance billing is permitted for those services; (2) a good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and (3) the amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

It is estimated that 20,000 of 25,000 estimated hospitalizations will require these notices. The $500 tolerance will be exceeded each time the plan payment rate for the inpatient stay would exceed $3333.33—which is probably almost all of them—if the plan lets the hospital balance bill. At 5 minutes of burden per notice times 20,000 annual notices, the total burden is 100,000 minutes or 1,667 hours of burden.

Encounter Data (§ 422.257)

Each M+C organization must submit to HCFA (in accordance with HCFA instructions) all data necessary and as stipulated under this section to characterize the context and purpose of each encounter between a Medicare enrollee and a provider, supplier, physician, or other practitioner.

The Act requires that the collection of inpatient hospital data for discharges beginning on or after July 1, 1997 and allows the collection of other data no earlier than July 1, 1998. The statutory language is clearly tied to the creation of risk-adjusted payment rates, as defined at § 422.256 (c) and (d) of this rule. Requirements concerning collection of encounter data apply to M+C organizations with respect to all their M+C plans, including medical savings accounts (MSAs) and private fee-for-service plans.

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.

These requirements are approved under OMB # 0938–0711, with an expiration date of July 31, 1998. The burden associated with submitting data for inpatient hospital care data for all discharges that occur on or after July 1, 1997, is currently .5 minutes per EMC bill and 1 minute per hard copy bill. Although there are currently three options for submitting bills, on average the total annual burden per plan is 46.5 hours, with an overall burden of annual 32,833 hours.

HCFA will provide advance notice to M+C organizations to collect and submit: (1) Physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and (2) all other data HCFA deems necessary beginning no earlier than October 1, 2000. We estimate the following burden for each category based on a projection of 15 seconds per claim: Physician: 72 million claims = 300,000 hours Outpatient hospital: 12 million claims = 50,000 hours HHA, Hospice, SNF: 2.4 million claims = 10,000 hours All other: 24 million claims = 100,000 hours

We will implement this provision by providing for direct transmission from the provider to HCFA with common PC-based technology. It should be noted that prior to implementing the requirement for M+C organizations to collect and submit physician, outpatient hospital, SNF, and HHA data HCFA will amend OMB # 0938–0711 and seek OMB PRA approval. As part of the PRA process the public will be given several opportunities to comment, via **Federal Register** notification, on the proposed collection prior to OMB approval and implementation.

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.

Currently HCFA plans on implementing this requirement pursuant to an administrative action or audit, based on data submitted to HCFA or one of its agents. Therefore, these requirements are currently not subject to the PRA as defined in 5 CFR 1320.4.

However, if HCFA were to implement these requirements on a prospective basis, as part of a program oversight activity, we will amend OMB # 0938–0711 and seek OMB PRA approval. As part of the PRA process the public will be given several opportunities to comment, via **Federal Register** notification, on the proposed collection prior to OMB approval and implementation.

Special Rules for Beneficiaries Enrolled in M+C MSA Plans (§ 422.262)

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 securities broker, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee, (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.

An M+C organization offering an M+C MSA plan will have to register with HCFA for each beneficiary enrolled. This will require a short form that would take no more than five minutes to fill out. The Act limits the number of MSA enrollees to 390,000; therefore, with maximum participation, registration with HCFA would take 32,500 hours. (i.e., 390,000 registration forms at 5 minutes each.)

Items 2 and 3, above, are IRS requirements and entail no reporting requirements for HCFA. Under item 4, above, we anticipate no further M+C MSA reporting requirements at this time.

Special Rules for Hospice Care (§ 422.266)

An M+C organization that has a contract under Subpart K of part 422 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 organization's service area, or (2) It is common practice to refer patients to hospice programs outside that area.

At present, one-twentieth of one percent (three thousand) of Medicare managed care enrollees have elected the hospice option. We estimate that informing beneficiaries about their hospice choices would take about ten minutes. For three thousand beneficiaries, this represents a total burden of 500 hours. On a organizational level the annual burden would be 500 hours / 450 M+C organizations (100 new/350 current) = 1.2 annual burden hours per entity.

Submission of Proposed Premiums and Related Information (§ 422.306)

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: (1) The information specified in paragraph (b), (c), or paragraph (d) of this section for the type of M+C plan involved, and (2) The enrollment capacity (if any) in relation to the M+C plan and area.

This collection effort will require the submission of benefit and pricing forms that will be used to price the benefit package sold and describe the benefit package being priced to Medicare beneficiaries. Both collection efforts will be completed at the same time, in order to approve both the benefit and pricing structure of a particular benefit package.

Organizations submitting benefit and pricing forms would include all M+C organizations plus any organization intending to contract with HCFA as a M+C organization.

The estimate of the hour burden of this collection of information is as follows:

Pricing portion of the Adjusted Community Rate Proposal; 1 response per year per respondent × 450 (350 current/100 new) annual respondents × 100 hours of estimated burden per response = 45,000 total annual burden hours.

The Plan Benefit Package portion of the Adjusted Community Rate Proposal; 1 response per year per respondent × 450 (350 current/100 new) annual respondents × 20 hours of estimated burden per response = 9,000 total annual burden hours.

Requirement for Additional Benefits (§ 422.312)

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 in writing 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.

The burden associated with this requirement is captured above in § 422.306.

State Licensure Requirement (§ 422.400)

Except in the case of a PSO granted a waiver under Subpart H of part 422, each M+C organization must: (1) 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; (2) 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 (3) Demonstrate to HCFA that—(i) 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 (ii) If applicable, it has obtained the State certification required under § 422.400(b).

The regulations at § 422.400 require health plans to demonstrate to HCFA that they meet the State licensure requirement of section 1855(a)(1) of the Social Security Act. As explained in the preamble, organizations must meet both the basic requirement of State licensure as a risk-bearing entity, as well as the requirement that the scope of licensure be consistent with the type (or types) of M+C plan(s) the organization will be offering. We are asking new organizations (i.e., other than current contractors) to submit, as part of the process of applying for an M+C contract, a written certification showing the organization's licensure status. As of the date of publication of this interim final regulation, we are working with the National Association of Insurance Commissioners to develop a form that may be used to satisfy this requirement. A written statement containing the same type of information that is requested in the form we are developing would also suffice to show compliance with the statutory requirement.

The written certification is a combination of information provided by the organization proposing to enter into an M+C contract, and information to be provided by the appropriate State regulatory body (e.g. the State department of insurance). This is necessary because the written certification serves two purposes. First, it provides us with written evidence of compliance with the State licensure requirement for all M+C plans an organization may wish to offer. Second, it serves to inform State regulators of the intention of organizations doing business within the State with regard to M+C offerings. The certification process enables the State to ensure that the organization is complying with the State's standards for licensure (for example, as noted in the preamble, an HMO that proposes to offer a Medicare point-of-service (POS) product may be informed by the State that HMO licensure does not allow an organization to offer POS products, and that licensure as an indemnity insurer is required in that State in order to offer a POS product).

The certification will have to be completed (or other written

documentation provided) only once by each M+C organization, unless the nature of the M+C plan(s) offered by the organization differ from the original certification (e.g., an HMO may decide at some later date, after its initial application to offer a POS product—though even in such a case, a new certification may not be necessary to the extent that we are aware that applicable State law does not require a different licensure status). We estimate that the time burden for the M+C organization is 10 minutes or less for completion of the certification form, or preparation of alternative written documentation. Similarly, we would estimate, that the time burden for the State regulatory body should be 15 minutes or less (including time necessary to verify information from electronic or paper files).

Because we are estimating that there will be an average of 100 new applicants per year for M+C contracts over the next 5 years, and because this requirement will be imposed for nearly all organizations on a one-time basis, we estimate the annual total burden to be 25 minutes per respondent × 100 annual responses for a total of 42 annual hours.

General Provisions (§ 422.501)/Contract Provisions (§ 422.502)

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.

Since the contract requirements associated with these sections are reflective the requirements and associated burden set forth in other sections of Part 422, the remaining burden associated with the requirements of these sections is the time required for a M+C organizations to read and sign the contract. It is estimated that it will take 100 M+C organizations on an annual basis, 2 hours each for a total annual burden of 200 hours. However, we solicit comment on the burden associated with these sections as it relates to the burden of meeting the requirements of the contract as reflected elsewhere in this regulation.

Nonrenewal of Contract (§ 422.506)

An M+C organization that does not intend to renew its contract, must notify HCFA, each Medicare enrollee, and the general public, before the end of the contract. Based on current experience HCFA receives 10 notifications of non-renewal on an annual basis. We estimate that the burden of notifying HCFA is 2 hours per notification for an annual burden of 20 hours.

We estimate the burden associated with notifying enrollees would take 16 hours per plan to draft and disseminate through mass mailings information of changes to affected beneficiaries for an annual burden of 160 hours.

We anticipate notification to the general public would be through the same notice published in a general circulation newspaper and would be an additional burden of 4 hours per organization for an annual burden of 40 hours.

Modification or Termination of Contract by Mutual Consent (§ 422.508)

An M+C organization that modifies or terminates it contract by written mutual consent must notify HCFA, each Medicare enrollee, and the general public, within timeframes specified by HCFA. Based on current experience HCFA receives less then 10 notifications of Modification or termination on an annual basis that would require notification of Medicare enrollees or the general public. However, we estimate that the burden of notifying HCFA is 2 hours per notification for an annual burden of 20 hours.

Termination of Contract by HCFA (§ 411.510)

If HCFA decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), the M+C organization notifies its Medicare enrollees and the general public by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area of the termination by mail and at least 30 days before the effective date of the termination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.4 and 5 CFR 1320.3(c).

Termination of Contract by the M+C Organization (§ 422.512)

The M+C organization may terminate the M+C contract if HCFA fails to substantially carry out the terms of the contract. The M+C organization must give advance notice as follows as required in paragraphs (a)(1) through (a)(3) of § 422.512. In summary, an M+C organization that does not intend to renew its contract, it must notify HCFA, each Medicare enrollee, and the general public, before the end of the contract.

Based upon current experience this requirement is imposed on fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c).

Reporting Requirements (§ 422.516)

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 requirements in § 422.516 (b)(1) through (b)(3). The burden associate with these requirements is currently captured under form HCFA–906, OMB #0938–0469. Although the burden associated with the completion of the HCFA–906 differs by provider type, on average, the annual burden per provider is 17 annual hours, for a total burden of 3,130 hours. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

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 under the Employee Retirement Income Security Act of 1974 (ERISA). 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.

These reporting requirements are currently imposed by the Department of Treasury and therefore impose no addition burden.

Each M+C organization must make the information reported to HCFA under § 422.502(f)(1) available to its enrollees upon reasonable request. This burden associated with this requirement is imposed pursuant to the dissemination of enrollment/disenrollment information referenced in Subpart B of this regulation.

Each organization must notify HCFA of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

The burden associate with these requirements is currently captured under form HCFA–906, OMB #0938–0469. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Change of Ownership (§ 422.550)

§ 422.550 is amended to require in paragraph (b) that an M+C organization must provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving

organization. The burden associated with these requirements, which is estimated to take 10 hours per respondent × 10 annual respondents, is currently captured under National Data Reporting Requirements, form HCFA–906, OMB #0938–0469. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

§ 422.562 General provisions.

An M+C organization, with respect to each M+C plan that it offers, must establish and maintain written procedures related to; (1) the grievance procedures as described in § 422.564, (2) making timely organization determinations, (3) an appeal process that meets the requirements of this Subpart for issues that involve organization determinations.

In addition, an M+C organization must ensure that all enrollees receive written information about the grievance and appeal procedures that are available to them through the M+C organization and complaint process available to the enrollee under the PRO process as set forth under section 1154(a)(14) of the Act.

While we believe the initial burden associated with meeting these requirements is captured elsewhere in this regulation, we solicit comment on the ongoing burden associated with maintaining and disseminating the information requirements set forth in this section.

Standard Timeframes and Notice Requirements for Organization Determinations (§ 422.568)

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 30 calendar days after the date the organization receives the request for a standard organization determination.

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.

The burden associated with this requirement is discussed below in § 422.572.

Expediting Certain Organization Determinations (§ 422.570)

To ask for an expedited determination, an enrollee or a health care professional 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. A physician may provide oral or written support for a request for an expedited determination.

If an M+C organization denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that: (1) Explains that the M+C organization will process the request using the 30-calendar-day timeframe for standard determinations, (2) 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 (3) provides instructions about the grievance process and its timeframes.

If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

The burden associated with this requirement is discussed below in § 422.572.

Timeframes and Notice Requirements for Expedited Organization Determinations (§ 422.572)

Except as provided in paragraph (b) of § 422.572, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician as warranted by the patient's medical condition or situation) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but not later than 72 hours after receiving the request.

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 finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination before or immediately upon expiration of the extension.

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.

Organizations that contract with HCFA under the M+C program are required to implement procedures for making timely organization determinations and for resolving reconsiderations and other levels of appeals with respect to these determinations. In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. A reconsideration consists of a review of an adverse organization determination (a decision by an M+C organization that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review. As discussed in detail in section II.M of this preamble, the organization determination and appeal requirements for M+C organizations that are set forth in this interim final rule are largely based on the existing rules for managed care organizations under Part 417, Subpart Q, Beneficiary Appeals.

Sections 422.568, 422.570, and 422.572 contain the applicable requirements for initial organization determinations, which include submission of an oral or written request from an enrollee, and notification procedures that the M+C organization must follow when it makes a determination. We estimate that approximately 20 percent of the approximately 1 million M+C enrollees may make a request for an organization determination in a year, with an estimated burden of 2 minutes per request. Estimated notification burden associated with these requests is 5 minutes per request. The total overall annual burden for enrollee requests and organizational notification burden is 33,333 hours and 83,333 hours respectively.

Request for a Standard Reconsideration (§ 422.582)

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.

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: (1) Be in writing; and(2) state why the request for reconsideration was not filed on time.

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.

The burden associated with this requirement is discussed below in § 422.602.

Expediting Certain Reconsiderations (§ 422.584)

To ask for an expedited reconsideration, an enrollee or a health care professional (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. A physician may provide oral or written support for a request for an expedited reconsideration.

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 45-day timeframe established in § 422.590(a); (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 45-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.

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).

The burden associated with this requirement is discussed below in § 422.602.

Timeframes and Responsibility for Reconsiderations (422.590)

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 45 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.

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.

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, or to obtain a good cause extension described in paragraph (e) 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.

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 finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination before or immediately upon expiration of the extension.

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.

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 within 24 hours. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

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.

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.

The burden associated with this requirement is discussed below in § 422.602.

Notice of Reconsidered Determination by the Independent Entity (§ 422.594)

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.

See discussion below.

Request for an ALJ Hearing (§ 422.602)

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.

Sections 422.582, 422.584, and 422.590 contain the applicable requirements for reconsiderations by an M+C organization of adverse organization determinations. The required procedures generally involve a written request from an enrollee, preparation of a brief written explanation and case file by the M+C organization, and notification of the decision by the M+C organization. Only about 0.5 percent of organization determinations, [that is, about 20,000 cases per year], ever reach the reconsideration stage. For these cases, we estimate a burden on the requesting enrollee of approximately 20 minutes per case and a burden on the M+C organization of approximately 4 hours, including both information collection and notification. Note that § 422.590 specifies that if an M+C organization affirms, in whole or in part, its adverse organization determination, it must forward the case to an independent entity contracted by HCFA for further review. We estimate that approximately 50 percent (10,000) of reconsidered cases result in a decision that is adverse to the enrollee, and thus review by the independent entity. For these cases, we estimate an additional burden on the M+C organization of approximately 2 hours per case. Thus, the estimated total annual burden on M+C organizations associated with reconsiderations is 100,000 hours (4 hours times 20,000 cases plus 2 hours times 10,000 cases).

About 30 percent of reconsideration requests that reach the independent entity level are resolved fully in favor of the enrollee. For the other 7,000 cases, an enrollee may pursue additional appeals, beginning with an appeal to an ALJ. Only about 10 percent of these cases are appealed to the ALJ, and for these 700 cases, we estimate an

incremental burden of 20 minutes on the enrollee to make the request for an appeal under § 422.602, and 2 hours on the M+C organization for additional information collection associated with the appeal. Finally, under §§ 422.608 and 422.612, enrollees or M+C organizations may appeal ALJ decisions to the Departmental Appeal Board, and subsequently request judicial review. We would estimate an incremental burden of an additional 2 to 4 hours per case, with only about 20 DAB cases and 10 judicial review cases per year.

How M+C Organizations Must Notify Enrollees of Noncoverage of Inpatient Hospital Care (§ 422.620)

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, and (3) the enrollee's appeal rights. 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.

The burden associated with this requirement is discussed below in § 422.622.

Requesting Immediate PRO Review of Noncoverage of Inpatient Hospital Care (§ 422.622)

For the immediate PRO review process, the enrollee must submit the request for immediate review in writing or by telephone to the PRO that has an agreement with the hospital under § 466.78 of this chapter 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.

Under § 422.620, an M+C organization is required to provide an M+C enrollee, before a hospital discharge, with a written notice of noncoverage if it decides that inpatient care is no longer necessary. Section 422.622 provides the procedures that are to be followed if an enrollee by the enrollee and the M+C organization if the enrollee wishes to request PRO review of the M+C organization's decision. We estimate that there will be no more than 1,000 of these type of cases per year under the M+C program. We estimate that the reporting burden for an M+C organization to provide written notice of noncoverage to be approximately 10 minutes per notice; for an M+C enrollee to complete a request for immediate PRO review to be approximately 10 minutes per request; and for the M+C organization to submit requested medical information to the PRO, to be approximately 2 hours per response.

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.

Given that this requirement is imposed pursuant to an administrative action against an organization, this requirement is not subject to the PRA as defined in 5 CFR 1320.4.

Request for Reconsideration (§ 422.650)

A request for reconsideration must be made in writing and filed with any HCFA office within 15 days from the date of the notice of the initial determination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

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. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Request for Hearing (§ 422.662)

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 within 15 days after the date of receipt of the notice of initial or reconsidered determination.

Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Disqualification of Hearing Officer (§ 422.668)

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.

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.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Time and Place of Hearing (§ 422.670)

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.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Record of Hearing (§ 422.686)

A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Notice and Effect of Hearing Decision (§ 422.690)

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. And, the hearing officer provides a copy of the hearing decision to each party. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are

not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Effect of Revised Determination (§ 422.698)

The revision of an initial or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

As a note, the public will be afforded several subsequent comment periods in future publications of **Federal Register** notices announcing our intention to seek OMB approval of standardized information collection requirements such as the ACR and contractor application forms that will be submitted to OMB in the near future.

We have submitted a copy of this rule to OMB for its review of the information collection requirements above. To obtain copies of the supporting statement for these collection requirements and any currently approved forms that are related to the proposed paperwork collections referenced above, E-mail your request, including your address, phone number and HCFA regulation identifier HCFA–1011, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

As noted above, comments on these information collection and record keeping requirements must be mailed and/or faxed to the designee referenced below, within ten working days of publication of this collection in the **Federal Register**:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–1030, Fax Number: (410) 786–1415

And

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer, Fax Number: (202) 395–6974 or (202) 395–5167

VII. Responses to Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in that document.

VIII. Waiver of Proposed Rulemaking and Waiver of Delayed Effective Date

Because the Secretary is exercising discretion in implementing sections 1851 through 1857 and section 1859 of the Act, ordinarily we would publish a notice of proposed rulemaking and afford a period for public comments. Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay. However, section 1856(b)(1) of the Act requires that these regulations be published by June 1, 1998, and provides that in order to carry out this requirement we may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

On January 20, 1998, we published a notice in the **Federal Register** in which we requested public comments on the implementation of the M+C program. We received approximately 90 items of correspondence in response to that notice. Further, on February 4, 1998, we held a public meeting to discuss issues and concerns from plans, providers, beneficiaries, and other interested parties on the requirements and implementation of the Medicare+Choice program. Approximately 600 individuals representing managed care organizations, local governmental agencies, and advocacy groups attended that meeting.

Because of the need to publish regulations timely and in light of the fact that we previously provided opportunity for public comment, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 90-day comment period for public comment. We also find good cause to waive the delay in the effective date of this rule.

IX. Effect of the Contract With America Advancement Act of 1996 (Public Law 104–121)

This rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). Ordinarily under 5 U.S.C. 801, as added by section 251 of Public Law 104–121, a major rule shall take effect 60 days after the later of (1) the date a report on the rule is submitted to the Congress, or (2) the date the rule is published in the **Federal Register**. However, section 808(2) of Title 5, United States Code, provides that, notwithstanding 5 U.S.C. 801, a major rule shall take effect at such time as the Federal agency determines if for good cause the agency finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. As explained above, for good cause we find that it was impracticable, unnecessary, or contrary to the public interest to complete notice and comment procedures before publication of this rule. Accordingly, pursuant to 5 U.S.C. 808(2), these regulations are effective on July 27, 1998.

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42 CFR Chapter IV is amended as set forth below.

A. Part 400

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. chapter 35.

2. In § 400.200, the definition for ''PRO'' is revised and the following definitions are added in alphabetical order to read as follows.

§ 400.200 General definitions.

* * * * *

ALJ stands for administrative law judge.

* * * * *

NCD stands for national coverage determination.

* * * * *

Peer review organization means an organization that has a contract with HCFA, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

PRO stands for peer review organization.

* * * * *

RRB stands for Railroad Retirement Board.

* * * * *

3. In § 400.202 a definition of ''national coverage determination'' is added in alphabetical order to read as follows.

§ 400.202 Definitions specific to Medicare.

* * * * *

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service, that HCFA

makes under section 1862(a)(1) of the Act, and publishes as a **Federal Register** notice or HCFA Ruling. (The term does not include coverage changes mandated by statute.)

* * * * *

B. Part 403

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 403.205, paragraph (d) introductory text is revised to read as follows:

§ 403.205 Medicare supplemental policy.

* * * * *

(d) Medicare supplemental policy does not include a Medicare+Choice plan or any of the following health insurance policies or health benefit plans:

* * * * *

C. Part 410

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Part 410 is amended as set forth below.

a. Section 410.57 is revised to read as follows:

§ 410.57 Pneumococcal vaccine and flu vaccine.

(a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

b. Section 410.152 is amended to add a paragraph (1) to read as follows:

§ 410.152 Amounts of Payment.

* * * * *

(1) *Amount of payment: Flu vaccine.* Medicare Part B pays 100 percent of the Medicare allowed charge.

D. Part 411

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 411.15 [Amended]

2. In § 411.15, in paragraph (e), the following changes are made:

a. The ''and'' at the end of paragraph (e)(2) is removed.

b. A semicolon and the word ''and'' are added at the end of paragraph (e)(3).

c. A new paragraph (e)(4) is added, to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(e) * * *

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness.

* * * * *

3. In § 411.355, a new paragraph (c)(5) is added, to read as follows:

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

* * * * *

(c) * * *

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

* * * * *

E. Part 417

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9); and 31 U.S.C. 9701.

2. Section 417.402 is revised to read as follows:

§ 417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) The changes made to section 1876 of the Act by section 4002 of the Balanced Budget Act (BBA) of 1997 are incorporated in section 422 except for 1876 cost contracts. Upon enactment of the BBA (August 5, 1997) no new cost contracts or service area expansions are accepted by HCFA except for current Health Care Prepayment Plans that may convert to 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2002.

3. In § 417.413, paragraphs (d)(1) and (d)(2) introductory text are revised and new paragraphs (d)(2) (iii) and (d)(8) are added to read as follows:

§ 417.413 Qualifying condition: Operating experience and enrollment.

* * * * *

(d) *Standard: Composition of enrollment.* (1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* HCFA may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

* * * * *

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

* * * * *

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

* * * * *

4. In § 417.426, a new paragraph (a)(4) is added to read as follows:

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* * * *

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

* * * * *

5. Section 417.428 is revised to read as follows:

§ 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.

* * * * *

(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.

* * * * *

(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:

Subpart A—General Provisions

Sec.
422.1 Basis and scope.
422.2 Definitions.
422.4 Types of M+C plans.
422.6 Application requirements.
422.8 Evaluation and determination procedures.
422.10 Cost-sharing in enrollment-related costs.

Subpart B—Eligibility, Election, and Enrollment

422.50 Eligibility to elect an M+C plan.
422.54 Continuation of enrollment
422.56 Limitations on enrollment in an M+C MSA plan.
422.57 Limited enrollment under M+C RFB plans.
422.60 Election process
422.62 Election of coverage under an M+C plan.
422.64 Information about the M+C program.
422.66 Coordination of enrollment and disenrollment through M+C organizations.
422.68 Effective dates of coverage and change of coverage.
422.74 Disenrollment by the M+C organization.
422.80 Approval of marketing materials and application forms.

Subpart C—Benefits and Beneficiary Protections

422.100 General requirements.
422.101 Requirements relating to basic benefits.
422.102 Supplemental benefits.
422.103 Benefits under an M+C MSA plan.
422.104 Special rules for supplemental benefits for M+C MSA plans.
422.105 Special rules for point of service option.
422.106 Special arrangements with employer groups.
422.108 Medicare secondary payer (MSP) procedures.
422.109 Effect of national coverage determinations (NCDs).
422.110 Discrimination against beneficiaries prohibited.
422.111 Disclosure requirements.
422.112 Access to services.
422.114 Access to services under an M+C private fee-for-service plan.
422.118 Confidentiality and accuracy of enrollee records.
422.128 Information on advance directives.
422.132 Protection against liability and loss of benefits.

Subpart D—Quality Assurance

422.152 Quality assessment and performance improvement program.
422.154 External review.
422.156 Compliance deemed on the basis of accreditation.
422.157 Accreditation organizations.
422.158 Procedures for approval of accreditation as a basis for deeming compliance.

Subpart E—Relationships With Providers

422.200 Basis and scope.
422.202 Participation procedures.
422.204 Provider credentialing and provider rights.
422.206 Interference with health care professionals' advice to enrollees prohibited.

422.208 Physician incentive plans: requirements and limitations.
422.210 Disclosure of physician incentive plans
422.212 Limitations on provider indemnification.
422.214 Special rules for services furnished by noncontract providers.
422.216 Special rules for M+C fee-for-service plans.
422.220 Exclusion of services furnished under a private contract.

Subpart F—Payments to Medicare+Choice Organizations

422.249 Terminology
422.250 General provisions.
422.252 Annual capitation rates.
422.254 Calculation and adjustment factors.
422.256 Adjustments to capitation rates and aggregate payments.
422.257 Encounter data.
422.258 Announcement of annual capitation rates and methodology changes.
422.262 Special rules for beneficiaries enrolled in M+C MSA plans.
422.264 Special rules for coverage that begins or ends during an inpatient hospital stay.
422.266 Special rules for hospice care.
422.268 Source of payment and effect of election of the M+C plan election on payment.

Subpart G—Premiums and Cost-Sharing

422.300 Basis and scope.
422.302 Terminology.
422.304 Rules governing premiums and cost-sharing.
422.306 Submission of proposed premiums and related information.
422.308 Limits on premiums and cost-sharing amounts.
422.309 Incorrect collections of premiums and cost-sharing.
422.310 Adjusted community rate (ACR) approval process.
422.312 Requirement for additional benefits.

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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Supbart 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 provide 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)(ii) 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 potions 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 mounts 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 1/12th 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, 1/12th 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 payments 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 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 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.
422.580 Reconsideration defined.
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.
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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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