

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**42 CFR Part 422**

[HCFA-1030-F]

RIN 0938-A129

**Medicare Program; Changes to the Medicare+Choice Program**

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

**ACTION:** Final rule.

**SUMMARY:** The purpose of this final rule is to set forth limited changes to the Medicare+Choice regulations published in our June 26, 1998 interim final rule (63 FR 34968). Those regulations implemented section 4001 of the Balanced Budget Act of 1997 (BBA), which established the Medicare+Choice (M+C) program. This final rule addresses selected issues raised by commenters on the June 26, 1998 interim final rule where we have identified the need for changes or where we believe that clarifications are needed as soon as possible. Among these issues are provider participation procedures, beneficiary enrollment options, and several access-related issues, including initial care assessment requirements, notification requirements when specialists are terminated from an M+C plan, and several coordination of care requirements.

**DATES:** *Effective date:* This final rule is effective March 19, 1999.

**FOR FURTHER INFORMATION CONTACT:** Tony Hausner (410) 786-1093 (for access to care issues). Debe McKeldin (410) 786-9159 (for enrollment issues). Tony Culotta (410) 786-4661 (for provider participation rules or other issues).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Balanced Budget Act of 1997*

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 (M+C) Program." (The existing Part C of the statute, which included provisions in section 1876 of the Act governing existing Medicare health maintenance organization (HMO) contracts, has been redesignated as Part D.) Under section 1851(a)(1) of the Act, 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.

As its name implies, the primary goal of the Medicare+Choice program is to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. 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 of the Act, 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) of the Act 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 health plans permitted to contract with Medicare, the M+C program introduces several other fundamental changes to the managed care component 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 enrollment period, in conjunction with 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 range of payment variation across the country and increase incentives for plans to operate in diverse geographic areas.

- Establishment of requirements concerning provider participation procedures.

*B. Summary of Interim Final Rule*

In our June 26, 1998 interim final rule (63 FR 34968), we set forth the new M+C regulations in 42 CFR part 422—Medicare+Choice Program. 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, access to services (including rules on enrollee assessments and notification upon termination of specialists), and others.

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

- Subpart E—Provider participation rules and the prohibition against interference with health care professionals' advice to enrollees.

- Subpart F—Payment methodology for M+C organizations, risk adjustment, and encounter data requirements.

- Subpart G—Requirements concerning premiums, cost sharing, and determination of adjusted community rate.

- Subpart H—Requirements concerning provider-sponsored organizations (PSOs).

- Subpart I—Organization compliance with State law and preemption by Federal law.

- Subpart K—Contract requirements.

- Subpart L—Change of ownership rules.

- Subpart M—Beneficiary grievances, organization determinations, and appeals.

- Subpart N—Contractor appeals of nonrenewals or terminations of contracts.

- Subpart O—Procedures for imposing intermediate sanctions.

On October 1, 1998, we issued a correction notice in the **Federal Register** (63 FR 52610) to correct technical errors that appeared in the interim final rule. All references in this document to regulation text are to the corrected text unless otherwise noted.

*C. Number and Type of Public Comments*

We received 87 items of correspondence containing comments on the June 26, 1998 interim final rule. Commenters included managed care organizations and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospitals and other providers, insurance companies, States, accrediting and peer review organizations, members of the Congress, and others. Consistent with the scope of the June 26, 1998 rule, most of the

comments addressed multiple issues, often in great detail. Listed below are the five areas of the regulation that generated the most concern (30 to 50 comments):

- Access issues, including requirements concerning coordination of care, initial assessments of enrollees' health care needs, timely pre-approval of post-stabilization services, and notification responsibilities when an organization terminates its relationship with a specialist.

- Quality improvement standards.
- Payment rates and service area policy.
- Provider participation rules.
- Beneficiary appeals and grievances.

Among the other issues that generated substantial numbers of comments were:

- Eligibility, election, and enrollment policies.
- Marketing restrictions.
- Risk adjustment methodology and encounter data submission.
- Contractual requirements.
- Preemption of State law by Federal law.
- May 1 deadline for Adjusted Community Rate (ACR) submissions and capacity waivers.

We also received many general comments on the M+C program and the impact of the interim final rule.

## II. Provisions of This Final Rule

### A. Summary

This final rule addresses a limited number of issues raised by commenters on the June 26, 1998 interim final rule. We have attempted to address some of the issues that provoked the most public comment, particularly in cases where we have become convinced that changes are necessary and have developed the policies necessary to implement the changes. We also have included policy clarifications in certain areas where the material in the interim final rule has been misinterpreted. Finally, to the extent possible, we are addressing time-sensitive issues, such as those that need to be resolved before publication of the comprehensive M+C final rule or those that may affect plans or beneficiaries in areas where Medicare risk contractors have chosen not to participate in the M+C program in 1999.

We intend to address all other issues raised by commenters on the M+C interim final rule in a comprehensive M+C final rule to be published later in 1999. (For example, this rule does not deal with any issues related to the quality standards contained in Part 422.1 subpart D of the regulations.)

On September 28, 1998, we issued Interim Quality Improvement System

for Managed Care (QISM) Standards that reflected the M+C interim final regulation as published in June 1998. To the extent that the changes contained in this regulation require changes to QISM, we will issue these changes shortly. We will issue a final QISM document after we have issued the comprehensive M+C final rule, later in 1999.

### B. Effective Date of Guaranteed Issue for Medigap Insurance

Section 4031 of the BBA established new rules under which Medicare beneficiaries are eligible to purchase a Medicare supplemental (Medigap) policy on a "guaranteed issue basis." Some of the situations addressed by the BBA involve beneficiaries who leave M+C plans (or managed care risk plans under section 1876 of the Act) and return to original Medicare. In the June 26, 1998 interim final rule, we indicated that further guidance on this subject was available from the National Association of Insurance Commissioners (NAIC), which had incorporated the BBA's Medigap changes into a revised Model Regulation issued on April 29, 1998. The Model Regulation suggested that the guaranteed issue provisions do not become effective until January 1, 2002, for an enrollee in an M+C organization whose contract terminates. (The NAIC subsequently determined that this effective date was incorrect, as discussed below.)

*Comment:* Several commenters asked us to clarify that the BBA protection regarding the guaranteed issue of Medigap policies A, B, C, and F took effect on July 1, 1998. They believe that this clarification is necessary to eliminate confusion resulting from the NAIC's original, erroneous interpretation that this guarantee was not effective until 2002. One commenter pointed out that this error stemmed from a misinterpretation of certain provisions of section 1851(e) of the Act, which discusses the circumstances under which a beneficiary who is enrolled in an M+C plan may disenroll from the plan and enroll in another M+C plan. The commenter offered a detailed analysis of the appropriate interpretation of these provisions.

*Response:* HCFA and the NAIC agree that the guaranteed issue provisions of the BBA became effective on July 1, 1998. On December 4, 1998, we published a notice in the **Federal Register** to clarify that, as a matter of Federal law, the guaranteed issue provision of section 1882(s)(3)(B)(ii) of the Act (added by section 4031(a) of the BBA) takes effect July 1, 1998; continues in effect through and beyond 2002; and

applies to any individual whose M+C election terminates under the "circumstances" specified in subparagraphs (A) through (D) of section 1851(e)(4) (63 FR 67081). (The notice also points out that the NAIC issued a memorandum on October 16, 1998, indicating that there was a mistake in its Model Regulation and that the effective date was July 1, 1998, not January 1, 2002.) As explained in detail in the December 4, 1998 notice, we agree with the commenter's analysis as to the appropriate interpretation of the provisions of section 1851(e). How these provisions are interpreted also has implications for beneficiaries' enrollment options under the M+C program, as discussed below in section II.C.

### C. Clarification of Effective Date of Obligation to Accept Enrollments During Special Election Periods (§§ 422.60 and 422.62)

Under § 422.60(a)(1), M+C organizations are required to accept without restrictions enrollments from eligible beneficiaries during initial coverage election periods, annual election periods (during the month of November each year), and special election periods. While the foregoing obligations to accept enrollees do not have a separate effective date from the general effective date of the June 26, 1998 M+C regulations, as in the case of the Medigap provisions discussed in section II.B above, there has been confusion about the effective date of the obligation to accept new enrollments during special election periods. This confusion results from the fact that the description of special election periods appears in § 422.62(b), a provision that specifies when individuals are entitled to disenroll from an M+C plan after disenrollment rights become limited in 2002 (or earlier in the case of an MSA plan). Because this disenrollment rights provision in § 422.62(b) is prefaced by a 2002 effective date (with a 1999 effective date for MSA plans), it is possible that the obligation under § 422.62(a)(1) to accept enrollments during a special election period could be read not to apply until these dates. For the following reasons, we believe such a reading would be incorrect, and are clarifying in this rule that the obligation to accept enrollments during special election periods applies in years prior to 2002.

A failure to adopt this clarification would result in what we believe would be an unintended elimination (albeit temporary) of an important beneficiary protection that has been in place since the inception of the pre-BBA Medicare

risk program. There is no indication in the legislative history of the BBA that the Congress intended to eliminate a beneficiary's longstanding right to enroll in other plans when the organization in which he or she is enrolled ceases to contract with Medicare. Under section 1876(c)(3)(ii), when a contract under section 1876 "is not renewed or is otherwise terminated," other HMOs with risk contracts "serving part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination." Similarly, if an HMO nonrenews a portion of its service area, risk contractors serving that part of the service area "are required to have an open enrollment period for individuals residing in that part of the service area . . . ." This beneficiary protection permits beneficiaries enrolled in an HMO that ceases to participate as a risk contractor to enroll in another HMO that serves the same area.

The new M+C provisions in the BBA do not include a provision that imposes the above requirement in the same manner as it is imposed in section 1876. As in the case of the Medigap protections under section 1876(c)(3)(F) (discussed in section II.B above), the Congress adopted a different approach to providing a similar beneficiary protection previously addressed in a different way under section 1876. In the case of Medigap protections, the Congress replaced a requirement that HMOs provide protections to enrollees when a contract terminates with new requirements that apply directly to Medigap insurers. In this case, the Congress replaced a direct requirement that HMOs have open enrollment when a contract is terminated with an indirect requirement that M+C organizations accept enrollment when the circumstances (set forth under section 1851(e)(4)) that give rise to a right to disenroll exist. In both cases, there is no reason to believe that the Congress intended to deprive beneficiaries of the benefits of these protections between 1999 and 2002. Indeed, there would be no rational reason for doing so.

Section 1851(e)(6), which is implemented in § 422.60(a)(1), requires that M+C organizations accept enrollments during initial enrollment periods, during the month of November, and during special election periods "described in" the first sentence in section 1851(e)(4). The first sentence in section 1851(e)(4) sets forth the circumstances under which a beneficiary is permitted to disenroll

after 2002, when the beneficiary "lock in" will go into effect. The first sentence in section 1851(e)(4) accordingly is prefaced with the clause "[e]ffective as of January 1, 2002." As one commenter noted, "The reference to January 1, 2002 specifically addresses the movement from one Medicare+Choice plan to another, and is part of a clearly laid out section that provides a gradual transition from the current system of totally free movement between plans to a restricted system of annual 'lock-ins'. The need for exceptions does not exist before January 1, 2002, and so the provision does not become effective until that date."

Thus, we believe that the reference to January 1, 2002 is best interpreted as relevant only for purposes of the right to *disenroll* that is the subject of section 1851(e)(4) itself, and not for purposes of the separate obligation to accept enrollments under section 1851(e)(6). In other words, section 1851(e)(6) incorporates the underlying circumstances that give rise to the right to disenroll, and provides that M+C organizations must accept enrollments when these circumstances exist. It does not incorporate the reference to 2002 in the first clause. Included in the circumstances listed under section 1851(e)(4) is the situation in which an organization's contract has been terminated "or the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides." Accordingly, for all plans offered by M+C organizations, the organization currently must accept enrollments from eligible individuals if an M+C plan is discontinued in the area the organization serves or under any of the other circumstances described in § 422.62(b). (We note that the organization would not have to accept enrollment in a plan that has reached its enrollment capacity, consistent with § 422.60(b).)

This interpretation is consistent with our interpretation of the new Medigap protections in the BBA (see section II.B and our December 4, 1998 **Federal Register** notice), which similarly provide for beneficiary rights when the circumstances specified in section 1851(e)(4) exist.

In order to clarify our interpretation in the regulations text, we are revising § 422.60(a)(1) to clarify that while the circumstances described in § 422.62(b)(1) through (b)(4) are incorporated under § 422.60(a)(1), the effective dates for the disenrollment rights under § 422.62(b) are not.

#### *D. Notification Requirement for Rule Changes (§ 422.111(d)(2))*

Section 1852(c) of the Act lists several areas where an M+C organization must disclose specific information to each M+C plan enrollee. These requirements are set forth under § 422.111 and are, in large part, a codification of program administration requirements under section 1876 of the Act. Among the disclosure provisions is a requirement under § 422.111(d)(2) (carried over from § 417.436(c)) that if an M+C organization intends to change its rules for a plan, it must submit the changes to us in accordance with the procedures for approval of marketing materials under § 422.80 and then notify all enrollees 30 days before the effective date of the change.

*Comment:* Several commenters asked how this requirement interacts with related provisions under § 422.64, which concerns the comparative information that we distribute about M+C plans. A commenter noted that under the 30-day rule set forth at § 422.111(d)(2), an M+C organization presumably could change plan rules between the time that we distribute information about an M+C plan and the effective date of a beneficiary's enrollment in that plan. The commenter suggested that enrollees should be notified at least 90 days before the effective date of any changes in plan rules. Another commenter suggested that failure to provide proper notice should be reported to beneficiaries and lead to enforcement sanctions.

*Response:* Section 422.64, which is based on section 1851(d) of the Act, outlines the general and comparative information that we distribute to all M+C eligible beneficiaries as part of the annual "open season" notification. For the most part, the comparative information describes the benefits, premiums, and service areas of all M+C plans; this information is largely derived from the documents an M+C organization submits by May 1 as part of the ACR approval process. After January 1, 2002, this information may not be changed after the ACR is approved until the calendar year following the year for which the information is provided. Under § 422.300(b), prior to 2002, premiums or benefits may be changed after an ACR is approved if the changes add benefits or lower premiums or cost sharing.

While § 422.111(d) provides for 45-day advance submission to us and 30-day advance notice to enrollees of changes in M+C plan rules, this provision does not grant an M+C organization authority to change rules

that it is otherwise prohibited from changing. To the extent that an M+C organization is permitted to change rules (for example, grievance procedures disclosed under § 422.111(b)(8) or prior authorization procedures disclosed under § 422.111(b)(7)), it must submit the changes for us to review 45 days in advance, and give enrollees 30 days advance notice. This general rule would apply to changes in benefits, premiums, or cost sharing prior to 2002, as permitted under § 422.300(b). (Currently, the primary vehicle through which organizations inform enrollees of changes in plan rules is the Annual Notification of Change (ANOC).)

The requirement under § 422.111(d) that organizations notify plan enrollees at least 30 days before the intended effective date of any rule changes does not conflict with the intent of the statute, as implemented through § 422.64, that M+C eligible individuals receive accurate comparative information about available M+C plans through our annual information campaign. However, we recognize the need to ensure that information organizations distribute to enrollees in their plans reflects all rule changes that will be in effect as of January 1 of a given year. Thus, to eliminate any possibility of otherwise permissible rule changes during the annual open season period, we are revising § 422.111(d) to: (1) Indicate that the 30-day notification rule applies only for mid-year changes in plan rules; and (2) Specify that an M+C organization must notify enrollees by October 15 of any plan policy changes that are scheduled to take effect on the following January 1. Under this policy, for example, an M+C organization would submit its ANOC for our review by September 1 in order to allow for the 45-day review period required under § 422.80(a)(1). This will ensure that current enrollees (and, upon request, prospective enrollees) receive accurate information about all plan rules in time for the annual election period each November, as well as promote coordination in the information distribution efforts by us and M+C organizations.

#### *E. Access to Services (§ 422.112)*

Section 422.112 establishes a series of requirements aimed at ensuring that enrollees in M+C plans have adequate access to services. As discussed in our June 26, 1998 interim final rule (63 FR 34989), these requirements stem from section 1852(d) of the Act and existing regulations and policies under part 417, as well as addressing recommendations from the Consumer Bill of Rights and Responsibilities. Commenters addressed

all aspects of these provisions, and we are continuing to consider their comments on many of the requirements contained in this section. In this limited final rule, we will address comments and clarify our policy on several access-related issues, as discussed below. We intend to address all other comments on access issues in the comprehensive final rule to be published later this year.

Please note that due to the numbering errors in the June 26, 1998 document, we published a correction notice in the **Federal Register** on October 1, 1998 (63 FR 52613). In that notice, we republished § 422.112 in its entirety. For purposes of this document, all references are to the corrected regulation citations.

#### 1. Coordination of Care (§§ 422.112(a)(4) and (b))

*Background.* Section 422.112 imposes two separate coordination requirements. First, under § 422.112(a)(4), M+C organizations must have procedures that enable the organization to identify individuals with serious or complex medical conditions, assess and monitor those conditions, and establish and implement treatment plans. As indicated in the preamble to the June 26, 1998 regulations, this requirement was based on recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, in its "Consumer Bill of Rights and Responsibilities." Also, under § 422.112 (b), to ensure continuity of care, M+C organizations must make a variety of arrangements, including designating a practitioner "having primary responsibility for coordinating the enrollee's overall health care," providing an ongoing source of primary care, and completing an initial assessment within 90 days of enrollment. As indicated in the preamble to the June 26, 1998 regulations, these provisions were based on the requirements developed as part of the Quality Improvement System for Managed Care (QISMC).

In view of the comments, we recognize the need to revise these provisions. The intent of these provisions will still be to require (1) plans to have procedures for identifying individuals with serious or complex medical conditions, assess and monitor those conditions, and implement treatment plans; and (2) ensure continuity of care. However, we need to allow for somewhat greater flexibility in arrangements since not all types of managed care plans require enrollees to be assigned to primary care providers (PCPs).

Approximately 13 public commenters addressed these coordination requirements. The comments and our responses are discussed below.

#### **Comments on § 422.112(a)(4)**

*Comment:* Several commenters requested that we define complex and serious medical conditions. One commenter recommended that M+C organizations be given discretion to define "complex or serious medical conditions" within broad parameters set by HCFA. Another commenter suggested that we delay implementation of the requirements until national criteria for the identification of complex and serious conditions are developed.

*Response:* The interim final regulation currently requires M+C organizations to develop procedures that enable the organization to identify individuals with complex or serious conditions, assess and monitor those conditions, and establish and implement treatment plans. The regulations do not place further requirements on M+C organizations as to these provisions. Thus, organizations have discretion to define the concept of a "complex or serious condition." We plan to develop a definition of this term, which could result in further guidance on this set of issues. Until we provide further guidance, we expect organizations to adopt their own definition and procedures to implement these provisions.

*Comment:* One commenter stated that M+C organizations should be allowed to limit the number of visits to a specialist, and that they should be allowed to ensure that the PCP remains involved in the care plan so that the patient continues to receive preventive services and other services not provided by the specialist.

*Response:* The regulations do not prohibit limiting the number of direct access visits, as long as the number of direct access visits to the specialist is adequate, consistent with the treatment plan. Furthermore, the regulations do not prohibit an M+C organization from ensuring that a PCP is involved, and we would encourage this relationship.

*Comment:* One commenter stated that if a specialist develops the treatment plan, then he or she should be the one to update it. Another commenter suggested that organizations be required to use physicians to develop the treatment plans.

*Response:* We agree with the recommendation that if a specialist develops a treatment plan, then he or she should be the one to update it. Thus, we will delete the requirement

that the treatment plan should be updated by the PCP.

We have added the requirement that the M+C organization "assures adequate coordination among providers." This requirement is added because of the changes in the coordination requirements in § 422.112(b), discussed below.

As to the development of the treatment plan, we believe that any health professional or a team of health professionals may develop the treatment plan.

*Comment:* One commenter requested that we require M+C organizations to permit enrollees with complex and serious conditions to have a choice of specialists; to use a specialist as their PCP; allow for the treatment plan to be updated by the PCP and the enrollee; and allow an enrollee who needs post-acute care to have a choice of post-acute provider in consultation with the PCP.

*Response:* While M+C organizations are encouraged to adopt these procedures, we do not believe that it would be appropriate to specify these requirements. As indicated above, we have eliminated the requirement that the treatment plan be updated by the PCP. Whoever develops the treatment plan is encouraged to consult with the enrollee.

*Comment:* Several commenters stated that requiring M+C organizations to develop treatment plans encourages over-utilization of specialists and micro-management of primary and specialty care.

*Response:* M+C organizations can control the number of visits to specialty care in the treatment plan. The development of treatment plans is good medical practice and is performed routinely in most medical settings.

*Comment:* One commenter (1) recommended that instead of direct access visits to specialists, we should require that M+C organizations operate comprehensive case management systems for chronically ill enrollees; and (2) contended that the BBA did not provide statutory authority to issue the requirements dealing with serious and complex conditions.

*Response:* The requirements are imposed pursuant to our authority under section 1856(b)(1) of the Act to establish M+C standards by regulation. These standards were based upon the President's Advisory Commission's "Consumer Bill of Rights and Responsibilities" mentioned above. While we encourage M+C organizations to develop comprehensive case management systems, this is not a requirement. We have determined that developing treatment plans that include

an adequate number of direct access visits to specialists is the most appropriate requirement at this time.

*Comment:* Several commenters recommended that we require that the treatment plan for enrollees with complex and serious conditions be completed in either 14 or 30 days, and that these persons be reassessed every 90 days.

*Response:* M+C organizations are encouraged to consider these recommendations, but we do not believe it is necessary to specify these requirements. Existing provisions already require that the treatment plan be appropriate, time-specific, and updated periodically. Comments on § 422.112(b)

*Comment:* Several commenters stated that M+C organizations that have open access arrangements and PPOs cannot meet the requirements that organizations ensure continuity of care through the "the use of a practitioner who is specifically designated as having primary responsibility for coordinating the enrollee's overall health care." They recommended that we revise these requirements to provide more flexibility for these types of M+C organizations.

*Response:* We concur with this recommendation. Therefore, we have made the following changes to this section:

(1) We have deleted the requirement that the M+C organization use a practitioner who has primary responsibility for coordinating health care. We recognize that open access plans and PPOs do not have a single professional who coordinates care, and that they may use other mechanisms to coordinate care.

(2) We have revised the requirement to specify that M+C organizations develop "policies that specify under what circumstances services need to be coordinated and the methods for coordination." We have modified this requirement because not all organizations assign health care professionals to coordinate care; they may use other methods to achieve coordination where needed.

(3) We have modified the requirement that an M+C organization must provide an ongoing source of primary care, and instead require that an organization offer to provide each enrollee with an ongoing source of primary care and provide this source of primary care to all who accept the offer. Again, we modified this requirement because not all organizations require that enrollees be assigned to a PCP. However, all organizations are required to have an adequate network of PCPs and specialists and, thus, be able to ensure

that every enrollee can have a PCP if he or she so chooses.

We have made these changes to the coordination provisions to provide sufficient flexibility to ensure that beneficiaries can choose the type of M+C plan option that best meets their needs. The Congress intended the M+C program to allow for maximum choice of types of plans and wants us to assure that all plans that have open arrangements are included in the program. Nevertheless, we still want to ensure coordination of care, and therefore we have maintained most of the various coordination requirements of this section and have made only a few changes to these requirements.

Furthermore, because of this increased flexibility, to ensure that adequate coordination occurs for complex or serious medical conditions, we have added to § 422.112(a)(4) the requirement that the M+C organization assures that adequate coordination occurs among providers.

## 2. Initial Care Assessments (§ 422.112(b)(5)(i))

*Background.* Another issue that we believe should be addressed at this time involves § 422.112(b)(5)(i), which requires M+C organizations to conduct an initial assessment of each enrollee's health care needs within 90 days of the effective date of enrollment. Although a number of commenters strongly endorsed the requirement, we received many other comments that indicated the need for further guidance to maximize compliance efforts by M+C organizations. The intent of the requirement is to ensure that organizations have sufficient information about enrollees to identify and meet the enrollees' health care needs. We believe that requiring initial assessments is consistent with current industry practices and need not result in burdening M+C organizations with additional administrative responsibilities.

Approximately 16 public comments addressed the initial assessment requirement. The comments and our responses are discussed below.

*Comment:* Many commenters requested that we clarify the "form" of the initial health assessment. Commenters inquired whether the assessment could be carried out through a telephone call, or mailed questionnaire, or whether it must be a physical examination. Further, commenters questioned whether, under certain circumstances, some enrollees could be exempted from the initial assessment requirement. For example, commenters indicated that an M+C

organization should not be required to complete an initial assessment for individuals who were commercial members of a managed care plan and then "age-in" to the organization's M+C plan. Similarly, enrollees who remain under the care of network providers or retain the same primary care provider, despite enrolling in a different M+C organization, should not be subject to the assessment requirement.

*Response:* We believe that M+C organizations should have the flexibility to choose the form and substance of the initial assessment. Thus, the assessment may take the form of a phone call, questionnaire, home visit, or physical examination. However, the assessment instrument must ensure that the M+C organization and its provider network have the information required for effective and continuous patient care and quality review, as required under § 422.112(b)(5). The assessment should also be sufficient to identify enrollees with complex or serious medical conditions, consistent with § 422.112(a)(4).

We recognize that in some situations it would be duplicative and unnecessary to subject certain enrollees to the initial assessment requirement. Consequently, we would not expect M+C organizations to conduct initial assessments on enrollees for whom the necessary, up-to-date information on their care needs is already available, such as enrollees who age-in, are already under the care of network providers, or who retain the same primary care provider when enrolling with a different M+C organization.

*Comment:* Several commenters suggested that we only require M+C organizations to make "best efforts" to conduct the initial assessment, since 100 percent compliance is not achievable. They asserted that 100 percent compliance is not an achievable standard because enrollees may refuse to cooperate in carrying out the initial assessment. Commenters requested that we identify the minimal standard an M+C organization should meet to comply with the initial assessment requirement. For example, one commenter suggested that if an M+C organization makes three unsuccessful attempts to contact an enrollee, to arrange for an initial assessment, this should be considered a sufficient "best effort."

*Response:* We understand that an M+C organization, through no fault of its own, may not be able to achieve full compliance with the initial assessment requirement. Rather than maintain a regulatory standard that may be unachievable, we are revising the

regulation to require M+C organizations to make "best efforts" to conduct the initial assessment of each enrollee's health care needs within 90 days of the effective date of enrollment. We are specifying that a "best-effort" attempt must include following up on unsuccessful attempts to contact an enrollee. The revised regulation is not intended to release the M+C organization from its obligation to conduct the initial assessment, but to acknowledge that 100 percent compliance may not be a realistic standard.

We also recognize that some enrollees may refuse to cooperate with an organization's efforts to conduct the initial assessment. If this occurs, the M+C organization should fully document the refusal in the enrollee's medical record.

*Comment:* Some commenters suggested that we should delay implementing the initial assessment requirement until an instrument is developed that sufficiently identifies complex or serious medical conditions.

*Response:* As noted above, we believe that an M+C organization should have the flexibility to use an assessment instrument of its own choice. Although we are not providing further specifications for the health assessment at this time, we may do so in the future. We will work with plan, industry, provider, and consumer representatives in developing further guidance in this area. Also, as discussed above, we are working to better define the concept of complex or serious medical conditions.

*Comment:* Two commenters suggested that we clarify who will pay for the initial assessment. They also requested that we require M+C organizations to provide accurate eligibility lists to the primary care provider in a timely manner.

*Response:* M+C organizations are required to either directly furnish or arrange for the initial assessment. Like all other services provided by an M+C organization, initial assessment costs are covered in the capitated payment paid to the M+C organization. Provider compensation will depend upon the contractual relationship between the provider and the M+C organization.

We recognize that providing accurate eligibility lists is a desirable administrative practice. However, we do not believe it is necessary to require M+C organizations to provide eligibility lists, unless we subsequently determine that absence of such a requirement results in noncompliance with the initial assessment provisions.

*Comment:* One commenter requested clarification regarding the point in the

enrollment process after which the M+C organization could conduct the initial assessment. Another commenter suggested that we require that the assessment be conducted within 30 days of enrollment.

*Response:* As stated above, M+C organizations are required to conduct the initial assessment within 90 days of the effective date of enrollment. We believe this is a reasonable minimum standard, when viewed in conjunction with related access requirements under § 422.112, such as an appropriate treatment plan for individuals with serious medical conditions and the requirement for timely access to care and member services. Given the potential for pre-enrollment health screening, it is not appropriate for an M+C organization to conduct the initial assessment before the effective date of enrollment.

### 3. Involuntary Terminations (§ 422.112(a)(5))

*Background.* In our June 26, 1998 interim final regulation, § 422.112(a)(2) established the requirements that an M+C organization must meet when it terminates an M+C plan or specialist. Subsequently, due to the numbering errors in the June 26, 1998 document, we published a correction notice on October 1, 1998 (63 FR 52613), which sets forth these "involuntary termination" requirements under § 422.112(a)(5). For purposes of this document, all references are to the corrected regulation citations. Section 422.112(a)(5) provides that if an M+C organization terminates an M+C plan or specialist other than for cause, the M+C organization must inform beneficiaries at the time of termination of their right to maintain access to specialists, provide the names of other M+C plans in the area that contract with specialists of the beneficiaries' choice, and explain the process the beneficiary would need to follow should he or she decide to return to original Medicare.

#### Comments and Responses

We received fourteen comments on the involuntary termination provisions. Several commenters remarked that the numbering of the section was confusing and mistaken. As noted above, we made the appropriate changes in the October 1, 1998 correction notice.

*Comment:* One commenter questioned the statutory source of a beneficiary's right to maintain access to specialists.

*Response:* Section 1852(d)(iv) of the Act requires M+C organizations to provide access to the appropriate providers, including credentialed

specialists, for medically necessary treatment and services.

*Comment:* Most of the comments on § 422.112(a)(5) opposed these notification requirements. As discussed in detail below, these commenters cited a variety of reasons for their opposition, including the administrative burden and feasibility of obtaining the necessary information, unnecessary duplication in the regulations, and absence of necessary detail. Although most commenters opposed the notification requirements, one commenter asserted that the requirements were reasonable and necessary to protect the interests of Medicare beneficiaries. This commenter recommended that the notification requirements apply for all terminations of physicians and other health care professionals, rather than only for terminations of specialists.

Commenters raised the following objections:

(1) Administrative burden and feasibility.

Commenters objected to the perceived administrative burden associated with the notification requirements of § 422.112(a)(5). In particular, commenters found infeasible the provision that plans must provide the names of other M+C plans in the area that contract with specialists of the beneficiary's choice. They noted that plans do not have access to competing plans' network information. They stated that details of another plan's contractual relationships with its specialists was proprietary information. Commenters also argued that § 422.112(a)(5) would be difficult for plans to implement because they do not track real-time information regarding which beneficiaries are receiving care from specific specialists.

(2) Unnecessary duplication in the regulations.

Commenters pointed out that in several areas, the provisions of § 422.112(a)(5) overlap with other provisions of the M+C regulations. Several commenters mistakenly referred to the general notification requirements under § 422.111(e) when discussing the requirements for involuntary terminations of specialists under § 422.112(a)(5). Others simply noted that the two sections both dealt with provider terminations and that this duplication served no purpose. Some commenters also stated that it was confusing and unnecessary to include both plan and specialist terminations in § 422.112(a)(5), since enrollee notification upon plan termination was addressed previously in § 422.62. Other commenters assumed that these provisions implied that an enrollee

whose specialist was terminated was free to disenroll from his or her plan and have a special election period as described under § 422.62(b).

(3) Absence of necessary detail.

Several commenters found it unclear which beneficiaries must be notified when a specialist is terminated. Also, they asked for further guidance regarding the meaning of terms such as "other than for cause" and "involuntary termination."

In view of these objections, commenters proposed several alternatives. Some suggested we delete § 422.112(a)(5) entirely. Others recommended that it should suffice for an M+C organization to inform those beneficiaries who had been under the treatment of the formerly contracted specialist how they can access comparable specialty services within the plan.

*Response:* Based on these comments, we recognized that revisions to § 422.112(a)(5) were necessary. We considered revising § 422.112(a)(5) by replacing the requirement that an M+C organization must provide the names of other M+C plans in the area that contract with specialists of the beneficiary's choice with the requirement that the M+C organization must provide the names of specialists within the plan's provider network through whom enrollees can obtain necessary care. Instead, after careful review of both the comments regarding duplicative regulations and of the regulations themselves, we believe that the better course is to delete § 422.112(a)(5) completely.

Under the notification requirements § 422.111(e), an M+C organization must make a good faith effort to provide written notice of the termination of a contracted provider within 15 working days 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. Thus, notification to beneficiaries is not limited to the termination of specialists, but includes other physician and provider types. Furthermore, § 422.111(e) applies to all types of terminations, not just those that are "involuntary" and "other than for cause," as under § 422.112(a)(5). Given the elimination of the requirement that M+C organizations must provide the names of other M+C plans in the area that contract with specialists of the beneficiary's choice, we believe that having separate notification requirements in § 422.112, "Access to services," serves no purpose.

Similarly, we believe that the notification requirements for plan termination in § 422.112(a)(5) are sufficiently addressed in § 422.62(b) and § 422.74. Thus, it is unnecessary to include notification requirements for plan termination in § 422.112(a)(5). Consequently, we are deleting § 422.112(a)(5) in its entirety.

Thus, we agree with commenters that § 422.112(a)(5) unnecessarily duplicates other M+C provisions. Moreover, this overlap serves as a real source of confusion as evidenced by the mistakes commenters themselves made. For example, we believe the similarity between § 422.62(b) and § 422.112(a)(5) prompted commenters to mistakenly assume that § 422.112(a)(5) entitles an enrollee whose specialist is terminated to disenroll from his or her plan and have a special election period.

More importantly, we believe removing § 422.112(a)(5) from the M+C regulation in no way compromises a Medicare beneficiary's access to adequate health care from all appropriate providers. We are convinced that the remaining provisions, particularly § 422.111(e), continue to require adequate notification and access requirements for needed care, including specialty care. Finally, we would expect that the specialists themselves would be both best able and most willing to inform their own patients of their other plan affiliations; plans should not interfere with the ability of providers to communicate such information to their patients.

In addition to the fact that we deemed §§ 422.111(e), 422.62(b), and 422.74 more than adequate safeguards of a beneficiary's access to needed care, we also realized that portions of § 422.112(a)(5)'s requirements were major obstacles to its effective implementation. We agree that it may be impractical for plans to ascertain with which other plans a given specialist contracts. Furthermore, it may be unreasonable to expect M+C organizations to turn over their specialist lists to competing organizations.

We note that the deletion of § 422.112(a)(5) renders moot the terminology questions about which types of terminations were subject to these requirements. After the removal of § 422.112(a)(5), the notification standard for which enrollees are to be notified is the "regular basis" standard articulated in § 422.111(e). As stated previously, application of this standard is not limited to specialists, but instead includes all contracted providers.

*Comment:* Two commenters wanted to know if the provisions for involuntary termination were related to the special requirements for individuals with complex or serious medical conditions.

*Response:* We believe this comment was prompted by the organization of § 422.112(a), which was revised in the October 1, 1998 correction notice. Like the requirements concerning individuals with complex medical conditions, the involuntary termination provisions are concerned with an enrollee's access to specialists. However, the involuntary termination requirements are not limited to individuals with serious medical conditions.

#### F. Provider Participation Rules (§§ 422.202 and 422.204)

Section 1852(j) of the Act sets forth the statutory provisions regarding provider participation. These provisions include rules regarding participation procedures, consultation in medical policies, prohibitions on interference with provider advice to enrollees, and limitations on physician incentive plans. Regulations implementing these rules are located in subpart E of part 422. Although we received many comments on all aspects of the subpart E regulations, the two areas that generated the most controversy were the notice and appeal rights associated with provider participation procedures (§ 422.202(a)) and the related provider rights associated with denials, suspension, or terminations of contracts (§ 422.204(c)). In this final rule, we will address comments on these two areas; comments on other aspects of subpart E will be addressed in the subsequent final rule.

Section 1852(j)(1) establishes the underlying requirements for the regulations under discussion here. The statute generally requires that an M+C organization establish "reasonable procedures," under an agreement between a physician and the organization, governing the participation of a physician under an M+C plan. It then specifies that these procedures include—

- Providing notice of the rules regarding participation;
- Providing written notice of participation decisions that are adverse to physicians; and
- Providing a process within the organization for appealing adverse decisions.

These requirements represented new Federal requirements for Medicare contracting organizations. Thus, as discussed in our June 26, 1998, interim

final rule (63 FR 34967), we consulted a variety of sources in developing the regulations necessary to implement the provisions of section 1852(j)(1). Under our broad authority under section 1856(b)(1) to establish M+C standards by regulation, the implementing regulations included several discretionary provisions. Foremost among these were the following:

- Specification of the types of participation rules that are subject to the disclosure, notification, and appeal rights established by the statute.
- Application of the provider participation procedures to practitioners other than physicians.
- Requiring advance notification of material changes in a broad range of provider participation rules.
- Establishment of specific procedures, and applicability rules, relating to the appeal of adverse decisions involving participation rules.

We received 30 comments on these issues. Eighteen commenters, mainly beneficiary advocacy groups or representatives of physicians and other health care professionals, generally supported the new provider participation rules. Twelve commenters, generally representing managed care organizations, expressed opposition to the changes. Discussed below are the comments we received on these issues and our responses to those comments.

*Comment:* Noting that the statute generally applies the standards for provider relationships with M+C organizations only to physicians, four commenters objected to our decision to apply these protections to all health care professionals. They believe that this expansion contradicts the clear intent of the statute and imposes an unwarranted burden on M+C organizations. Other commenters strongly supported the decision to apply the provider participation rules to both physicians and other health care professionals. Several commenters requested that the list of providers to whom the participation rules apply be expanded to include institutional providers, such as hospitals, nursing homes, and Federally qualified community health centers (FQHCs), as well as pharmacies.

*Response:* As commenters noted, the requirements of sections 1852(j)(1) and (j)(2) of the Act, concerning provider participation procedures and consultation in medical policies, respectively, apply specifically to plan relationships with physicians. In the interim final rule, we extended these provisions in §§ 422.202 and 422.204 of the M+C regulations to include health care professionals other than physicians. The list of health care

professionals generally encompassed all licensed, independent practitioners for whom coverage for services could be provided under an M+C plan.

We have carefully reviewed both the statute itself and the comments on this issue. We note that section 1852(j)(3) of the Act, concerning prohibiting interference with provider advice to enrollees, is not limited to physicians but applies to all health care professionals. Thus, an argument can be made that the limited applicability of the provisions in sections 1851(j)(1) and (j)(2) to physicians clearly suggests that the Congress intended to exclude health care professionals other than physicians from the protections of these provisions. Based on this review, we have decided to revise the regulations to comply with the strict statutory construction of these provisions. Thus, we are revising the appropriate provisions of §§ 422.202 and 422.204 so that the applicable notice and appeal rights and consultation requirements will apply only to physicians, as defined under section 1861(r) of the Act.

We recognize that many commenters believe that it is appropriate to extend the statutory provider participation protections to health care professionals other than physicians, and that many States as well as the NCQA have adopted standards that apply these rules to all "practitioners." Moreover, we continue to believe that section 1856(b)(1) clearly provides the Secretary with the authority to establish these standards. However, given that the introduction of the M+C provider participation requirements reportedly may prove difficult for many M+C organizations to implement, we have become convinced that the most prudent policy at this time is to limit the applicability of these provisions to physicians, as specified in the statute.

*Comment:* Several commenters objected to what they perceive as the expansive interpretation under § 422.202(a) of what constitute "participation rules." They believe that the examples included under § 422.202(a)(1) of what are considered "participation rules" are much broader than those intended under the BBA. These commenters indicated that the breadth of the participation rules, particularly when combined with the provider appeal rights provisions under § 422.204(c), place unreasonable and unwarranted administrative burdens on M+C organizations without producing any concomitant benefits for M+C enrollees. Specifically, they asserted that the regulatory interpretation of "participation rules" includes most of an organization's administrative policies

and procedures, rather than only those that directly related to decisions about provider participation.

*Response:* As noted above, section 1852(j) of the Act requires that a plan have reasonable procedures that include providing written notice of the rules regarding participation. Because neither the statute nor the existing part 417 regulations, which did not include provider participation procedures, provide guidance as to what is meant by "participation rules," we looked to other sources. The examples of participation rules that are established under § 422.202(a)(1) stem largely from section 6 of the NAIC's Managed Care Plan Network Adequacy Model Act. (This model act focuses on the establishment of written agreements establishing participation standards between managed care plans and participating providers.) As stated in the preamble of the June 26, 1998, interim final rule, our intent was to adopt a "broad definition of procedures that might affect participation" including all procedures that might affect how a provider would participate in a plan (63 FR 35000).

Based on our review of the comments, we agree that this interpretation is unnecessarily expansive. We believe that it is preferable to adopt a narrower interpretation of what constitute "rules regarding participation" that would focus on whether a physician can participate under a given M+C plan. Thus, we are revising § 422.202(a)(1) to indicate that the written notice of the rules of participation will include terms of payment, credentialing policies, and other rules directly related to participation decisions. We are deleting from the regulations reference to other administrative policies and programs that are unlikely to directly affect a physician's participation, such as utilization review procedures, data reporting, confidentiality policies, etc. We believe that this change will ensure that the related requirements under § 422.202(a), such as the notice of material changes and the appeal rights for adverse decisions cannot be construed to include policies that are not directly related to participation decisions. We would still expect an M+C organization to distribute full information about its administrative policies to participating physicians, as well as to other participating health care professionals and providers, and these changes would not affect the organization policies subject to the consultation requirements of § 422.202(b).

*Comment:* In view of our interpretation of the scope of

participation rules, several commenters suggested that an M+C organization should not be required to disclose its participation rules to all health care professionals, but only to indicate that the rules existed and would be made available upon request. These commenters also indicated that requiring M+C organizations to disclose their participation rules to prospective providers would result in dissemination of what they consider proprietary information.

*Response:* As discussed above, we have narrowed both the applicability and the scope of the provider participation procedures required under § 422.202(a). We continue to believe, as noted in the June 26, 1998 interim final rule (63 FR 35000), that advance disclosure of the required participation rules to potential participating physicians is the best way to reduce subsequent appeals. However, we note that the regulations only require that an M+C organization have reasonable procedures in this regard. We do not believe that the policy of disseminating participation rules upon request is inherently unreasonable, but we also do not intend to mandate the release of what an organization considers proprietary information.

*Comment:* Commenters both supported and opposed the requirement under § 422.202(a)(2) that a plan's procedures include providing health care professionals with written notice of material changes in participation rules before those rules take effect. Again, commenters asserted that the scope of this requirement was overly broad, and recommended that the notification be limited to changes that affect the terms or conditions of a health care professional's participation. Three commenters suggested that changes mandated through Federal law or regulation should be exempted from the advance notification requirement. Another commenter asked whether an M+C organization was required to obtain signatures from health care professionals to acknowledge receipt of the notice.

*Response:* We believe that reductions in the scope of what constitute participation rules should negate most of these objections. We agree that in the unlikely event that immediate changes are mandated through Federal law or regulation, an organization should be exempt from the requirement that written notice be provided before the changes are put into effect. There is no requirement that an organization obtain signatures acknowledging receipt of a notice of changes, although an

organization is free to make this policy part of its participation procedures.

*Comment:* Commenters asked for an explanation of the meaning of a "material" change under § 422.202(a)(2) and of an "adverse" decision under § 422.202(a)(3).

*Response:* We believe that these are widely used terms that are generally understood, and do not believe that it would be appropriate to specify more detailed criteria as to how these terms should be applied. We believe that M+C organizations will be in the best position to determine whether a change in rules would be significant enough to be considered "material" as this term is generally defined. We assume that any change that could affect participation decisions would be material. Similarly, it should be fairly clear whether a change would be viewed as adversely affecting a physician.

*Comment:* The requirement under § 422.202(a)(4) that an M+C organization's provider participation procedures include establishment of a process for appealing adverse decisions also provoked mixed responses, as did the accompanying requirement that the appeals process for termination decisions conform to the requirements of § 422.204(c). One commenter suggested that we clarify under § 422.202(a)(4) that the requirement for an appeals process only applies in cases of adverse "participation" decisions, not any decision that a health care professional views as adverse. Approximately 10 commenters strongly supported these requirements, with several requesting that we add more specificity to the appeals procedures required in termination cases, including an opportunity for a terminated health care professional to obtain a reconsideration by HCFA of a denied appeal.

Other commenters objected to various aspects of these requirements, including both the scope of their applicability and what they perceived as the overly prescriptive detail of the appeal procedures in termination cases. One particular point of contention was the application of the appeals requirements to denials of an initial application to participate. Commenters believe requiring M+C organizations to convene hearing panels whenever a health care professional is denied participation under a plan was unreasonable, especially if we have already approved the plan network's adequacy.

Several commenters suggested that we make a distinction between (1) situations where an organization refuses to accept a health care professional's application to participate under a plan

(presumably because it already has sufficient practitioners of a given type) and (2) situations where the organization denies participation to a specific health care professional based on review of an application, while continuing to accept applications generally. Other commenters asserted that contract nonrenewals and expirations should not be considered denials, citing parallels with our contract nonrenewal policies; one of these commenters also noted that we should permit "mutual consent" terminations without the comprehensive disclosure and notification material required under § 422.204(c)(1). One commenter suggested that appeal rights should only apply when a termination is based on quality of care issues, not when a termination was simply a "business decision."

*Response:* In light of our narrowed definition of participation rules, we agree to the suggestion that "participation" be inserted between "adverse" and "decisions" in § 422.202(a)(4). We also agree that it would not be appropriate to grant appeal rights to physicians who have never been accepted into the M+C organization's network, and that the Congress intended only that an organization grant rights to its current contracting physicians. This interpretation is supported by the fact that section 1852(j)(1) refers to the required procedures as being "under an agreement between a physician and an organization." To clarify this point, we have revised § 422.204(c)(1) by deleting the reference to "denials" of an agreement.

In support of the contention that physician contract nonrenewals and expirations should not be subject to appeal, commenters erroneously stated that this is the case with respect to HCFA non-renewal decisions. In fact, as set forth in subpart N of part 422, these decisions are subject to appeal. With respect to "mutual consent" terminations, to the extent the physician is voluntarily leaving the organization's network, we agree that appeal rights do not have to be provided.

Finally, we have not adopted the suggestion to limit appeal rights to situations where terminations are based on quality of care issues. We believe that the elimination of appeal rights for any termination characterized as a "business decision" would undermine the intent of the provider protection provisions.

*Comment:* As noted above, several commenters recommended that we add more specificity to the appeals

procedures required in termination cases, including an opportunity for a terminated health care professional to obtain a reconsideration of a denied appeal before HCFA. Other commenters objected to what they perceived as the overly prescriptive detail of the appeal procedures in termination cases. One commenter suggested that although it supported the overall principle that requires appeals for adverse participation decisions, it was concerned that the detailed due process requirements established under § 422.204(c) may be overly burdensome.

Other commenters strongly objected to both § 422.204(c)(1), which spells out the required elements of a notification of denial, suspension, or termination, and to § 422.204(c)(2), which provides for a hearing panel composed of a majority of "peers" of the affected health care professional. They particularly objected to the release of "standards and profiling data" and the numbers and mix of health care professionals needed by the plan, and indicated that these required elements would prove unduly burdensome, intrusive, and often irrelevant to a given case. These commenters also asserted that the use of peer panels was unnecessary and difficult to implement, particularly when nonphysicians were involved. Again, a number of commenters representing health care professionals supported these requirements in their entirety.

*Response:* Again, the reductions in the scope and applicability of participation procedures under subpart E of part 422 should reduce concerns that the related due process requirements will be overly burdensome. In particular, we believe that the requirement to convene a hearing panel composed of a majority of peers of the affected physician should not prove difficult to implement. We do not believe it is appropriate for us to establish an independent process for resolving participation disputes between physicians and M+C organizations. Such a process would constitute unwarranted interference in the business relationships between M+C organizations and physicians.

We agree that it may not be necessary in all cases for an M+C organization to include in its written notice to a physician information about the standards and profiling data used to evaluate the physician and the numbers and mix of physicians that the organization needs. Therefore, we are revising § 422.204(c)(1) to indicate that this information must be included in the notification of a decision to suspend or terminate an agreement with a

physician only to the extent that it is relevant to the decision.

#### *G. Risk Adjustment and Encounter Data (§§ 422.256(d) and 422.257)*

Section 1853 of the Act sets forth the requirements related to calculating the annual capitation rates for the M+C program. These provisions were discussed in detail in the June 26, 1998 interim final rule (63 FR 35004). Effective by no later than January 1, 2000, section 1853(a)(3)(C) of the Act requires that the Secretary implement a risk-adjusted payment methodology that accounts for variations in per capita cost based on health status and other demographic factors. Section 1853(a)(3)(B) addresses the collection of encounter data from M+C organizations that are needed to implement a risk adjustment methodology. The regulatory requirements needed to implement these BBA provisions are set forth in subpart F of part 422. We published a notice in the **Federal Register** on September 8, 1998, soliciting further recommendations about the methodology for implementing risk-adjusted payments (63 FR 47506).

We received about 20 comments from managed care industry representatives and others recommending that we delay or phase in the adoption of risk-adjusted M+C payments. Many of these commenters also expressed concern over our plans to collect encounter data. We have considered these comments, as well as those received in response to the September 8, 1998, notice. As required under section 1853(b)(2) of the Act, we released on January 15, 1999, the Advance Notice of Methodological Changes for CY 2000 Medicare+Choice Payment Rates. In this notice, we describe the risk adjustment methodology that will be employed in determining M+C payments in 2000, including the transition strategy that we have adopted as part of that methodology. We also respond in the notice to the major issues raised in the comments that we have received on risk adjustment. We will, however, respond formally to the comments in the comprehensive M+C rule to be published later in 1999. The January 15, 1999, notice is available on the HCFA Web site (<http://www.hcfa.gov/stats/hmorates/45d1999/45day.htm>).

#### *H. May 1 Deadline for ACR Submissions and Enrollment Capacity Limits (§ 422.306(a))*

Consistent with section 1854(a) of the Act, an M+C organization must submit by May 1 of each year an ACR proposal for each plan it wishes to offer in the following year. Regulations

implementing this requirement are set forth under § 422.306. The ACR submission must identify the service area and enrollment capacity of each plan. As discussed in the June 26, 1998 interim final rule, these requirements will apply for contract periods beginning on or after January 1, 2000.

*Comment:* Several commenters representing managed care organizations indicated that they believe that the May 1 deadline for ACR submissions is too early. They noted that this deadline is 4 months earlier than the deadline under section 1876 and cited the new ACR proposal methodology, difficulties in collecting necessary data, and pricing uncertainties as reasons why the May 1 deadline is unreasonable. Commenters suggested moving the date for ACR submissions back to either July 1 or August 1, or keeping the May 1 deadline but allowing a subsequent opportunity to make limited modifications to benefits, premiums, or copayments. Commenters also inquired as to what if any changes we intend to make regarding implementation of our service area policy.

*Response:* Although we recognize the difficulties inherent to estimating the costs of a benefit package for 2000 based on at most 4 months of experience under the 1999 benefit package, the May 1 deadline stems from section 1854(a) of the Act and thus is not discretionary. (We note that the President's FY 2000 budget includes a proposal that would permit us to extend the deadline for ACR submissions until July 1.) We intend to issue instructions concerning implementation of service area policy and other requirements for 2000 in advance of the May 1, 1999, deadline for ACR submissions. We can assure M+C organizations that we will not introduce any policy modifications via the subsequent comprehensive M+C final rule that would impose any significant new administrative requirements on M+C plan operations before the year 2000 ACR submission and review cycle.

*Comment:* Commenters indicated that requiring an organization to establish a capacity limit by May 1 was very difficult, given that it may be impossible to confirm the participation of provider groups at that time. They asked that this deadline be extended.

*Response:* Again, section 1854(a)(1)(B) of the Act specifies that an M+C organization must inform HCFA of any limit on enrollment capacity by May 1 of a given year. However, we recognize the possibility of changing circumstances after that time, and would not want an organization to limit its enrollment unnecessarily or be

forced to accept enrollees without being able to ensure proper access to care. Therefore, we intend to establish an administrative process for reviewing requests for enrollment capacity waivers. Further guidance in this regard is under development and will be issued as soon as possible.

#### *I. Compliance With Rehabilitation Act of 1973 (§§ 422.502(h) and 422.110(c))*

Sections 422.502(h) and 422.110(c) specify several anti-discrimination statutes with which an M+C organization must comply, including the Civil Rights Act of 1964, Age Discrimination Act of 1975, and The Americans with Disabilities Act.

*Comment:* One commenter noted that the Rehabilitation Act of 1973 had been inadvertently omitted from the lists of applicable anti-discrimination statutes.

*Response:* We agree with the commenter and will add the Rehabilitation Act of 1973 to the required statutes listed under §§ 422.502(h) and 422.110(c).

#### **III. Changes to the M+C Regulations**

For the convenience of the reader, listed below are all changes to the M+C regulations that are set forth in this final rule:

- Section 422.60(a) has been revised to clarify that an individual enrolled in an M+C plan has a right to a special election period under any of the circumstances described in § 422.62(b)(1) through (b)(4). Thus, an individual enrolled in an M+C plan that withdraws or is terminated from the M+C program has an opportunity for a special election period among other M+C plans in the affected area.

- In §§ 422.110(c) and 422.502(h)(iii), we have added the Rehabilitation Act of 1973 to the list of anti-discrimination laws with which an M+C organization must comply.

- We have revised § 422.111(d) to specify that for rule changes that will become effective on January 1 of each year, an M+C organization must notify enrollees by October 15 of the previous year. The existing 30-day notification rule still applies for midyear changes.

- We have revised § 422.112(a)(4) and (b)(1) through (b)(3) to eliminate the requirement that a treatment plan may be prepared and updated only by a primary care provider (PCP) and to clarify how and when care is coordinated.

- We have deleted § 422.112(a)(5), which set forth separate notification requirements for the involuntary termination of plans and specialists.

- We have revised § 422.112(b)(5)(i) to specify that an organization must

make a "best-effort" attempt to conduct required initial assessments, including following up on unsuccessful attempts to contact an enrollee.

- We have made revisions throughout §§ 422.202 and 422.204 to limiting the applicability of the provider participation requirements to physicians.

- Under § 422.202(a)(1), we have adopted a less expansive interpretation of what constitute participation rules, basically limiting the notification requirements associated with participation rules to policies directly related to participation decisions.

- Section 422.204(c) has been revised to indicate that the availability of the provider appeals process applies only to cases involving suspension or termination of participation privileges, rather than including initial denials of an application to participate, and to clarify what information must be included in notifications of appeal rights.

#### **IV. Collection of Information Requirements—Paperwork Reduction Act**

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;

- The accuracy of the agency's estimate of the information collection burden;

- The quality, utility, and clarity of the information to be collected; and
- 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 requirement discussed below.

The following sections of this document contain revised information collection requirements:

##### *Section 422.202 Participation Procedures*

Section 422.202(a) requires an M+C organization that operates a coordinated care plan or network MSA plan to provide for the participation of

individual physicians, and the management and members of groups of physicians. To accomplish this, M+C plans must establish and maintain procedures set forth in this section and provide written notice of—(1) rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions; (2) material changes in participation rules before the changes are put into effect; and (3) participation decisions that are adverse to physicians' participation.

The disclosure requirements associated with this section have been revised and the associated burden reduced by requiring that only contracting physicians and not all contracting individual health care professionals receive written notice of the streamlined disclosure requirements summarized above.

In the "Collection of Information Requirements" section of the June 26, 1998, interim final rule (63 FR 34967), we noted that we believed the above 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 retaining the 1 token hour of burden assigned to these requirements.

#### *Section 422.204 Provider Credentialing and Provider Rights*

Section 422.204(c)(1) requires an M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees must give the affected individual written notice of the reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization, and the affected physician's right to appeal the action and the process and timing for requesting a hearing.

The disclosure requirements associated with this section have been revised and the associated burden reduced by requiring that only contracting physicians and not all contracting individual health care professionals receive written notice of the disclosure requirements summarized above.

In the "Collection of Information Requirements" section of the June 26, 1998, interim final rule, we estimated the burden associated with these requirements to be on average 10 hours per M+C organization on an annual basis. While the number of necessary disclosures has been reduced by requiring disclosures only to contracting

physicians, the scope of the disclosure requirement has been expanded to include the disclosure, if relevant, of the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization. Therefore, we are retaining the previous estimate of 10 hours of annual burden per M+C organization.

Section 422.204 (c)(3) requires an M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care to give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

The disclosure requirements associated with this section have been revised and the associated burden reduced by requiring that only suspended or terminated physicians be reported by the M+C organization to the appropriate licensing bodies, disciplinary bodies, or other appropriate authorities.

In the "Collection of Information Requirements" section of the June 26, 1998, interim final rule, we estimated that on average the annual burden associated with this requirement to be 2.25 hours per M+C organization. While the number of necessary disclosures has been reduced by requiring disclosures related only to contracting physicians, as previously noted, we have no exact data available to estimate how often this situation might occur. Therefore, we are retaining the previous estimated average burden of 2.25 hours per M+C organization.

We have submitted a copy of this final rule to OMB for its review of the revised information collection requirements in §§ 422.202 and 422.204. These revised requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following:

Health Care Financing Administration,  
Office of Information Services,  
Information Technology Investment  
Management Group, Division of  
HCFA Enterprise Standards, Room  
N2-14-13, 7500 Security Boulevard,  
Baltimore, MD 21244-1850. Attn:  
John Burke HCFA-1030-FC.

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.

## **V. Regulatory Impact Statement**

We have examined the impact of this final 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. Small entities that are providers will be affected by this rule, but we do not expect that effect to be of an economically significant nature.

The Unfunded Mandate Reform Act of 1995, in section 202, 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, or tribal governments, in the aggregate, or by the private sector, of \$100 million. This rule has no consequential effect on State, local, or tribal governments. The impact on the private sector is well below the threshold.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any 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 604 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.

#### *Summary of the Proposed Rule*

As discussed in detail above, this rule sets forth limited changes to the Medicare+Choice regulations published in our June 26, 1998 interim final rule (63 FR 34968). Those regulations implemented section 4001 of the Balanced Budget Act of 1997, which established the Medicare+Choice program. We note that we received a number of comments on the impact analysis contained in the June 26, 1998 interim final rule. Many of the commenters asserted that our analysis did not fully take into account the costs

associated with various aspects of the M+C regulations, including, for example, the quality standards and the provider participation procedures. One commenter asserted that the costs of discretionary provisions such as these would be between \$1 and 2 million for an M+C organization with 35,000 enrollees. Other commenters acknowledged that it was difficult to quantify the costs of various facets of the M+C program, but expressed the belief that the new regulations would impose a significant and costly administrative burden on M+C organizations.

We recognize that greater quantification in our estimates of the impact of the M+C regulations on managed care organizations is desirable. We note, however, that only one commenter offered any financial estimate of the costs associated with the M+C provisions, and that estimate was completely unsubstantiated. Thus, we continue to solicit any quantitative data that can help to assess the overall costs of complying with the regulations, or the costs associated with any particular provisions.

At this time, we are in the process of developing a statistically-based model for evaluating the impact of managed care policies on M+C organizations; however, this model is likely to focus heavily on payment rates and risk adjustment methodology, rather than administrative burden. We intend to respond more fully to comments on the overall impact of the M+C program and its implementing regulations in the comprehensive final rule to be published later this year.

Again, this final rule makes only limited changes to the provisions set forth in our June 26, 1998 interim final rule. These changes include:

- Adoption of a less expansive interpretation of what constitute participation rules, basically limiting the notification requirements associated with participation rules to policies directly related to participation decisions.
- Limiting the applicability of the provider participation requirements to physicians.
- Clarifying that the availability of the provider appeals process applies only to cases involving suspension or termination of participation privileges, rather than including initial denials of an application to participate.
- Specifying that the requirement for an initial assessment within 90 days of enrollment may be considered met for patients who "age in" to a plan or who switch plans, but remain under the care of the same primary care provider. We

also clarify that an M+C organization may choose the form of the initial assessment.

- Clarifying that individuals enrolled in an M+C plan that withdraws or is terminated from the M+C program have an opportunity for a special election period among other M+C plans in the affected area, effective July 1, 1998.
- Elimination of the separate notification requirements for the involuntary termination of specialists.
- Revising the coordination of care requirements to clarify how and when care is coordinated and not limit the coordination function to primary care providers.

For the most part, we do not believe that these changes will result in any significant changes in the economic impact of the M+C regulations. The reductions in the scope and applicability of the provider participation procedures are the only provisions that we believe have any potential for measurable impact. Although we do not expect the volume of provider appeals to result in substantial costs for M+C organizations, clearly, these changes can only reduce the associated costs. Similarly, we anticipate that the changes concerning notification rules for involuntary terminations of specialists, as well as the clarifications regarding coordination of care policy and completion of the initial assessments, have the potential for only incremental cost implications. Thus, we believe that this final rule clearly does not constitute a major rule under Executive Order 12866 or as defined in Title 5, U.S. Code, section 804(2).

In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 422**

Health maintenance organizations (HMO), Medicare+Choice, Provider sponsored organizations (PSO).

42 CFR chapter IV part 422 is amended as set forth below.

**PART 422—MEDICARE+CHOICE PROGRAM**

1. The authority citation for part 422 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. In § 422.60, paragraph (a)(1) is revised to read as follows:

**§ 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 the M+C organization offers and who elect an M+C plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (b)(4).

\* \* \* \* \*

3. In § 422.110, paragraph (c) is revised to read as follows:

**§ 422.110 Discrimination against beneficiaries prohibited.**

\* \* \* \* \*

(c) Plans are required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act (see § 422.502(h)).

4. In § 422.111, paragraph (d) is revised to read as follows:

**§ 422.111 Disclosure requirements.**

\* \* \* \* \*

(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.
- (2) For changes that take effect on January 1, notify all enrollees by the previous October 15.
- (3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

\* \* \* \* \*

5. Section 422.112 is revised to read as follows:

**§ 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 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 accomplish this, the M+C organization must meet the following requirements:

- (1) *Provider network.* 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.

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of 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), notwithstanding that the M+C organization maintains a PCP or some other means for continuity of care.

(4) *Serious medical conditions.* Ensure that for each plan, the M+C organization has in effect HCFA-approved procedures that enable the M+C organization, through appropriate health care professionals, to—

(i) Identify individuals with complex or serious medical conditions;

(ii) Assess those conditions, and use medical procedures to diagnose and monitor them on an ongoing basis; and

(iii) Establish and implement a treatment plan that—

(A) Is appropriate to those conditions;

(B) Includes an adequate number of direct access visits to specialists consistent with the treatment plan;

(C) Is time-specific and updated periodically; and

(D) Ensures adequate coordination of care among providers.

(5) *Service area expansion.* 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.

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

(7) *Written standards.* Establish written standards for the following:

(i) 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.

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

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

(8) *Hours of operation.* Ensure that—

(i) The hours of operation of its M+C plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(9) *Cultural considerations.* (i) Ensure that 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.

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

(b) *Rules for all M+C organizations to ensure continuity of care.* The M+C organization must ensure continuity of care and integration of services through arrangements that include, but are not limited to the following—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan 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; and

(4) 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—

(i) The M+C organization makes a "best-effort" attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) 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

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) 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

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

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

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

(ii) Without required prior authorization.

(2) *Financial responsibility.* The M+C organization may not deny payment for a condition—

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

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

(3) *Stabilized condition.* 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) *Limits on charges to enrollees.* For emergency services obtained outside the M+C plan's provider network, the M+C 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 M+C organization, whichever is less.

6. Section 422.202 is revised to read as follows:

#### § 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 physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(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 physicians.

(4) A process for appealing adverse participation decisions, including the right of physicians to present information and their views on the decision. In the case of a termination or suspension 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 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 physicians; 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 must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

7. In § 422.204, paragraph (c) is revised to read as follows:

**§ 422.204 Provider credentialing and provider rights.**

\* \* \* \* \*

(c) *Suspension or termination of contract.* An M+C organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

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

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization.

(ii) The affected physician'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 physician.

(3) *Notice to licensing or disciplinary bodies.* An M+C organization that suspends or terminates a contract with a physician 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.

8. In § 422.502, paragraph (h)(1) is revised to read as follows:

**§ 422.502 Contract provisions.**

\* \* \* \* \*

(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 Rehabilitation Act of 1973;

(iv) The Americans With Disabilities Act;

(v) Other laws applicable to recipients of Federal funds; and

(vi) All other applicable laws and rules.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 29, 1999.

**Nancy-Ann Min DeParle,**  
*Administrator, Health Care Financing Administration.*

Approved: February 10, 1999.

**Donna E. Shalala,**  
*Secretary.*

[FR Doc. 99-3751 Filed 2-11-99; 11:31 am]

BILLING CODE 4120-01-P