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Health Care Financing Administration

42 CFR Parts 417 and 422

Medicare Program; Medicare+Choice Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 417 and 422

[HCFA–1030–FC]

RIN 0938–AI29

Medicare Program; Medicare+Choice Program

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period responds to comments on the June 26, 1998 interim final rule that implemented the Medicare+Choice (M+C) program and makes revisions to those regulations where warranted. We also are making revisions to the regulations that are necessary to reflect the changes to the M+C program resulting from the Balanced Budget Refinement Act of 1999 (BBRA). Revisions to the regulations reflecting changes in the law made by the BBRA are subject to public comment. Issues discussed in this rule include eligibility, election, and enrollment policies; marketing requirements; access requirements; service area and benefit policy; quality improvement standards; payment rates, risk adjustment methodology, and encounter data submission; provider participation rules; beneficiary appeals and grievances; contractual requirements; and preemption of State law by Federal law.

This final rule also addresses comments on the interim final rule published on December 2, 1997, which implemented user fees for section 1876 risk contractors for 1998, and formed the basis for the M+C user fee provisions in the June 26, 1998 interim final rule, and the provider-sponsored organization (PSO) interim final rule published April 14, 1998.

DATES: *Effective date:* This final rule is effective July 31, 2000.

Comment period: Comments on provisions reflecting provisions of the Balanced Budget Refinement Act of 1999 will be considered if received at the appropriate address, as provided below, no later than August 28, 2000. We will not consider comments concerning regulatory provisions that remain unchanged or that are revised in this final rule based on previous public comment.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1030-FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Since comments must be received by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver by courier, your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201; or C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the two above addresses may be delayed and received too late to be considered. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1030–FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690–7890).

For comments that relate to information collection requirements, see section IV of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Marty Abeln (410) 786–1032 (for issues related to user fees, service area, point-of-service option, PSOs, and intermediate sanctions).

Wendy Burger (410) 786–1566 and Lynn Orlosky (410) 786–5930 (for issues related to eligibility, elections, and enrollment).

Carol Barnes (410) 786–5496 (for issues related to continuation areas and marketing).

Anne Manley (410) 786–1096 (for issues related to emergency and urgently needed services, provider participation rules, and Federal preemption).

Eileen Zerhusen (410) 786–7803 (for issues related to post-stabilization care).

Tony Hausner (410) 786–1093 (for issues related to access, discrimination, and physician incentive rules).

Amy Chapper (410) 786–0367 (for issues related to information disclosure and confidentiality).

Brian Agnew (410) 786–5964 (for issues related to quality assurance and accreditation).

Al D'Alberto (410) 786–1100 (for issues related to payments, premiums, and ACRs).

James Hart (410) 786–4474 (for issues related to risk adjustment and encounter data).

Chris Eisenberg (410) 786–5509 (for issues related to contracts and contract appeals).

Michele Edmondson (410) 786–6478 (for issues related to beneficiary appeals).

Anita Heygster (410) 786–4486 (for issues related to M+C private fee-for-service plans).

Cindy Mason (410) 786–6680 (for issues related to M+C MSA plans).

SUPPLEMENTARY INFORMATION: For the convenience of the reader, we are providing a complete outline of this final rule, including a topical listing of the major areas raised by the comments, along with numerical regulatory citations.

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I. Background

A. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 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 previous Part C of the statute, which included provisions in section 1876 of the Act governing existing Medicare health maintenance

organization (HMO) contracts, was 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 (''Original Medicare'') or a Part C M+C plan, if one is offered where he or she lives.

As its name implies, the primary goal of the M+C program is to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The M+C statute authorizes a variety of private health plan options for beneficiaries, including both the traditional managed care plans (such as those offered by HMOs) that traditionally have been offered under section 1876 of the Act, and new options that were not previously authorized. Specifically, section 1851(a)(2) of the Act describes three types of M+C plans authorized under Part C:

- 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.

An entity contracting with us to offer any of the above plans to Medicare beneficiaries is called an ''M+C organization.''

In addition to expanding the types of health plans that can be offered to Medicare beneficiaries, 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 us of uniform, comprehensive information about M+C plans that is needed to promote informed choices by beneficiaries;
- Revisions in the way we calculate payment rates to M+C organizations that will narrow the range of payment variation across the country and increase incentives for organizations to offer M+C plans in diverse geographic areas; and
- Establishment of requirements concerning provider participation procedures.

B. Overview of M+C Regulations

1. Interim Final Rule

On June 26, 1998, we published in the **Federal Register** a comprehensive interim final rule (63 FR 34968) to implement the provisions of section 4001 of the BBA that established the M+C program. That interim final rule 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 definitions 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.
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2. Correction Notice

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.

3. February 17, 1999 Final Rule

Additionally, on February 17, 1999, we published a final rule in the **Federal Register** (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. It specifically addressed only a limited number of issues raised by commenters on the June 26, 1998 interim final rule. We indicated in the preamble to the February 17, 1999 final rule that we intended 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 at a later date. The types of comments we addressed in the February final rule are discussed in more detail in section II.A.2.

C. M+C Provisions of the Balanced Budget Refinement Act of 1999

On November 29, 1999, as we were completing the development of this final rule, the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) was enacted. The BBRA includes a number of provisions that affect the M+C program, and these provisions have necessitated a number of corresponding changes so that the changes in the law made by the BBRA are reflected in the text of the M+C regulations. For the most part, the statutory changes are self-explanatory, and have already taken effect. As noted above, we are accepting public comment on conforming changes to the M+C regulations made as a result of the BBRA provisions. We are revising the regulations to reflect the provisions of the BBRA as follows:

1. Changes in M+C Enrollment Rules (Section 501 of the BBRA)

a. Enrollment in Alternative M+C Plans and Medigap Coverage After Involuntary Terminations

Section 1851(e)(4) of the Act establishes special election periods during which M+C-eligible individuals may disenroll from an M+C plan or elect another M+C plan, including a special election period when an M+C organization or we have terminated a plan or the organization has otherwise discontinued providing the plan in the area in which the individual resides. Section 501(a)(1) of the BBRA revised section 1851(e)(4) to specify that this special election period now becomes available either upon termination or discontinuation or when the organization ''has notified the individual of an impending termination or discontinuation of such a plan.'' We have revised § 422.62(b)(1) to reflect this earlier opportunity for an affected

enrollee to elect an alternative M+C plan or return to original Medicare. We note that section 501(b) of the BBRA set forth conforming amendments to section 1882(s)(3) of the Act (concerning beneficiary rights to guaranteed issue of a Medicare supplemental policy, that is, a Medigap policy) to allow an individual guaranteed issue rights to a Medigap policy within 63 days of an organization's notification of an impending termination or service area reduction.

b. Open Enrollment for Institutionalized Individuals (Section 501(b))

Section 1851(e) of the Act establishes the time frames, or election periods, for making or changing elections. Section 501(b) of the BBRA amended section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. Thus, on or after January 1, 2002 (which represents the first day when limitations are placed on an M+C-eligible individual's enrollment and disenrollment opportunities), M+C-eligible individuals who are institutionalized, as defined by HCFA, may continue to change from original Medicare to an M+C plan, from an M+C plan to original Medicare, or from one M+C plan to another. We have added § 422.62(a)(6) to reflect this provision, with conforming changes at § 422.62(a)(4)(i) and § 422.62(a)(5)(i). We intend to provide guidance on the meaning of the term ''institutionalized'' in due time to permit orderly implementation of this change before it takes effect in 2002.

c. Continued Enrollment for Certain M+C Enrollees

Section 1851(b)(1) of the Act establishes the residence requirements for eligibility to elect an M+C plan. Section 501(c) of the BBRA amended section 1851(b)(1) of the Act by adding a new subparagraph (C) to allow an individual to choose to continue enrollment in an M+C plan offered by the organization if (1) the M+C organization eliminates the M+C plan in the service area in which the individual resides and, (2) no other M+C plan is offered in the service area at the time of the elimination of the M+C plan in the service area and, (3) the M+C organization chooses to allow the option to continue enrollment in an M+C plan offered by the organization. If the individual chooses to retain his or her enrollment in the M+C plan, the M+C organization may require that he or she agree to obtain the full range of basic benefits (excluding emergency and urgently needed care) through facilities designated by the organization within the plan's HCFA-approved service area. In the case of home health services, since this is a basic benefit that by its nature involves receipt of services in the home, while the provider of the home health services may be located in the service area, actual services would have to be offered in the beneficiary's home. We have reflected this provision in § 422.74(b)(3), with a conforming change made in § 422.66(e)(2).

2. Change in Effective Date of Elections (Section 502 of the BBRA)

Section 1851(f) of the Act establishes the effective dates for elections and changes to elections made during the various enrollment periods. Prior to enactment of the BBRA, section 1851(f)(2) stated that an election made during an open enrollment period was effective the first day of the following calendar month. Section of the 502 BBRA amended section 1851(f)(2) of the Act to state that an election made during an open enrollment period is effective the first day of the following calendar month, except that if the election or change in election is made after the 10th day of the calendar month, the election is effective the first day of the second calendar month following the date the election or change in election is made. We have revised § 422.68(c) to reflect this provision.

3. Extension of Reasonable Cost Contracts (Section 503 of the BBRA)

Section 503 of the BBRA amended section 1876(h)(5)(B) of the Act to permit the extension or renewal of Medicare cost contracts for an additional 2 years, that is, through December 31, 2004. We are revising § 417.402(b) to effect this change.

4. Phase-In of New Risk Adjustment Methodology (Section 511 of the BBRA)

Consistent with section 1853(a) of the Act, § 422.256 of the M+C regulations provides that M+C capitation payments are adjusted for age, gender, institutional status, and other appropriate factors, including health status, beginning January 1, 2000. In the January 15, 1999, Advance Notice of Methodological Changes for the CY 2000 M+C Payment Rates, we announced the risk adjustment methodology to implement this requirement. One element of the risk adjustment methodology we developed was a transition period during which M+C payments would be based on a blend of payment amounts under the previous system of demographic adjustments and payment amounts based on principal inpatient hospital diagnoses (the PIP–DCG risk adjustment methodology). Under a blend, payment amounts for each enrollee are separately determined using the demographic and risk methodologies, respectively. Those payment amounts are then blended according to the percentages for the transition year. On January 15, 1999, we announced the following transition schedule:

Year	Demographic method (percent)	Risk method (percent)
CY 2000	90	10
CY 2001	70	30
CY 2002	45	55
CY 2003	20	80
CY 2004	.....	100

(Using encounter data from multiple sites of care.)

Section 511(a) of the BBRA revised the original transition schedule for 2000 and 2001 to provide that the blend percentages will be:

Year	Demographic method (percent)	Risk method (percent)
CY 2000	90	10
CY 2001	90	10
CY 2002	at least 80	no more than 20

This provision does not require any changes in the existing M+C regulations, but we have described it here for the convenience of the reader.

5. Encouraging Offering of M+C Plans in Areas Without Plans (Section 512 of the BBRA)

Section 512 of the BBRA amended section 1853 of the Act by adding a new paragraph (i) to provide for ''new entry bonus'' payments to encourage M+C organizations to offer plans in payment areas (generally, counties) that currently do not have M+C plans serving the area. Under this provision, which we are incorporating into regulations under § 422.250(g), the amount of the monthly payment otherwise made to an M+C organization that offers the first M+C plan in a previously unserved county will be increased by 5 percent for the first 12 months that the plan is offered and by 3 percent for the second 12 months. These bonus payments will be available only for plans that are first offered during the 2-year period beginning January 1, 2000, and only in counties where no M+C plan has been offered, or where any plan offered was no longer offered as of January 1, 2000.

New section 1853(i)(3) specifies that if more than one M+C organization first

offers a plan in an uncovered area on the same date, the new entry bonus applies to the payments of both organizations. The BBRA does not expressly address situations in which an M+C organization or organizations begin offering more than one M+C plan simultaneously. Since the bonus is offered to the *organization* that first offers an M+C plan in an area, or to all *organizations* that do so on the same date, we interpret this to mean that the bonus would apply to all plans offered by a bonus-eligible organization on the same date. Thus, when an M+C organization offers two M+C plans simultaneously in a previously unserved county, the organization will receive the bonus payment for both plans. Similarly, if two or more M+C organizations first offer two M+C plans on the same date, each M+C organization will receive the bonus payments for each of its plans. Consistent with section 1853(i)(3) of the Act, the bonus payments are not available to M+C organizations offering a plan in a county that is already partially served by another plan, even if the new plan includes a portion of the payment area not previously covered by an existing plan. As we have stated in OPL 2000.117, a plan is considered to be offered when the sponsoring M+C organization has a contract in effect to serve beneficiaries in the previously unserved area and the plan is open for enrollment.

6. Modification of 5-Year Re-Entry Rule for Contract Terminations (Section 513 of the BBRA)

Section 513(a) of the BBRA amended section 1857(c)(4) of the Act to reduce from 5 to 2 years the period during which an M+C organization that has terminated its M+C contract at the organization's request is barred from re-entering into an M+C contract (absent our finding of special circumstances warranting an exception). Section 513(b)(1) further amended section 1857(c)(4) to provide for a new exception to this general exclusion period if, during the 6-month period after an M+C organization notified us of its intention to terminate an M+C contract, a legislative or regulatory change was adopted that resulted in increased Medicare payment amounts for the given payment area. In addition, section 513(b)(2) of the BBRA expressly states that the creation of the new exception does not affect our existing authority to grant an exception to this rule where ''circumstances which warrant special consideration,'' including in the circumstances identified in OPL #103 (OPL 99.103). OPL 99.103 states that we will grant an exception, for example, when an organization proposes to offer a different M+C plan type than it had previously offered, or an organization is proposing to introduce an M+C plan (1) in a geographic area currently served by two or fewer M+C plans, or (2) in an area other than that from which the organization had previously withdrawn when it ended its earlier contract with the Medicare program. We have incorporated the BBRA's revisions to section 1857(c)(4) of the Act into § 422.501(b)(5).

7. Flexibility to Tailor Benefits under M+C Plans (Section 515 of the BBRA)

Section 515 of the BBRA amended section 1854 of the Act to permit M+C organizations to elect to apply the premium and benefit provisions of section 1854 of the Act uniformly to separate segments of a service area, provided that the segments are composed of one or more M+C payment areas. This change, which is effective for contract years beginning on or after January 1, 2001, is largely consistent with our existing administrative policy, under which an M+C organization may offer multiple M+C plans, each with its own HCFA-approved service area, but must offer uniform benefits and premiums within each plan. For a full discussion of the implications of this change, and the conforming changes to the M+C regulations, we refer the reader to section II.C.3 of this preamble.

8. Delay in Deadline for Submission of Adjusted Community Rates (Section 516 of the BBRA)

Section 516 of the BBRA amended section 1854(a)(1) of the Act to delay the annual deadline for submission of adjusted community rate (ACR) proposals and information about enrollment capacity from May 1 to July 1. The statute provides that this change was effective for information submitted by M+C organizations in 1999 for benefits in calendar year 2000, and we are making changes to §§ 422.60(b)(1), 422.300(b)(2), and 422.306(a)(1) to reflect the new law.

9. Reduction in Adjustment in National Per Capita M+C Growth Percentage for 2002 (Section 517 of the BBRA)

An important element in the methodology used to calculate M+C payment rates involves the determination by the Secretary under section 1853(c)(6) of the Act of a ''national per capita M+C growth percentage.'' Each year, when determining M+C capitation rates, as explained in detail in the June 1998 interim final rule (63 FR 35004), this national growth percentage is applied to the area-specific component of the blended rate and to the minimum amount, also referred to as the ''floor''. The national per capita growth percentage is HCFA's estimate of the per capita rate of growth in expenditures. Section 1853(c)(6)(B) of the Act provided that in years from 1998 through 2002, the national per capita M+C growth percentage would be reduced, by 0.8 percentage points in 1998 and 0.5 percentage points in 1999 through 2002. Section 517 of the BBRA amended section 1853(c)(6)(B)(v) of the Act to change the adjustment for 2002 from 0.5 percentage point reduction to a reduction of 0.3 percentage points, and we are revising § 422.254(b)(2) to reflect this change.

10. Deeming of M+C Organizations to Meet Requirements (Section 518 of the BBRA)

Section 518 of the BBRA amended section 1852(e)(4) of the Act to set forth several changes related to (1) the process by which an M+C organization can be deemed, based on an accreditation organization's findings, to meet M+C requirements and (2) the standards for which such deeming is permissible. Revised section 1852(e)(4) now includes the following among requirements that must be deemed met if an accreditation body applies and enforces standards at least as stringent as those in this part: those requirements derived from section 1852(b) (concerning antidiscrimination), section 1852(d) (concerning access to services), section 1852(i) (concerning information on advance directives), and section 1852(j) (concerning provider participation rules), in addition to the requirements under section 1852(e)(1) and (2) concerning an M+C organization's quality assurance program and under 1852(h) concerning the confidentiality and accuracy of enrollee records. We are revising § 422.156(b) to add these requirements. In addition, new section 1852(e)(4) specifies that the Secretary must make a determination within 210 days on a private accrediting organization's application to act as an accrediting organization for M+C requirements. This provision in effect mandates the same approval time frame that applies to original Medicare accreditation under section 1865(b) of the Act, and we are incorporating this requirement into § 422.158(e).

11. Quality Assurance Requirements for PPO Plans (Section 520 of the BBRA)

Section 520 of the BBRA amended section 1852(e)(2) of the Act to change the quality assurance requirements for PPO plans, effective for contract years beginning on or after January 1, 2000. In the past, PPO plans had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans. New section 1852(e)(2)(D) establishes that, for purposes of the M+C quality assurance requirements, a PPO plan is an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization. We are incorporating this definition into the M+C regulations at § 422.4. The quality assurance requirements that now will apply for PPO plans are identical to the existing requirements for non-network M+C MSA plans and M+C private fee-for-service plans. Thus, as set forth under revised § 422.152, M+C organizations are no longer required to conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the quality assessment and performance improvement requirements that apply to all plans, such as those relating to health information and program review. See section II.E of this preamble for further detail on the quality assurance requirements for various types of plans.

12. User Fee for M+C Organizations Based on Number of Enrolled Beneficiaries (Section 522 of the BBRA)

Under section 1857(e)(2) of the Act, the Secretary is directed to collect ''user fees'' from M+C organizations in order to pay for the costs associated with the enrollment and information distribution activities required for the M+C program under section 1851 of the Act and for the health insurance counseling and assistance programs under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66). Before enactment of the BBRA, the aggregate amount to be collected from all M+C organizations was the lesser of (1) the estimated costs to be incurred by the Secretary in carrying out the applicable information dissemination activities or (2) an amount contingent upon the enactment of appropriations. An individual M+C organization's user fee was equal to its pro rata share of the aggregate amount of fees to be collected from all M+C organizations. Section 522 of the BBRA amended section 1857(e)(2) of the Act to provide that the aggregate amount of user fees to be collected from M+C organizations to carry out the required beneficiary education activities will be based on the lesser of the estimated costs of information dissemination or, for 2001 and thereafter, the ''M+C portion'' of $100 million, with the M+C portion representing the Secretary's estimate of the ratio of the average number of M+C enrollees for a fiscal year to the average total number of Medicare beneficiaries for the fiscal year. We are revising § 422.10 to reflect the new statutory provisions. Consistent with section 522(b) of the BBRA, these changes are effective for user fees charged on or after January 1, 2001, and the Secretary may not increase the user fees for the 3-month period beginning October 2000, above those in effect during the previous 9 months. While we will comply with this latter limitation, we are not including it in regulations text, just as Congress did not include it in the text of section 1857(e).

13. Clarification Regarding Operation of M+C Plans by Religious Fraternal Benefit Societies (Section 523 of the BBRA)

Section 523 of the BBRA amended section 1859(e)(2) of the Act to clarify that a religious fraternal benefit (RFB) society may offer any type of M+C plan, not just an M+C coordinated care plan. We are revising the definition of an RFB plan in § 422.2 to reflect this change.

14. Rules Regarding Physician Referrals for M+C Program (Section 524 of the BBRA)

Section 524 of the BBRA amended section 1877(b)(3) of the Act to specify that certain Medicare rules establishing prohibitions on physician referrals do not apply for purposes of M+C organizations offering M+C coordinated care plans, although they do apply for purposes of M+C MSA plans and private fee-for-service plans. As discussed in section II.E.10 of this preamble, this policy was incorporated into § 411.355(c)(5) of the Medicare regulations through our June 26, 1998 interim final rule.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on June 26, 1998 Interim Final Rule

We received 87 items of correspondence containing hundreds of specific 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:

- 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.
- Deadline for ACR submissions and capacity waivers.

2. Issues in February 17, 1999 Final Rule

In the February 17, 1999 final rule, we attempted to address those issues raised by public commenters where we were convinced that changes were needed and could quickly develop policies necessary to implement the changes. We also included policy clarifications for certain areas in which the material in the interim final rule had been misinterpreted. Also, to the extent possible, we addressed time-sensitive issues, such as those that needed to be resolved before publication of this comprehensive M+C final rule or those that could affect plans or beneficiaries in areas where Medicare risk contractors

initially chose not to participate in the M+C program. Some of the specific issues we addressed related to 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 coordination of care requirements.

3. Organization of Final Rule With Comment Period

In this comprehensive M+C final rule with comment period, we address all comments received on the interim final rule that were not addressed in the February 17, 1999 final rule. (As noted above, we are also incorporating changes necessitated by the BBRA, subject to public comment.) For the most part, we will address issues according to the numerical order of the related regulation sections. However, many of the comments raise interrelated issues that involve multiple sections of the regulations. In these cases, we generally address all comments on these issues together, whenever the first relevant section of the regulations arises. Also, we note that all comments on the definitions set forth in § 422.2 are addressed in the context of the requirements with which the applicable definitions are associated.

4. General Comments and Subpart A Issues

a. Administrative Procedure Act Issues

We received two comments on various aspects of the M+C rulemaking process, as discussed below.

Comment: A commenter contended that the June 26, 1998 interim final rule did not conform to requirements in the Administrative Procedure Act (APA). First, the commenter alleged that HCFA did not engage in ''reasoned decision making'' because in certain instances cited by the commenter, the preamble contained ''no discussion of * * * factual predicates, no discussion of alternatives that were evaluated and rejected, and no cost-benefit analysis.'' The commenter specifically cited requirements for a compliance plan and certifications by executives in connection with this contention. Second, the commenter contended that the regulations should have been subjected to prior notice and comment. The commenter argued that the authority in section 1856(b)(1) to issue interim final regulations only applied to existing standards under section 1876, and that failure to publish the rule by June 1 constituted ''a failure to satisfy a condition precedent for issuance of an interim final rule without notice and comment.'' Finally, the commenter argued that the rule impermissibly provided for compliance with our instructions, contending that this was an attempt to require compliance with instructions that should themselves be subjected to notice and comment.

Another commenter commended us on our success in issuing comprehensive regulations for a complex new program in a short period of time.

Response: The interim final rule includes an extensive preamble that explains the basis and purpose of the regulations, and meets the cited requirements of the APA. We believe that this preamble more than satisfies the requirements in the law for explaining the reasoning behind the decisions we made in the interim final rule. In some cases when we actively considered alternative approaches and rejected them, we included discussion of this in the interim final rule preamble. For example, in the discussion of grievance procedures (63 FR 35022–35023), we indicated that ''we considered'' including detailed requirements for M+C organization grievance procedures in the interim final rule, and ''we considered requiring certain time frames for addressing grievances.'' Our reasons for not doing so in that rule were also set out in detail.

We do not believe that the APA—or certain court decisions cited by the commenter—require us to discuss in the preamble every possible alternative that might have been considered to the approaches taken in the rule, but only to explain our reasons for the choices we made. To the extent we have received specific comments advocating alternative approaches, we explain in this final rule why we have not adopted these suggestions, where this is the case.

With respect to the specific requirement that M+C organizations have a plan in place for ensuring compliance with applicable State and Federal laws, we indicated in the preamble that we believe that such a plan was part of the administrative and managerial capabilities that should be in place to carry out the contract and *comply with* obligations under the contract. Many organizations agree with this conclusion, and had compliance plans in place before this requirement was adopted. We believe that this is an important component of proper management, like an accountable board of directors. We explained in the preamble that we were establishing this requirement as an M+C standard under our authority in section 1856(b)(1) to establish M+C standards by regulation.

As to the requirement for certifications as to the accuracy of data, we clearly explained in the preamble that we believed that since payments to M+C organizations are based on such data, the submission of the data is part of a ''claim'' for payment in the amount dictated by the data in question. We further explained that a certification of the accuracy of this information will help ensure accurate data submissions, and assist us and the DHHS Office of Inspector General in anti-fraud activities. We believe this is a clear and logical explanation of reasoned decision making in imposing this requirement.

We disagree with the commenter's contention that we were required to provide prior notice and comment before publishing final regulations. Section 1856(a)(1) gives the Secretary the authority to promulgate regulations establishing the standards that will apply under the M+C program, and that the Secretary is authorized to ''promulgate regulations that *take effect* on an interim basis, after notice and *pending opportunity for public comment*.'' (Emphasis added.) The commenter suggests that this authority only applies to requirements that are based on existing section 1876 standards. This is incorrect, and is contradicted by other BBA provisions citing this rulemaking authority. The reference to section 1876 merely provides that, ''consistent with the requirements of this part'' (meaning only to the extent that the BBA does not provide or authorize alternative approaches), ''standards established under this subsection shall be *based on* standards established under section 1876 *to carry out analogous provisions* of such section.'' section 1856(b)(2). This provision thus only applies to the extent we determine that doing so would be ''consistent with'' the new Part C provisions, and only with respect to those provisions in Part C that are ''analogous'' to a section 1876 standard. Even in this case, the new standards need only be ''based on'' the 1876 standards, not necessarily identical to such standards.

The commenter's interpretation that section 1856(b)(1) of the Act applies only to the repromulgation of existing 1876 standards is also contradicted by other references in the BBA to this rulemaking authority. For example, section 1876(k)(2), added by section 4002 of the BBA, provides for rules dealing with ''grandfathered'' Part B only enrollees. Since Part B only enrollees were permitted under section 1876, there were no section 1876 standards addressing the treatment of ''grandfathered'' enrollees. Yet, section

1876(k)(2) provides that such enrollees may ''continue [grandfathered] enrollment in * * * accordance with *regulations described in section 1856(b)(1).*'' Section 1876(k)(2). This makes clear that the rulemaking authority in section 1856(b)(1) is broader than the commenter contends.

The commenter's contention that we cannot avail ourselves of the interim final rule authority because the rule was not published by June 1, 1998, is illogical. If the Congress authorized interim final regulations because it wanted the rules to be in place by June 1, it would not wish regulations that have already missed this deadline to be delayed further by notice and comment rulemaking. Indeed, the fact that rules were not published by June 1 made the desirability and necessity of issuance in interim final form with an opportunity for public comment all the *more* urgent.

Finally, with respect to our instructions, we intend only to issue instructions that implement or interpret substantive provisions included in these regulations. To the extent the commenter believes that subsequent instructions are issued that should have been subjected to notice and comment, it can make this argument at that time. The fact that we require compliance with guidance we issue to implement these rules is fully consistent with the APA.

b. Types of M+C Plans (§ 422.4)

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

A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the M+C organization to deliver the benefit package approved by us. The network is approved by us to ensure that all applicable requirements are met, including access and availability, service area, and quality. Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care. Coordinated care plans include plans offered by HMOs, PSOs, and PPOs, as well as other types of network plans (except network MSA plans). We received no comments on our definition of coordinated care plan.

ii. Religious and Fraternal Benefit Society Plan

One specific type of M+C plan authorized by the BBA is a religious and fraternal benefit society plan (RFB plan), which is defined in section 1859(e) of the Act. An RFB plan is a new plan that may be offered under the M+C program. In § 422.2, an RFB society is defined as an organization that (1) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act and (2) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches. As noted above, an RFB plan was defined in the BBA as a coordinated care plan that is offered by an RFB society. We received two comments regarding RFB plans.

Comment: Two commenters noted that the definition of religious and fraternal benefit (RFB) society found in § 422.2 of the regulations would be clearer if the word ''benefit'' were added to the beginning of this definition.

Response: We agree that the word ''benefit'' was inadvertently omitted and have added the word ''benefit'' after the words ''religious and fraternal'' in that section.

Comment: One commenter asked whether RFB society plans are limited to being a coordinated care plan, or whether an RFB society could also offer a private fee-for-service plan or an MSA plan. A related question asked by the commenter is whether RFB plans can include a point of service (POS) option.

Response: As noted above, under the BBA, a RFB society could only offer a coordinated care plan as a RFB plan. Section 523 of the BBRA, however, amended section 1859(e)(2) of the Act to provide that an RFB society may offer any type of M+C plan. An RFB plan that operates as an M+C coordinated care plan may include a POS option, as could any other M+C coordinated care plan.

iii. M+C MSA Plans (§ 422.4(a)(2))

The comments received regarding M+C MSA plans are discussed in section III of this preamble. iv. Multiple Plans (§ 422.4(b))

In the interim final rule, we specified that under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO offering a coordinated care plan, has received from us a waiver of the State licensing requirement).

Comment: Noting that an M+C organization can offer multiple plans under a single contract with us, a commenter asked how multiple plans would work, and whether each would be required to have a separate health services delivery system. The commenter stated that in order to reduce the administrative cost of multiple plans, we should maximize assessment of compliance with Medicare requirements at the M+C organization level and minimize compliance assessment at the individual plan level.

Response: An M+C organization may offer multiple M+C plans under a single contract with us. Each M+C plan must have its own HCFA-approved service area, and a separate ACR submission that also must be approved by us. For coordinated care and network MSA plans, we will verify that each plan has a health care provider network under contract that meets M+C standards for access and availability to health care services for beneficiaries who enroll in the given plan. Although we will attempt to achieve all appropriate monitoring efficiencies when contractual elements are identical across plans, we have a responsibility to ensure compliance at the plan level when requirements are plan-specific, such as those noted above.

c. Application Requirements and Procedures (§§ 422.6 and 422.8)

These sections set forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan. One of the new requirements we set forth in the interim final rule was that organizations wishing to contract with us must submit documentation of their appropriate State licensure, or submit documentation of State certification that the entity is, in fact, able to offer health insurance or health benefits coverage meeting State fiscal solvency standards and is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health care services. We further specified that entities meeting the definition of a PSO can be exempted from this requirement if they meet conditions for a waiver, which can be granted by us in accordance with subpart H of part 422. Section 422.8 of the interim final rule describes the application requirements for entities seeking to contract with us to offer M+C plans, as well as our application evaluation procedures.

Comment: One commenter suggested that our use of terms referring to entities that qualify for M+C contracts (M+C organization) and applicants for such contracts are inconsistent and confusing. For instance, at §§ 422.8(a)(3), 422.8(e), and 422.8(g), we use the term ''entity'' to refer to an organization applying to become an M+C organization, while at §§ 422.8(d)

and (f) we use the term ''M+C organization.''

Response: Clearly, we should not refer to an organization that has not obtained approval from us to become a contractor under the M+C program as an ''M+C organization.'' Accordingly, we have revised § 422.8 to uniformly refer to organizations that apply to become M+C organizations as ''contract applicants.'' This is consistent with our use of this term elsewhere in this final rule.

We likewise agree with the comment that organizations that have received approval to operate as an M+C organization should uniformly be called an ''M+C organization.'' Accordingly, we have revised applicable subsections of § 422.8 to uniformly use the term ''M+C organization'' to refer to an existing contractor under the Medicare+Choice program.

d. User Fees (§ 422.10)

This section implements section 1857(e)(2) of the Act, as revised by section 522 of the BBRA. Section 1857(e)(2) requires that M+C organizations share in costs associated with beneficiary enrollment in M+C plans, including the costs of providing information and counseling on plan choices. It sets forth the maximum amount of the aggregate ''user fees'' that can be collected from M+C organizations as well as the procedures that we follow to assess and collect these amounts from M+C organizations.

In the June 26, 1998 interim final rule, we referred to interim final regulations published on December 2, 1997, which implemented section 1857(e)(2) for risk contractors under section 1876. (Under section 1876(k)(4)(D), the obligation under section 1857(e)(2) applied to section 1876 contractors in 1998.) These December 1997 interim final regulations set forth a methodology for determining an individual organization's ''pro rata share'' of the beneficiary costs to be assessed (62 FR 63669). We also explained in the June 26, 1998 interim final rule that we were simply adopting at § 422.10, for purposes of the M+C program, the user fee provisions previously set forth in § 417.472(h) of the December 1997 interim final rule. As we indicated in the June 26, 1998 interim final rule, we are addressing the comments received on the substance of the December 1997 interim final rule in this comprehensive M+C final rule. (Since there are no remaining section 1876 risk contractors, § 417.472(h) itself no longer has any applicability.)

As described above, section 522 of the BBRA subsequently amended the user fee provisions set forth in section 1857(e)(2) of the Act, effective for user fees charged on or after January 1, 2001. Revised section 1857(e)(2) now establishes that beginning in the year 2001 the maximum amount of aggregate user fees that we may collect during a fiscal year from M+C organizations will be determined by the percentage of Medicare enrollees in M+C plans. Specifically, we will calculate: the annual average number of Medicare beneficiaries enrolled in M+C plans during a fiscal year divided by the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year. This ratio will be multiplied by $100,000,000 to determine the maximum aggregate user fees we may collect from all M+C organizations in a given fiscal year. (Under section 1857(e)(2), we collect the lesser of (1) the actual costs of carrying out the required information dissemination activities or (2) the maximum aggregate amount permitted under the Act.)

We received five letters of comment regarding the interim final rule of December 2, 1997, which established the assessment method under which all M+C organizations are assessed the same fixed percentage of their total monthly Medicare payments, in order to collect the M+C user fee. Two commenters supported the user fee assessment methodology selected by us and considered that it was equitable both to organizations and beneficiaries; three commenters opposed the methodology. We also received six letters commenting on the same methodology in response to the interim final M+C regulation of June 26, 1998. Again, three commenters argued that the user fee was unfair to M+C organizations since it resulted in these organizations funding an information campaign for all Medicare beneficiaries, not just those enrolled in M+C organizations. These latter concerns are now moot in light of the BBRA amendments limiting M+C user fees to the percentage of information dissemination costs representing the percentage of total Medicare beneficiaries that are M+C enrollees. Comments that remain relevant are discussed below.

Comment: A commenter expressed concern about the costs of the education campaign implemented by us and how the funds collected from M+C organizations would be spent. The commenter asked that we make available detailed information on the budget, resource allocation, and past and projected expenditures for the beneficiary information campaign, in order to justify the user fee funding levels. The commenter also expressed concern that we should not collect more in user fees than entitled by law. Specifically, the commenter noted that at § 422.10(d), we are only entitled to collect the lesser of the estimated costs necessary to implement educational activities in that fiscal year or the appropriated amount. The commenter also stated that the reduction in M+C payments due to the assessment of the user fee will deter new organizations from entering the M+C program.

Response: Although not required under the statute or the BBA, we provide an annual report to the Congress that includes an assessment of the implementation of the M+C program. This report also provides budgetary information on the expenditures of the fees we have collected to fund the M+C information campaign. As stated in revised § 422.10(d)(2), beginning in fiscal year 2001, we will collect in a fiscal year the lesser of either the amount needed to implement the required information dissemination and other activities, or the amount equal to the M+C portion of $100 million. The fees collected from any one organization would represent a very small percentage of the total annual Medicare payments to that organization, and we do not believe that they would deter an organization from entering the M+C program.

Comment: A commenter argued that the assessment method adopted by us, under which a percentage of the monthly payment to an M+C organization is assessed, is unfair because it results in organizations in high capitation payment areas paying more (in total dollars) than organizations in lower payment areas. The commenter expressed the view that it is unfair to charge an organization in New York more than an organization in Nebraska.

Response: In selecting an assessment methodology, we sought an approach that is as financially equitable as possible regardless of an M+C organization's size or geographical location. We also wanted a methodology that would not present a barrier to participation for smaller and new M+C organizations. We adopted the percentage of payment approach because it bases each organization's assessment on the total Medicare dollars flowing to that particular organization. Thus, the fee each organization pays is directly proportional to the total dollars the organization receives from the Medicare program. M+C organizations that receive larger payments (based on monthly enrollment and payment levels) will pay more in total dollars

than M+C organizations with less Medicare money coming in.

Comment: A commenter stated that the assessment of a user fee should be directly related to the costs of providing services. Since no evidence has been presented that the costs of a national mail campaign are higher in one county than another, the user fee should be even across all counties.

Response: While the fees collected from M+C organizations will be used primarily to fund a national information campaign designed to reach all Medicare beneficiaries, some funds will go to local efforts, where, as noted above, costs do vary. In any event, this assessment is not an organization-specific ''user fee'' such as those imposed under the user fee statute. The assessments are not based on specific costs associated with an individual M+C organization, but on a share of aggregate costs. Specifically, the statute provides for each M+C organization to pay its pro rata share ''as determined by the Secretary'' of the ''aggregate amount'' spent on the specified costs. Thus, data on actual costs associated with an individual organization are not relevant. Rather, we consider the fee as an assessment to be levied in a manner that, to the extent possible, equitably balances the financial impact on all organizations.

Comment: A commenter stated that we should not use the user fee assessment as a way to equalize Medicare managed care payments in different areas of the country. Noting that the Congress has provided for a minimum update in high payment areas, the commenter contended that we will be violating the spirit of the law by taking more from organizations offering M+C plans in these areas.

Response: No consideration was given to using the user fee assessment methodology as a tool to adjust the level of Medicare payment to M+C organizations in different parts of the country. In fact, since the percentage impact on all M+C Medicare payments is equal (a fixed percentage of total payment), this is the one approach that maintains the relative payment levels of all organizations.

Comment: Another commenter asserted that the user fee assessment method we selected—with fees based on percentage of an organization's M+C payment—has the effect of penalizing those M+C plan enrollees who reside in counties with higher payment rates. The commenter wrote that enrollees in high payment rate areas will pay much more for their existing benefits.

Response: In terms of total dollars, it is true that M+C organizations in high payment areas will pay more on a per member basis than organizations in lower payment areas. However, as previously noted, the assessment percentage is the same for all organizations. A method that does not take into account the total dollars flowing to each plan would be regressive and unfair, because it would have a disproportionately high financial impact on organizations (and their members) located in mid to lower payment areas and those with low enrollment.

Comment: One commenter recommended that all M+C organizations pay a minimum user fee amount and then, on top of that minimum amount, organizations should also pay a flat monthly amount for each member. The commenter stated that this approach would ensure that the user fee is reasonably related to the benefit that the organization will receive from the M+C program.

Response: We considered the approach suggested by the commenter but rejected it because, unless the flat fee were set at a very low level, it would present an entry barrier for organizations with relatively low enrollment levels. We also rejected a flat per member monthly assessment because it does not adjust for the geographic variation in our monthly capitation payments to M+C organizations.

B. Eligibility, Election, and Enrollment

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

Section 1851(a) of the Act sets forth the criteria for an individual to be eligible to elect an M+C plan. Consistent with the statute, § 422.50 specifies that an individual is eligible to elect an M+C plan if he or she:

- Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or Competitive Medical Plan (CMP) with a risk contract under part 417 on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);
- Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or other health plan offered by an M+C organization may continue to be enrolled in the M+C plan, or if enrolled in another health plan, may enroll in an M+C plan offered by the organization, if the individual is otherwise eligible to enroll in the M+C plan;
- Resides in the service area of the plan, except that an individual who resides in a continuation area of an M+C plan while enrolled in a health plan offered by the M+C organization may continue to be enrolled with the M+C organization as an M+C plan enrollee under the terms that apply to enrollees in the continuation area;
- Completes and signs an election form and gives information required for enrollment; and
- Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

We specified in the interim final rule that an M+C-eligible individual may not be enrolled in more than one M+C plan at any given time. Comments on the M+C eligibility rules are discussed below.

Comment: Several commenters objected to the omission from the regulations of any provision permitting individuals to remain enrolled with an organization upon becoming Medicare eligible if they were enrolled with the organization as a commercial enrollee, but live outside the Medicare service area. In particular, commenters recommended that beneficiaries residing outside of an M+C plan's service area be allowed to remain enrolled with the M+C organization offering the M+C plan as an M+C plan enrollee upon becoming eligible for Medicare, even if they live outside the M+C service area. Commenters noted that the previous regulations in Part 417 that applied to section 1876 risk contracts allowed an individual enrolled with an organization as a commercial enrollee to remain enrolled with the organization as a Medicare enrollee upon becoming eligible for Medicare even if the individual did not live in the Medicare service area. Several commenters asserted that the continuation area option provided for in the BBA (discussed in further detail below) was not an adequate replacement for the previous option; they believe that prohibiting out-of-area members from voluntarily remaining enrolled in M+C plans unduly restricts the options available to beneficiaries and causes unnecessary disruptions in care. One commenter noted that section 1851(b)(1)(A) of the Act gives us the discretion to make an exception to the requirement that the individual reside in the M+C plan's geographic area.

Response: The last commenter is correct that section 1851(b)(1)(A) states that, ''*Except as the Secretary may otherwise provide* (emphasis added), an individual is eligible to elect an M+C plan offered by the M+C organization

only if the plan serves the geographic area in which the individual resides.'' In accordance with the statute, existing § 422.250(a) generally limits eligibility to elect an M+C plan to individuals living in the plan's service area. The only discretion exercised by the Secretary in the M+C regulations was to permit individuals the option of continuing enrollment in the plan if they move out of the service area and into a plan's ''continuation area'' (which can be established pursuant to section 1851(b)(1)(B) of the statute and § 422.254 of the M+C regulations, as discussed in detail below.)

Based on the comments we received on the interim final rule, however, as well as the reluctance of M+C organizations to establish formal continuation areas, we have become convinced that the regulations should be amended to provide for additional choices for beneficiaries. Thus, we are amending § 422.50 (with conforming changes to §§ 422.66(d)(1) and 422.74(b)(2) and (b)(4)) to permit M+C organizations to offer a ''seamless conversion'' option to individuals who, upon becoming entitled to Medicare, live outside of an M+C plan's service area but are already enrolled in a commercial health plan offered by the same organization. If an M+C organization chooses to offer this option, it must offer the option to all individuals who were enrolled in a commercial health plan offered by the organization at the time they become Medicare-eligible. We do not believe it is appropriate to limit the availability of this option only to beneficiaries who had previously been enrolled in employer group health care plans, but instead are providing that both individual and employer group members of commercial health plans may elect to remain enrolled with their organization under an M+C plan under an expanded ''seamless conversion'' option. Similarly, we note that this expanded eligibility requirement is not limited to situations in which an enrollee becomes eligible for Medicare by virtue of age (referred to in the past as ''age in'' enrollees), but will apply to all newly eligible Medicare beneficiaries, including the ESRD and disabled population. (As noted above, we previously determined, in the interim final rule, that people with ESRD who are enrolled with an organization before becoming Medicare eligible may remain enrolled with the organization as an M+C plan enrollee.) We note that organizations that wish to offer this option must meet the M+C access standards under § 422.112, and must furnish the same benefits to these enrollees as to enrollees who reside in the plan service area. Such enrollees should be made aware by the M+C organization of the extent to which they will need to travel into the plan service area to obtain service.

Comment: One commenter pointed out that State-authorized managed long term care plans may identify a chronically ill target population to be served, while the M+C regulations at § 422.50 do not allow an M+C plan to discriminate within an approved service area among those who are eligible to enroll in M+C plans. The regulations also do not provide for plans to enroll special populations. The commenter asked whether these provisions are waivable to permit plans authorized as managed long-term care plans under State law to participate in the M+C program.

Response: There is no authority in the statute to ''waive'' the requirement that M+C organizations accept all M+C-eligible individuals in the service area who wish to enroll. However, we have approved demonstration projects under independent demonstration authority that involve managed care entities that restrict Medicare enrollment to long-term care populations. Long-term care plans may be able to participate in Medicare under such a demonstration.

Comment: One commenter asked for clarification regarding whether individuals who are enrolled only in Medicare Part B or who have ESRD, and were grandfathered into M+C plans as of January 1, 1999, can move from plan to plan in the same M+C organization or to another organization. The commenter supported allowing the individual to move between plans and organizations. Another commenter suggested that we allow an individual enrolled only in Medicare Part B who retained his or her enrollment in an M+C plan as of January 1, 1999, to enroll in another M+C organization for a period of time after disenrolling from an M+C plan. In addition, the commenter suggested that individuals enrolled only in Medicare Part B should be able to enroll in an M+C plan at any time until 2002.

Response: We agree that grandfathered Part B-only individuals and individuals with ESRD should be allowed to move between plans within an M+C organization, and have specified that this is permissible in OPL 99.084, issued on February 26, 1999. With respect to beneficiaries with ESRD, this policy is based on section 1851(a)(3)(B) of the Act, which we interpret as permitting an existing enrollee who develops ESRD while enrolled with an organization to remain enrolled with that organization. This is an exception to the general rule that an individual medically determined to have ESRD is not eligible to enroll in an M+C plan. However, we do not have statutory authority to permit a beneficiary with ESRD to enroll in a plan offered by a different M+C organization. Similarly, under section 1851(a)(3) of the Act, Part B-only enrollees generally are ineligible to enroll in an M+C plan. Section 1876(k)(2) of the Act, however, permitted a Part B-only beneficiary enrolled with an organization under a section 1876 risk contract on December 31, 1998, to continue enrollment in that organization if the organization has entered into an M+C contract effective January 1, 1999. Again, we have no statutory authority to expand upon this exception by permitting that individual to enroll with a different M+C organization from the one in which he or she was enrolled on December 31, 1998, under a section 1876 risk contract.

Comment: One commenter stated that individuals enrolled only in Medicare Part B who disenroll from M+C should be permitted to immediately enroll in Medicare Part A, and the surcharge for late enrollment should be eliminated.

Response: Provisions affording such beneficiaries these protections have been in place for some time. The Omnibus Reconciliation Act of 1990 established the Transfer Enrollment Period (TEP) during which individuals who have Part B only and whose coverage in a Medicare managed care plan is terminated for any reason may immediately enroll in Premium Part A. This provision is found at section 1818(c)(7) of the Social Security Act, and § 406.21(f) of our regulations, which also provide for relief from the premium surcharge for late enrollment. Under the TEP provisions, individuals may enroll in Premium Part A during any month in which they are still enrolled in the managed care plan or during the 8–month period following the last month of coverage under the plan. Under certain circumstances enrollment may occur up to 3 months in advance. If the individual enrolls in Premium Part A while still enrolled in the managed care plan or during the first full month when not so enrolled, Part A coverage is effective with the month of enrollment or, at the individual's option, the first day of any of the following 3 months. If enrollment occurs during the 7 remaining months of the TEP, Part A coverage is effective the month after the month of enrollment.

Comment: One commenter suggested that the regulation be revised to permit individuals with ESRD who have been

enrolled in a commercial plan or a Medicare Cost HMO offered by the M+C organization to enroll in an M+C plan of that organization.

Response: Existing § 422.50(a)(2) provides this protection, stating that an individual who develops ESRD while enrolled in an M+C plan, or in a health plan offered by the M+C organization offering an M+C plan in the area in which the individual resides, may continue to be enrolled in an M+C organization as an M+C plan enrollee. Also, consistent with section 1851(a)(3)(B) of the Act, we have specified in OPL99.084 that individuals with ESRD may move among plans within an M+C organization. (We note that under this final rule, the individual may remain enrolled even if he or she does not live in the service area if new § 422.50(a)(3)(ii) applies.) For purposes of § 422.50(a)(2), ''a health plan offered by the M+C organization'' includes any commercial health plan and any cost contract held by that organization. In the case of an individual who develops ESRD while enrolled in a commercial plan offered by a cost contractor, the section 1876 rules similarly allow such an individual to remain enrolled with that organization under its cost contract after becoming eligible for Medicare.

Comment: One commenter believes that we are interpreting the phrase ''entitled to benefits under Part A and enrolled in Part B'' incorrectly.

Response: Our interpretation of this phrase is explained in detail in the interim final rule (63 FR 34979), and we would refer the commenter to that detailed explanation. To briefly reiterate our reasoning, we believe that the Congress intended that a newly eligible individual be given the opportunity to be enrolled in an M+C plan only after he or she is actually entitled to receive benefits under Part A and Part B. This view is supported by language in section 1851(e)(1) of the Act, which refers to ''the time an individual first becomes entitled to benefits under Part A and enrolled under Part B,'' and provides for the Secretary to specify an initial coverage election period under which such an individual may elect coverage under an M+C plan ''effective as of the first date on which the individual may *receive* such [Part A and Part B] coverage'' (emphasis added). While an individual technically may have ''enrolled'' in Part B once an application has been completed, such an individual's right actually to ''receive'' coverage of services under Part B may not occur for a period of months. (See 63 FR 34979.) Since M+C organizations are paid in part from Part B trust funds, we do not believe it would be appropriate for an individual to be enrolled in an M+C plan before he or she is entitled to ''receive'' Part B trust fund payments. We therefore have interpreted ''enrolled in Part B'' to mean entitled to receive Part B coverage. Consistent with section 1856(b)(2) of the Act (which provides for use of section 1876 standards to carry out analogous M+C provisions), this interpretation follows our longstanding interpretation of identical language in section 1876(d) of the Act.

2. Continuation of Enrollment (§ 422.54)

Section 1851(b)(1)(B) of the Act permits M+C organizations to offer enrollees the option of continued enrollment in an M+C plan when enrollees leave the plan's service area to reside elsewhere (that is, in the ''continuation'' area) on a permanent basis. M+C organizations that choose to offer a continuation of enrollment option must explain the option in marketing materials, and make it available to all enrollees in the service area of the plan. Enrollees may choose to exercise the option of continued enrollment when they move out of the plan's service area, or they may choose to disenroll.

An M+C organization must obtain our approval of the continuation area and related marketing materials, and meet the access requirements under section 1851(b)(1)(B) of the Act, before it may offer a continuation of enrollment option to Medicare beneficiaries.

The payment rate for the M+C organization is based on the rate and adjustment factors that correspond to the beneficiary's permanent residence. Under section 1851(b)(1)(B) of the Act, the M+C organization must, at a minimum, provide or arrange for the provision of Medicare-covered benefits under section 1852(a)(1)(A) of the Act in the continuation area. This does not include any additional benefits the organization is required to provide to noncontinuation area members under section 1852(a)(1)(B) of the Act.

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

We are defining ''reasonable cost sharing'' in the continuation area as limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

The interim final rule also provides that appeals and grievances of enrollees in the continuation area must be handled in the same timely fashion as for other enrollees. The ultimate responsibility for the handling of appeals and grievances is with the organization that is receiving payment from us.

We received 11 comments requesting further guidance regarding the continuation of enrollment option. Generally, commenters endorsed the continuation of enrollment concept and urged us to define continuation areas broadly in order to enhance coverage options for enrollees.

Comment: One commenter asked whether the beneficiary may choose the continuation area option verbally or in writing.

Response: Our current policy, as outlined in OPL 99.100 (which was published August 9, 1999), requires that the beneficiary choose the continuation area in writing, so that there is documentation of this choice. We further believe that in the absence of an affirmative choice to remain enrolled in an M+C plan under the different terms that apply to continuation enrollees, a move out of an M+C service area should be treated as a decision to disenroll from the M+C plan. We accordingly have amended § 422.54(c)(2) to provide that a beneficiary's choice to continue enrollment in a continuation area must be made in a manner specified by us, and that in the absence of such a choice, the beneficiary will be considered to have chosen to disenroll from the M+C plan if he or she moves out of its service area.

Comment: Commenters recommended that the benefits in the continuation area should reflect the level of reimbursement the M+C organization receives, and thus should include any additional benefits.

Response: As the commenters point out, the existing continuation of enrollment regulations at § 422.54(d) require, at a minimum, that M+C plans provide Medicare-covered services in the continuation area. We recognize that this permits M+C plans to offer less generous benefits in the continuation area while still receiving the full Medicare payment. Section 1851(b)(1)(B) of the Act provides that individuals exercising the continuation of enrollment option have access to the ''full range of basic benefits'' described in section 1852(a)(1)(A) of the Act. However, section 1852(a)(1)(A) of the Act refers only to those benefits available under Parts A and B, and not

to additional benefits, which are described in section 1852(a)(1)(B) of the Act. Thus, although we agree that it would be preferable that M+C organizations be required to provide additional benefits to continuation area enrollees, the statute does not support this requirement. Therefore, we are considering a legislative proposal that would correct this inequity.

Comment: Several commenters inquired about the process for applying to us for a continuation area.

Response: We are adding a continuation area chapter to the M+C application for new M+C organization applicants. A separate application form will be available for current M+C contractors who wish to apply for a continuation area. Further guidance regarding the application process will be available in a forthcoming OPL.

Comment: One commenter asked whether a member must use only Medicare-certified facilities in the continuation area.

Response: The pertinent requirements in § 422.204(a)(3) apply equally to services furnished in a continuation area. Under § 422.204(a)(3), benefits must be provided through, or payments must be made to, providers that meet applicable title XVIII requirements. Further, a hospital, nursing home, home health agency, or other ''provider of services'' as defined in section 1861(u) of the Act, must have a provider agreement with us in place. (See section II.E of this preamble for further details on this requirement.) We believe these requirements help to assure the quality of care that is provided to beneficiaries.

Comment: Another commenter suggested that we allow M+C organizations a 1-year transition period to establish continuation areas and implement any continuation area requirements.

Response: We believe the regulations provide organizations with sufficient opportunity to implement continuation area requirements. M+C organizations are not required to establish a continuation area for their enrollees. Thus, an M+C organization may choose not to offer a continuation area until it is ready to implement the requirements outlined in § 422.54.

Comment: One commenter questioned whether State licensing regulations may supersede the potential advantages or enrollment flexibility of the continuation area.

Response: We believe the commenter is questioning how State licensing requirements will affect an M+C organization's ability to establish or offer the continuation of enrollment option. Section 422.400(a) states that an M+C organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage. Therefore, an M+C organization may establish a continuation area only in a State in which it is licensed under State law or otherwise authorized to operate. The individual States have the authority to determine whether they are going to require licensure or, for example, permit the M+C organization to use the licensure of an affiliate if it wishes to establish an out-of-State continuation area. Although we are not aware of State laws that unduly restrict the establishment of continuation areas, we would refer the reader to section II.I of this preamble for a detailed discussion of situations in which State laws are preempted by M+C laws and regulations.

Comment: Some commenters contended that we interpreted section 1851(b)(1)(B) of the Act too restrictively. For example, commenters objected to the requirement in § 422.54 that an M+C plan's service area must be geographically distinct from its continuation area. Commenters also questioned whether enrollees who move to continuation areas in counties adjacent to the M+C plan's service area may continue to receive services in the M+C plan's service area.

Response: A continuation area, as defined at § 422.54(a), is an additional area outside the service area in which the M+C organization furnishes or arranges for furnishing services to its enrollees. The regulation does not prohibit continuation areas adjacent to the M+C plan's service area, as the commenter appears to believe. Further, we agree that enrollees residing in a continuation area adjacent to the M+C plan's service area may receive services in the M+C plan's service area, as long as the access and service requirements of § 422.112 are met.

Comment: One commenter suggested that we allow enrollees to obtain services in the continuation area, even if they are not living in the continuation area permanently.

Response: The continuation area is intended for those enrollees who reside permanently outside of the service area (and permanently inside the continuation area) and want to remain enrolled in the plan. We do not have the authority to direct M+C plans to offer enrollees, temporarily residing in the continuation area, benefits in excess of the urgent/emergent care required by the statute and those benefits voluntarily offered by an M+C plan in its traveler/visitor policy.

Comment: One commenter requested clarification regarding whether the continuation of enrollment option is intended to replace current travel programs. The commenter also inquired whether an enrollee would remain enrolled for the first 12 months with coverage only for emergency and urgently needed care, and then convert to a continuation of enrollment option.

Response: The continuation of enrollment option is not designed to replace current travel programs. In general, the purpose of traveler/visitor programs is to allow enrollees the opportunity to continue obtaining health care services while traveling outside the service area of the M+C plan in which they are enrolled. In contrast, the continuation of enrollment option is intended to permit enrollees to remain enrolled with an M+C plan if they move permanently outside of the plan's service area. If the enrollee moves permanently into an area other than a continuation area, the member must be disenrolled as soon as the M+C organization is aware of the move and the enrollee has been notified. If an enrollee moves permanently into a geographic area designated as a continuation area, and chooses to remain a member of the M+C plan as a continuation of enrollment member, the enrollee must receive, at a minimum, Medicare-covered services. If an enrollee moves temporarily into the continuation area, or any area outside the service area, the M+C plan must provide coverage for emergency and urgently needed care. With respect to the question of whether an enrollee would remain enrolled for the ''first 12 months'' after a move, before converting to a continuation enrollment option, an individual can be a continuation enrollee as soon as he or she moves permanently to the continuation area. There is no waiting period.

3. Election Process (§ 422.60)

The general rule for acceptance of enrollees is that, except for the limitations on enrollment in an M+C MSA plan (§ 422.62(d)(1)), and for cases in which a plan has reached its enrollment capacity, each M+C organization must accept without restriction eligible individuals who elect an M+C plan during initial coverage election periods, annual election periods, and special election periods specified in §§ 422.62(a)(1), (a)(2), and (b).

Additionally, M+C organizations must accept elections during the open enrollment periods specified in

§§ 422.62(a)(3), (a)(4), (a)(5), and new (a)(6) if their M+C plans are open to new enrollees.

We stated in the interim final rule that the election form must comply with our instructions regarding content and format and have been approved by us as described in § 422.80. The form must be completed and signed by the M+C eligible individual (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between the DHHS and its designees and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary.

We further stated that the M+C organization must file and retain election forms for the period specified in our instructions. An election in an M+C plan is considered to have been made on the date the election form is received by the M+C organization. Also, the M+C organization must have an effective system for receiving, controlling, and processing election forms that requires that each election form is dated as of the day it is received and election forms are processed in chronological order, by date of receipt. Additionally, the M+C organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by us. We also provided that a notice of acceptance, in a format specified by us, informs the beneficiary of the date on which enrollment will be effective under § 422.68; and if the M+C plan is enrolled to capacity, explains the procedures that will be followed when vacancies occur. Also, a notice of denial explains the reasons for denial in a format specified by us. Within 30 days from receipt of the election form (or from the date a vacancy occurs for an individual who was accepted for future enrollment), the M+C organization transmits the information necessary for us to add the beneficiary to our records as an enrollee of the M+C organization.

Comment: Several commenters had concerns with allowing M+C organization representatives to assist individuals in completing any part of the election forms. One commenter believes that the common practice should be the beneficiary completing and signing his or her own form. Another commenter believes M+C organizations should be allowed to assist beneficiaries in completing the election forms only in limited circumstances, such as if the enrollee is disabled and needs assistance, and that organizations abusing this process should be subjected to meaningful penalties. One commenter suggested that when assistance is provided to a beneficiary in completing the election form, a reason for the assistance also be documented on the form, especially if an M+C organization agent completes the form. In contrast, two commenters supported a provision that permits individuals to assist a Medicare beneficiary in completing an election form.

Response: As discussed in the preamble of the interim final rule (63 FR 34984), section 1851(h)(4)(B) of the Act indicates that the ''fair marketing standards'' may include a prohibition against an M+C organization (or agent of such an organization) completing any portion of any election form used to carry out elections on behalf of any individual. However, we have decided at this time not to prohibit an M+C organization (or agent of such an organization) from assisting beneficiaries in completing the election form. We recognize that we must provide accommodations for persons with disabilities and for situations in which such a prohibition could represent a potential physical burden to beneficiaries. We believe requiring the signature of the individual who assisted the beneficiary in completing the form and an indication of his or her relationship to the beneficiary is a fair compromise.

We agree that the M+C organization should be allowed to assist beneficiaries in completing the election form only under limited circumstances. For this reason, representatives should be assisting the beneficiary in completing the election forms only when assistance is needed, such as for a person who is disabled, illiterate, or otherwise impaired by age or health. In fact, in some circumstances assistance may be required to comply with civil rights requirements, for example, to ensure that individuals with disabilities or limited English proficiency have an equal opportunity to participate. Any M+C organization that unduly influences beneficiaries through this assistance should be identified by our monitoring procedures and subject to sanctions as specified in § 422.750.

We believe requiring the signature and identifying their relationship to the individual who is enrolling in the M+C plan is a sufficient beneficiary protection. It provides adequate information to monitor a beneficiary's understanding that the form is for enrollment. The reason why an individual needs assistance should not be included on the enrollment form because it could undermine a Medicare beneficiary's right to privacy by disclosing health related information without his or her consent.

Comment: One commenter asked how enrollment and disenrollment requirements under Medicare compare to Medicaid rules, which the commenter erroneously believes allow the enrollee to enroll and disenroll at any time.

Response: Dually eligible individuals, that is, those individuals who are entitled to Medicare as well as Medicaid, have the same freedom of choice under Medicare as those who are entitled to Medicare only. M+C election provisions under section 1851(e) of the Act and § 422.62 of our regulations apply to all M+C-eligible individuals, and prior to 2002, permit Medicare enrollees to disenroll at any time. Under Medicaid rules, in contrast, managed care organizations (MCOs) are permitted to preclude Medicaid enrollees from disenrolling without cause for up to a year. MCOs are required only to permit disenrollment without cause in the first 90 days of enrollment, and annually thereafter. See section 1932(a)(4) of the Act.

Comment: One commenter requested clarification on when M+C organizations are required to be open for enrollment. In particular, the commenter expressed confusion over the meaning of the term ''open enrollment period.''

Response: We recognize the potential for confusion associated with the use of the term ''open enrollment period.'' In accordance with section 1851(e)(6)(A) of the statute, § 422.60(a)(1) specifies that M+C organizations must be ''open for enrollment'' (that is, must accept enrollments) during annual, initial coverage, or special election periods unless they have reached enrollment capacity. However, under section 1851(e)(6)(B) of the Act, an M+C organization may accept elections at *such other* times as the organization provides. These latter time periods, during which an M+C organization has the discretion to decide whether to be ''open'' for enrollment are frequently referred to as ''open enrollment'' periods. We note that, if an M+C organization chooses to be open to new enrollees during all or a portion of these discretionary ''open enrollment'' periods, it must be open for all M+C-eligible individuals.

Comment: One commenter found § 422.60(a)(2), which states that M+C organizations must accept elections during open enrollment periods if their plans are open to new enrollees, to be confusing and detrimental to newly eligible individuals. The commenter believes that new Medicare eligibles

should not be limited to these time frames.

Response: The new enrollees being referred to in § 422.60(a)(2) are individuals newly electing the M+C plan and not individuals newly eligible for Medicare. Individuals newly eligible to Medicare are given a different ''open enrollment'' period under which they may elect or change M+C plans. In particular, §§ 422.62(a)(4)(ii) and 422.62(a)(5)(ii) allow newly eligible individuals to make an election beginning the month the individual is entitled to Medicare Parts A and B and ending on the last day of the sixth month of entitlement (in 2002) or the third month of entitlement (in 2003 and thereafter) or on December 31, whichever is earlier. Therefore, we do not believe a regulatory change is necessary.

Comment: One commenter asked if we would be modifying our enrollment transmission schedule to account for the 30-day period in which the M+C organization must transmit the enrollment information as stated in § 422.60(e)(6).

Response: Based on this comment, we are amending § 422.60(e)(6) to state that ''upon receipt of the election form (or from the date a vacancy occurs for an individual who has been accepted for enrollment), the M+C organization transmits the information, within time frames specified by us, necessary for us to add the beneficiary to our records as an enrollee of the M+C organization.'' We are also revising § 422.60(f)(3) to state that ''upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA.'' These changes will allow us the flexibility to vary the time frames in the future, should technological or policy changes warrant it.

Comment: One commenter asked that we clarify and provide guidance as to when an election is considered to have been made.

Response: Section 1851(f)(2) of the Act, as revised by section 502 of the BBRA, states that the effective date of coverage during continuous open enrollment periods is the first day of the first calendar month following the date on which the ''election is made,'' except that if the election or change of election is made after the 10th day of a calendar month, the election or change of election takes effect on the first day of the second calendar month following the date on which the election or change is made. As noted in the preamble of the interim rule, it was necessary to define when an election is made in order to establish the effective date of coverage and to establish the date of our liability for payment. Therefore, the regulations at § 422.60(d) state that an election is considered to have been made on the date it is received by the M+C organization.

4. Enrollment Capacity (§ 422.60(b))

Sections 422.60(b) and 422.306(a) of the original M+C regulations required M+C organizations to submit information on the enrollment capacity of plans they offer by May 1 of each year. As noted in section I.C.8 of this preamble, section 516 of the BBRA amended section 1854(a)(1) of the Act to move the annual deadline for submission of ACR proposals and enrollment capacity data (if any) from May 1 to July 1, effective in 1999. If a plan reaches its HCFA-approved capacity limit, the M+C organization offering the plan generally is not obligated to accept new enrollees.

Comment: One commenter requested that we change the date that M+C organizations must notify us of the need for a capacity limit from May 1 to a date later in the year in order to allow the M+C organizations more time to analyze the previous year's capacity and better determine the need for a capacity waiver.

Response: While we had no discretion under the BBA to make the change in question, as just noted, Congress has done so. We have revised §§ 422.60(b)(1) and 422.306(a)(1) to reflect this BBRA change.

Comment: A commenter asked that we clarify our language on capacity limits within a service area. The commenter also asked what would happen if there are too many patients and too few providers.

Response: Section 422.60(b) allows an M+C organization to limit enrollment in the M+C plans it offers during any enrollment period, subject to our approval. If an M+C organization elects to establish a capacity limit for an M+C plan, the request normally must be submitted to us at the time the Adjusted Community Rate Proposal (ACRP) is submitted (except as provided in new § 422.60(b)(3)), as discussed below. This submission should take into account the number of providers, and how many patients they can serve. The situation described by the commenter, in which ''there are too many patients and too few providers'' generally should not occur if capacity is limited to the number submitted by the M+C organization on July 1.

As the commenter suggested, however, we recognize that under certain circumstances, there may be a legitimate need for an M+C organization to request a capacity limit or a revision of a capacity limit for an M+C plan during the contract year. The circumstances under which a capacity limit will be approved after the ACRP date would likely occur when a portion of a provider network that furnishes services under an M+C plan becomes unavailable during the course of a contract year. We have provided for HCFA to consider enrollment capacity requests outside of the ACR process under new § 422.60(b)(3), which permits consideration of such requests only if the health and safety of beneficiaries is at risk, such as if the provider network is no longer available to serve enrollees in all or a portion of the service area. The requirements for a midyear capacity limit request are also described in OPL99.095.

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

All M+C plans must be open to M+C-eligible enrollees residing in the service area served by the plan during initial coverage election periods, annual election periods, and special election periods, unless such enrollment in the plan is limited based upon a limit on enrollment capacity.

The initial coverage election period is the period during which a newly M+C-eligible individual may make an initial election. This period begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement. An election made during this period is effective when entitlement to Part A and Part B coverage begins.

The month of November is the annual election period for the following calendar year. During the annual election period, an individual eligible to enroll in an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan. This election is effective on January 1.

Special election periods are periods during which enrollment must be made open to certain beneficiaries, for various reasons specified in the statute, or by us. We specify the effective date of elections made during special election periods.

M+C plans may be open to new enrollees at other times of the year (that is, during open enrollment periods) at the discretion of the M+C organization offering the plan.

From 1998 through 2001, the number of elections or changes that an M+C-eligible individual may make is not limited (except for M+C MSA plans).

Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan any number of times. In 2002, an individual who is eligible to elect an M+C plan in 2002 generally may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan only once during the first 6 months of that year. For 2003 and subsequent years, an individual who is eligible to elect an M+C plan generally may elect or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan only once during the first 3 months of the year. (Note that consistent with section 501(b) of the BBRA, the restrictions that begin in 2002 do not apply to institutionalized individuals.) Even after the above limitations on changes in elections are in place, if certain circumstances exist, an individual may discontinue the election of an M+C plan offered by an M+C organization and change his or her election to original Medicare or to a different M+C plan. These circumstances include:

- When the individual is no longer eligible to be enrolled in a certain plan due to a change of residence,
- When HCFA terminates the organization's contract for the plan, or the organization terminates the plan or discontinues offering the plan in the service or continuation area in which the individual resides,
- When the M+C organization has violated a material provision of its contract or materially misrepresented the plan's provisions in marketing the plan to the individual, or
- When the individual meets such other exceptional conditions as we may provide.

Comment: Several commenters expressed concern because the new M+C election periods do not coincide with the time frames under which M+C eligible individuals elect health benefit options through their employer group health plans. The commenters believe these individuals should not be subject to the M+C election periods. One commenter pointed out that employer groups will experience considerable disruption in their yearly enrollment process, and, as a result, may have to stop offering their retirees wrap-around coverage to M+C plans, or they will have to modify their entire enrollment process.

Response: Section 422.62(b) states that we may grant special election periods for individuals who meet exceptional conditions. We have determined that the dilemma addressed by the commenters presents an ''exceptional condition'' that justifies the establishment of a special election period for M+C-eligible individuals who are members of an employer group plan that has open enrollment at a time other than the month of November. This is because such an individual could only change one part of his or her coverage at a time, which effectively would lock the beneficiary into his or her existing plan. As set forth in OPL 99.100, such M+C-eligible individuals may choose to elect an M+C plan offered by their employer during their employer group's open season, which constitutes a special election period for these individuals, as well as during the other election periods established under section 1851(e) of the Act.

Comment: Several commenters were opposed to the establishment of ''lock-in'' requirements beginning in 2002. They believe it will eliminate competition created in an environment where managed care plans compete continuously for enrollments. Several commenters also wanted to know who will be responsible for keeping track of the number of elections made by an individual once lock-in takes effect in 2002. They noted that beneficiaries and M+C organizations may not be aware of the number of elections an individual has made during a particular election period. One commenter recommended that we develop a mechanism that will allow exceptions to the limit of one change under §§ 422.62(a)(4) and (5).

Response: Sections 1851(e)(2)(B) and (C) of the Act limit an individual's election to one change during the open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. This ''lock-in'' requirement represents a gradual transition from the current system, under which a beneficiary may make any number of elections during the continuous open enrollment periods outlined in section 1851(e)(2)(A) of the Act to a restrictive system of annual ''lock-in.'' We do not have the authority to modify this requirement, or to provide for any exceptions to this limit. We are aware of the need for us to maintain a history of the number of times an individual has made an election during a specific election period. Such information will be necessary in order to determine whether an individual is eligible to elect an M+C plan at a given time.

Comment: One commenter believes that limiting the open enrollment and disenrollment opportunities defined in §§ 422.62(a)(4) and (5) to one election per period should not apply to plan changes within the same M+C organization.

Response: Section 1851(a)(1) of the Act requires that an M+C-eligible individual ''elect'' to receive benefits through the original Medicare fee-for-service program or through enrollment in an M+C ''plan.'' That is, enrollment in an M+C ''plan'' constitutes an election under Part C. Section 1851(e) of the Act further limits the ''election'' of an M+C ''plan'' or of original Medicare to one change during open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. Therefore the law does not permit us to allow M+C-eligible individuals to move from plan to plan without considering it an election, even if the change in plans occurs among plans offered by the same M+C organization.

Comment: One commenter requested further clarification of enrollment and disenrollment periods, while another asked whether a beneficiary who defaults to original Medicare has the option to elect an M+C plan.

Response: An individual who defaults to original Medicare may elect another M+C plan during any election period during which the plan is accepting new enrollments. As discussed in detail above, section 1851(e) of the Act and § 422.62 of the M+C regulations describe the election periods in which individuals can enroll in and disenroll from an M+C plan. M+C-eligible individuals may make or change an election during an initial coverage election period, an annual election period, a special election period, or an ''open enrollment'' period. The initial coverage election period is the 3-month period prior to the month an individual becomes entitled to Medicare Part A and Part B. The annual election period is November of every year. Special election periods are also allowed when M+C-eligible individuals experience certain circumstances that warrant the need to make a change in election. These include our termination of the M+C plan contract or M+C organization termination or discontinuance of the M+C plan in the service or continuation area in which the individual resides, a change in place of residence to a place outside of the M+C plan's service or continuation area, demonstration by the individual that the M+C organization substantially violated a material provision of its contract or materially misrepresented the M+C plan's provisions in marketing materials, or

other exceptional conditions as provided by us. In addition, § 422.62(c) also provides for a special election period for individuals age 65. Beginning in 2002 individuals age 65 who elect an M+C plan during the initial enrollment period may disenroll from the M+C plan and elect coverage under original Medicare within 12 months of their enrollment in an M+C plan.

Through 2001, open enrollment periods are continuous, that is, every month through 2001. Beginning in 2002, the open enrollment periods are the first 6 months of the year, or the first 6 months of Medicare Part A and Part B entitlement (or December 31, 2002, whichever is earlier). In 2003 and in subsequent years, the open enrollment periods are the first 3 months of the year, or the first 3 months of Medicare Part A and Part B entitlement (or December 31, 2003, whichever is earlier). Again, open enrollment periods remain continuous for institutionalized individuals during and after 2002.

The election rules for M+C MSA plans (see § 422.62(d)) include some exceptions to the election periods described above. M+C-eligible individuals may only enroll in an MSA plan during an initial coverage election period or an annual election period. They may not make an election of an MSA plan during open enrollment periods or special election periods. M+C-eligible individuals may only disenroll from an MSA plan during annual election periods and special election periods, excluding special election periods for individuals age 65. In addition, if an individual elects an M+C MSA plan for the first time during the annual November election period, he/she may revoke that election by December 15 of that same year.

Comment: One commenter supported the special election period for individuals age 65 as outlined at § 422.62(c), and requested that the provision also apply to newly eligible individuals with disabilities.

Response: Section 422.62(c) implements the last sentence in section 1851(e)(4) of the Act, which applies only to individuals who enroll in an M+C plan upon turning 65. Congress chose to provide this opportunity to individuals who become eligible based on age, but did not provide for such a benefit in the case of individuals who become eligible based on disability or ESRD status. We thus cannot apply section 1851(e)(4) of the Act to individuals who are not 65, since they do not meet an explicit condition set forth in the statute.

Comment: One commenter noted that § 422.62(b)(3) allows an individual a special election period if the M+C organization violates a material provision of its contract with the individual. However, it does not allow the M+C organization an opportunity to comment on the enrollee's assertion that the contract was violated. The commenter stated that we should be sensitive to the severity of this issue and should establish a timely and fair review process. Two other commenters stated that we should develop reasonable, consistent guidelines for establishing special election periods for exceptional conditions, as provided at § 422.62(b)(4).

Response: Section 1851(e)(4) of the Act gives us the authority to develop guidelines to establish special election periods for exceptional conditions and to establish the procedures for granting a special election period for contract violations that specify when individuals are entitled to disenroll from an M+C plan after disenrollment rights become limited in 2002. This authority provides us with the discretion and the time to develop beneficiary protection requirements that will be sensitive to the issues identified by the commenters. As we gradually transition from the current system of totally free movement to a restrictive system of annual ''lock-in,'' we have every intention of developing reasonable and consistent guidelines as the need for these guidelines in the year 2002 approaches.

Comment: One commenter requested that we clarify at § 422.62(a)(2)(ii) that eligible beneficiaries may elect to enroll in managed care demonstrations, section 1876 cost plans, and health care prepayment plans during the annual election period.

Response: The annual election period is an election period for M+C organizations operating under section 1851 of the Act. Health care prepayment plans, section 1876 cost plans, and some managed care demonstrations do not fall under section 1851 of the Act. Therefore, we do not have the authority to require these plans and demonstrations to be open for enrollment during an annual election period. Although such plans and demonstrations have the option of being open for enrollment to eligible individuals during that same time frame, this regulation only addresses requirements under section 1851 of the Act.

6. Information About the M+C Program (§ 422.64)

a. Overview

Section 422.64 contains requirements related to information about M+C plans. Paragraph (a) applies to M+C organizations, and requires that organizations annually provide to us, using a prescribed format and terminology, the information we need to carry out our annual information campaign for all Medicare beneficiaries. However, the remaining paragraphs of existing § 422.64 essentially reflect statutory provisions governing our information distribution activities.

Comment: Several commenters expressed confusion about whether we or M+C organizations were responsible for various information distribution requirements specified under § 422.64.

Response: We recognize the commenter's concerns and believe that the best means to avoid introducing confusion in this regard is to eliminate from the regulations the portions of § 422.64 that serve solely to delineate our responsibilities. Deleting these provisions from the Code of Federal Regulations in no way affects our information distribution responsibilities that had been reflected in these provisions, since these are set forth in the statute in sections 1851(d)(1) through (d)(4) of the Act. Also, we note that § 422.111 continues to list the information that M+C organizations are responsible for disseminating to their plan enrollees.

Comment: Two commenters were concerned that the many changes introduced by the M+C program to the plan enrollment and disenrollment process (for example, changes to the effective date, annual open enrollment, lock-in requirements) would lead to beneficiary confusion and disruption of the program, and stressed the need for improved communication with beneficiaries.

Response: We agree that the many changes necessary for the implementation of the M+C program will require that we carry out substantial educational efforts for beneficiaries and the health industry. We are strongly committed to keeping beneficiaries informed and educated about their choices, and have undertaken many efforts to accomplish this task. For example, we have created a toll-free line for M+C information (1–800–MEDICARE), developed the Medicare & You handbook, and have carried out special educational and publicity campaigns to inform M+C-eligible individuals about the availability of plans offered in different areas and about the election process. In 1999, we began conducting a nationally coordinated educational and publicity campaign about M+C plans and the election process that occurs every November. We also provide information

via our Internet website (www.Medicare.gov), which is a Medicare beneficiary-centered consumer website designed to provide a broad array of information on program benefits and health promotion. These are just a few of the many efforts we have begun to disseminate information to beneficiaries and prospective beneficiaries on their coverage options under the M+C program, and we believe that they should alleviate the potential confusion associated with the M+C program.

b. Access

Comment: A commenter recommended that § 422.64 specifically require notification and disclosure of Medicare's screening Pap smear benefit and of the ability of beneficiaries to directly access specialists to obtain this preventive service.

Response: The 2000 Medicare & You handbook includes a description of the new preventive benefits. With respect to direct access to a specialist who would perform a pap smear, § 422.112(a)(3) guarantees female M+C enrollees ''direct access to a women's health specialist within the network for women's routine and preventive health care services,'' which would include Pap smears (see section II.C of this preamble for further details on this issue.)

c. Performance Measures

Comment: Several commenters expressed concerns about the validity, reliability, and comparability of information to be provided by us to Medicare beneficiaries, particularly through Medicare Compare, our Internet-based database of comparative information on M+C plans. The commenters want us to ensure that the information presented to beneficiaries is objective, accurate, and complete. They also emphasize the importance of recognizing the audience for particular types of information.

Response: Medicare Compare is our electronic database of health plan comparison information. The database is designed to educate beneficiaries and others about their health care options so they can make informed health care choices. The information for this database is compiled by us with cooperation from M+C organizations. The Medicare Compare database is also updated regularly to reflect changes in cost and benefits. We are continuing to implement enhancements to ensure that the data submitted by M+C organizations are valid and reliable. Medicare also collects quality-of-care information known as Health Plan Employer Data and Information Set (HEDIS) from M+C organizations and we carefully check it for accuracy. This information should help beneficiaries compare the quality of health care that an M+C organization delivers by explaining how well the organization keeps enrollees healthy or treats them when they are sick. Medicare's Consumer Assessment of Health Plans Study (CAHPS), developed in collaboration with the Agency for Healthcare Research and Quality, is an initiative to collect and report information on beneficiaries' experience in receiving care through M+C organizations. We have also worked closely with the industry and researchers in order to provide the most accurate information for the Medicare & You 2000 handbook.

d. Continuation and Improvements

Comment: Commenters were concerned about the amount of information provided to Medicare beneficiaries by us. They recommend that the information specified in § 422.64 be included in the general information brochures and contain the customer service telephone numbers for each M+C organization. They also suggested that we need to differentiate between information provided to beneficiaries in written form, and that available to interested persons via the Internet. Written comparative information, which is to be available to all beneficiaries at specified intervals, should be easy to understand and focused in content.

Response: We provide access to information from a variety of sources. Beneficiaries, M+C organizations, providers, family members, and others can receive up-to-date information about the Medicare health plans available in their area, Medicare health benefits, fraud and abuse, nursing homes, appeals and grievances, patient rights, etc., at the following locations:

- Internet at www.Medicare.gov. Local libraries or senior centers may be able to help the person find the information on their computers.
- Medicare Choices Help line at 1–800–MEDICAR(E) and TTY for the speech and hearing impaired at 1–877–486–2048.
- State Health Insurance Assistance Program (SHIP) in the beneficiary's area.
- Local outreach events.

Comment: Several commenters encouraged us to evaluate all aspects of the information campaign in order to determine the most effective approach for reaching beneficiaries.

Response: We aim for timely distribution of all of our materials. We are legislatively mandated to mail specified information on the M+C program and individual M+C plans to beneficiaries at least 15 days prior to the annual election period. We are evaluating the impact of this timing on beneficiary decision making. Our ongoing evaluation of National Medicare Education Program (NMEP) includes assessment of telephone referrals, including toll-free line and State Health Insurance Assistance Programs (SHIPs), which are entities jointly funded by us and by the States to provide information and counseling to Medicare beneficiaries. The toll-free line has been operational nationally since March 15, 1999.

e. Beneficiary Input

Comment: Several commenters noted that in developing any educational materials or activities, it is important to ensure that the information is meaningful to beneficiaries. These commenters believe that we need to convey information to beneficiaries in an organized, straightforward manner to assure as complete an understanding as possible. For example, the commenters suggest that materials should be reviewed to determine whether they will provide needed information or simply raise more questions among beneficiaries, or whether beneficiaries will understand that they do not need to make any changes. The commenters specifically recommended that we conduct focus groups to gauge beneficiary responses to the Medicare & You handbook, and would like us to revisit our future plans and communications.

Response: We have performed extensive evaluation of the Medicare & You handbook, including focus-testing the Medicare & You 1999, and customer-testing of the Medicare & You 2000. We also used the results of the NMEP evaluation, survey of beneficiaries, expert review, plain language review, and comments submitted to us by mail and the Internet. The results received from all of these sources were used in the development of the Medicare & You 2000 handbook. We will continue evaluating our efforts to improve beneficiary communication.

Comment: Two commenters offered suggestions on the public input approach outlined in the preamble of our June 26, 1998 interim final rule. (In that preamble, we discussed in detail the process of obtaining public input about data collection and dissemination of selected data. We addressed only those data elements that would be disseminated as part of Medicare Compare or as part of any beneficiary

information campaign efforts.) One commenter suggested ensuring that physicians are involved in determining data specifications for M+C organizations, and the other looked forward to seeing our strategy for public input.

Response: As discussed in the interim final rule, we recognize the importance of obtaining public input on data needed by beneficiaries to make health plan choices. We also agree that we need to ensure physician input, particularly in areas such as quality of care. Our strategy for obtaining public input into the process, which is well under way and wide ranging, includes the following:

- Obtaining public input through currently established communication activities (for example, committees, consultation avenues, public meetings, training seminars). Limited resources and time demands do not permit the establishment of separate or overlapping processes with those already established and working (such as industry council meetings). It may not always be possible to hold public meetings to invite interested individuals to comment and provide input on the process of determining data specifications.
- Obtaining public input through normal data collection clearance channels when we are the lead for the data collection activity. The OMB clearance process is a very effective and efficient way to obtain broad public comment on the content and format specifications for data collection (for example, the Plan Benefit Package). However, it may not always be possible to publish a notice or a summary of public processes regarding data elements to be collected.
- Obtaining public input through collaborative efforts with private industry, health care providers, researchers, and other interested parties. This approach allows the Federal government to be a partner with other experts (private and public) in the field of managed care and thereby not duplicate already successful and useful collaborative efforts (such as HEDIS).

Thus, our strategy strongly supports the use of efficient and effective methods of public input into the determination of information and specifications for beneficiary information campaign material. We also recognize the need to collaborate with organizations and individuals involved in the development of quality and performance measurements that support beneficiaries' increased understanding of managed care.

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

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

Additionally, an individual who wishes to disenroll from an M+C plan may change his or her election during the election periods specified in § 422.62 by either electing a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by us. Individuals may also disenroll by submitting a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by us or by filing the appropriate disenrollment form through other mechanisms as determined by us.

Under existing § 422.66(d)(1), an M+C plan offered by an M+C organization must accept any individual (residing in the service area or continuation area of the M+C plan) who is enrolled in a health plan offered by the M+C organization (regardless of whether the individual has end-stage renal disease—see §§ 422.50(a)(2) and (a)(3)) during the month immediately preceding the month in which he or she is entitled to both Part A and Part B. This is generally known as a ''conversion'' of enrollment for the enrollee (from commercial status to M+C enrollee status).

Subject to our approval, under § 422.66(d)(2), an M+C organization may set aside a reasonable number of vacancies in order to accommodate conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other M+C-eligible individuals.

If the individual enrolled in a health plan offered by an M+C organization chooses to remain enrolled with the organization as an M+C enrollee, the individual must complete and sign an election form as described in § 422.60(c)(1). In that case, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B. The M+C organization may disenroll an individual who is converting from its commercial plan to M+C status only under the conditions specified in § 422.74. The M+C organization must transmit the information necessary for us to add the individual to our records as specified in § 422.60(e)(6).

An individual who has made an election under this section is considered to have continued to have made that election until the individual changes the election under this section or the elected M+C plan is discontinued or no longer serves the service area in which the individual resides, and the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided in § 422.54, whichever occurs first.

Comment: Several commenters stated that they support procedures that would permit seamless continuation of coverage, under which an individual would be deemed to have elected an M+C plan at the time of the individual's initial coverage election period if they are enrolled in a commercial health plan that is offered by the same M+C organization. Several specific recommendations were made. One commenter recommended that we require M+C organizations to prospectively provide the necessary information that would allow us to default individuals into the M+C plan. One commenter recommended that M+C organizations notify individuals in their commercial plans who are about to become Medicare eligible that they are being enrolled in the M+C plan, and to transmit the necessary information to us. Another commenter suggested that we alert individuals through the mailing of the initial enrollment package. Two commenters were concerned about deeming an individual to have elected an M+C plan if the M+C organization offers more than one M+C plan from which he/she could receive benefits. One commenter suggested that if we decide to deem an individual to have elected an M+C plan, the organization should be required to provide the individual with a description of Medigap guaranteed issues and age rating policies. One commenter supported procedures that would permit seamless continuation of coverage, but expressed concerns about deeming an individual enrolled in an M+C plan if Medicare is a secondary payer.

Response: Although we have addressed an individual's right to choose to remain enrolled with an organization as an M+C enrollee upon becoming Medicare eligible (as discussed above), a default process through which an individual would be deemed by us to have elected a specific M+C plan would require that we identify M+C-eligible individuals, as well as their relevant health plan information before the individual's initial coverage election period. At

present we do not have access to information on the health plans in which specific individuals are enrolled, because such plans are private health plans, and do not have established linkages with our systems, nor is there a mechanism in our Medicare managed care data system to capture such information. While some M+C organizations may want to share this information with us, others may not. It should also be noted that enrollment in an M+C plan is contingent upon the individual's entitlement to Medicare Part A and Part B. Individuals that have not previously filed for Social Security and/or Medicare benefits will not have an entitlement record, nor will they receive an initial enrollment package from Medicare. Frequently, individuals in commercial plans who are about to ''age in'' to Medicare are still employed, and have not yet filed for Social Security or Medicare benefits. Individuals who have filed for benefits will receive general information on Medicare and comparative information on M+C plans available in their service area. They will have the opportunity to enroll in the M+C plan 3 months prior to their entitlement to Medicare Part A and Part B.

The expansion of the managed care provisions under the BBA has presented an extraordinary challenge to us and to the Medicare managed care data system that supports our information system business requirements. We anticipate that in the future, we will develop strategies to incorporate information collection activities in our managed care systems that will allow this kind of mechanism to be put in place. As we develop strategies that will incorporate additional information collection activities under our authority under section 1851(c)(2) of the Act, we will consider procedures necessary to identify in which plan a beneficiary wants to enroll if the M+C organization offers more than one M+C plan and also whether Medicare Secondary Payer rules apply. Until that time, and in accordance with § 422.66(d), an M+C plan offered by an M+C organization must accept enrollments from any eligible individual residing in the service area or continuation area of the M+C plan, who is enrolled in a commercial health plan offered by that same M+C organization during the month immediately preceding the month in which he/she is entitled to Medicare Part A and Part B.

Comment: Two commenters were opposed to the requirement in § 422.66(b)(3)(i) that disenrollment transactions be submitted within 15 days of receipt. Commenters pointed out that we do not process disenrollments every 15 days and suggested the requirement be modified to coincide with the 30-day requirement for enrollment transactions outlined at § 422.60(d)(6).

Response: Our intent when establishing this requirement was to ensure that a beneficiary's choice to disenroll would be handled as expeditiously as possible. We are in the process of implementing a system that will be capable of processing these transactions more than once a month. However, we recognize that until the systems are modified, the requirement may not allow a sufficient amount of time to process a disenrollment action. Therefore, we have modified the regulations at § 422.66(b)(3)(i) to state that the time frame to submit disenrollment transactions will be ''specified by HCFA,'' and have made a conforming change at § 422.66(f)(2). This will give us the flexibility to make changes as system enhancements are developed in the future. For the time being, we are specifying that disenrollment transactions be submitted within the same time frame as enrollment transactions.

Comment: Several commenters asked that we provide additional clarification in § 422.66(b)(5)(i) with respect to when an enrollment is not legally valid. Two of the commenters stated that we should clarify whether a lack of understanding would be included in the definition of a ''legally valid enrollment,'' and whether it would result in a retroactive disenrollment. One commenter stated that we should clarify that an enrollment is not legally valid if it is determined at a later date that the individual did not meet eligibility requirements at the time of enrollment.

Response: There are a number of circumstances that would result in an enrollment not being considered ''legally valid,'' and we agree that the lack of understanding of plan rules (such as the ''lock-in'') and ineligibility would be among these circumstances. However, a determination that an individual did not understand the terms of enrollment must be made on an individual basis. The criteria used in establishing evidence that an individual did not understand the terms of enrollment could include the following: continuing Medigap insurance coverage after receipt of the confirmation of enrollment letter from the M+C organization; an enrollment form signed by the member in situations where a legal representative should be signing for the member; enrolling in a supplemental insurance program immediately after enrolling in the M+C plan; or receiving nonemergency or nonurgent services out-of-plan immediately after the effective date of coverage under the plan. OPL 99.100 sets forth specific guidelines to assist M+C organizations when making determinations about lack of understanding and incorrect eligibility determinations.

Comment: One commenter asked for clarification of our process for approving retroactive disenrollments (either voluntary or involuntary) and the subsequent effective dates.

Response: Section 422.66(b)(5) describes retroactive disenrollments, which are disenrollments with a retroactive effective date in cases in which we determine that there was never a legally valid enrollment, or in which a valid request for disenrollment was properly made but not processed or acted upon. In cases of involuntary disenrollments, such as disenrollment for disruptive behavior or failure to pay premiums, the disenrollment actions are prospective and would not be retroactive. In cases in which we find that an enrollment was not legally valid, the disenrollment results in cancellation of the enrollment as of the effective date of the enrollment. Therefore, the effective dates for these retroactive disenrollments are based upon the effective dates for elections, as provided under § 422.68. If the election subsequently found to be invalid was made during the annual election period in November, the effective date would be the first day of the following calendar year. If the election was made during an open enrollment period, the election would be effective the first day of the first calendar month following the month in which the election is made (or for elections made after the 10th day of a month, the first day of the 2nd calendar month following the date of the election). Effective dates for elections made during a special election period vary, dependent on the situation, and guidelines concerning these effective dates are provided in instructions to the M+C organizations. Elections made during special election periods for individuals age 65 would be effective the first day of the first calendar month following the month in which the election is made.

Comment: Section 422.66(d) states that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by ''an'' M+C organization. One commenter stated that this section needs to clearly state that the M+C organization must accept any individual who is enrolled in a health plan offered by ''the'' M+C organization

offering the other plan in which the individual is enrolled.

Response: We agree that the use of the term ''an'' could imply that the requirement applies to any organization, such that all M+C organizations must accept all eligible individuals enrolled in any commercial health plan offered by any M+C organization. In fact, our intent is for the requirement to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling. Therefore, we are revising § 422.66(d)(1) to specify that a plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by ''the M+C organization.''

Comment: One commenter believes there is a conflict between paragraphs (3) and (5) in § 422.66(d). The commenter reads § 422.66(d)(3) to provide that the individual will convert to the M+C plan unless he disenrolls, while § 422.66(d)(5) provides that the individual must fill out an election form in order to convert.

Response: We do not agree that there is a conflict between the two sections of the regulation, but recognize that some clarification is desirable to prevent confusion. We are revising § 422.66(d)(3) of the regulation to refer to the individual affirmatively choosing to remain enrolled with the organization as an M+C enrollee, and to state that conversion is effective the month of entitlement to both Medicare Part A and Part B ''in accordance with the requirements in section § 422.66(d)(5).'' We also have deleted a reference in § 422.66(e)(2) to an individual being ''deemed'' to have made an election, since this reference is inconsistent with the requirement in § 422.66(d)(5) that an election form be completed and signed. These revisions will clarify that while we have established the effective date of coverage under § 422.66(d)(3), the coverage may begin only if the individual completes and signs an election form, as required at § 422.66(d)(5).

Comment: One commenter believes that § 422.66(e)(2) (which states that an individual is considered to have continued an election in an M+C plan until the M+C plan is discontinued or no longer services the area in which the individual resides, and the organization does not offer or the individual does not elect the option of continuing enrollment) may be interpreted to absolve the M+C organization of any obligations when the person leaves the service area and has not selected a new health plan or original Medicare. The commenter suggested that the regulations should make clear that an individual who leaves his or her M+C plan service area is entitled to a special election period, as is the case when the M+C plan ceases to serve the service area.

Response: If an M+C plan enrollee leaves the plan's service area, but has not informed the M+C organization offering the plan of a permanent move, the M+C organization does have continued obligations to cover emergency and urgent services that must be covered out of area. Once the M+C organization is made aware of such a permanent move, the organization is obligated under § 422.74(b)(2)(i) to disenroll the individual unless he or she has moved to a continuation area and requests to continue enrollment as a continuation area enrollee. With respect to the commenter's concern about a special election period being provided under these circumstances, § 422.62(b)(2) clearly provides an M+C plan enrollee who moves out of his or her M+C plan service area with the same right to a special election period that the enrollee gets under § 422.62(b)(1), cited by the commenter, in the case of an M+C plan termination.

Comment: One commenter was concerned about ensuring that all enrollees under a section 1876 risk contract—without regard to residence—be deemed to be enrollees of an M+C plan offered by the section 1876 contractor on January 1, 1999.

Response: We agree, and note that the interim final rule preamble states that we have interpreted the statute to allow an individual to transition from the section 1876 plan to an M+C plan ''without regard to location of residence'' (63 FR 34977). Our intent was to ensure that no individual enrolled in a section 1876 plan on December 31, 1998, would be adversely affected by the BBA changes, but instead would be able to maintain an established relationship with a Medicare contracting organization. Therefore, we clarified in the interim final rule that all individuals enrolled in a section 1876 plan on December 31, 1998 could convert to the corresponding M+C plan on January 1, 1999. We further clarified this ''grandfathering policy'' in OPL 99.084, dated February 26, 1999, which states that an individual who was enrolled in a section 1876 risk plan effective December 1, 1998 or earlier and remained with the risk plan on December 31, 1998, automatically continued to be enrolled in the M+C organization on January 1, 1999.

Comment: One commenter suggested that we include in the regulations text our operational policy recognizing State laws that govern who may sign election forms for beneficiaries. The commenter also believes we should clearly incorporate recognition of the State law, including health care consent laws.

Response: In general, and as previously discussed in the preamble of the June 26, 1998 interim final rule, we believe that the M+C-eligible individuals should personally complete and sign any election form or disenrollment request (referenced at § 422.66(b)) whenever possible. We also recognize that there may be times that an individual is unable to sign for himself or herself. Laws governing who may sign a health insurance application vary from State to State. Therefore, while the regulations provide for the beneficiary to sign an election form, we defer to State laws (for example, laws governing the exercise of a power of attorney) on who may sign on behalf of a beneficiary where a beneficiary signature is required. We do not believe it is necessary to make provision for this in the regulations text, because where State law permits another individual to sign for a beneficiary with respect to health care decisions, this authority would extend to cases in which the beneficiary's signature is required under Medicare regulations.

Comment: Section 422.66(d)(1) states that an M+C plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by an M+C organization during the month immediately preceding the month in which the individual is entitled to Medicare Part A and Part B. One commenter asked us to clarify whether the use of the term ''health plan'' refers only to fully insured products, or whether the term would include self-funded members.

Response: The term ''health plan'' in § 422.66(d)(1) refers to any commercial health plan that the M+C organization offers. This may include fully insured products, self-funded products, and indemnity products.

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

An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B. Also, for an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year. For an election or change of election made during the open

enrollment periods described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made (except that if the election or change of election is made after the 10th day of a calendar month, the election takes effect on the first day of the second calendar month after the date of the election.)

For an election or change of election made during a special election period as described in § 422.62(b), we determine the effective date of coverage, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage. For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

Comment: Several commenters objected to the effective date in the interim final rule for elections made during open enrollment periods, which was the first day of the month after the month the election is received. The commenters believe this effective date did not allow enough time to process the enrollment. They believed that this deadline would result in increased retroactive transactions and would be burdensome on M+C organizations. Commenters also expressed significant concerns over liability and access to services if Medicare entitlement is not verified expeditiously. Commenters also noted the need for us to make system changes to accommodate the new effective date requirements, and to clarify how we intend to implement the requirements with respect to M+C organization submission of data. The commenters recommended the effective dates be as they were under section 1876 of the Act which, under § 417.450(a)(2), may not be earlier than the first month after, nor later than the third month after, the month in which we receive the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in our records.

Response: Section 1851(f) of the Act supersedes all prior section 1876 requirements and specifically delineates the effective dates for elections made in the M+C program. Consistent with the changes to section 1851(f) of the Act made by section 502 of the BBRA, we are revising § 422.68(c) to provide that coverage is effective either on the first day of the calendar month after the date of an election or change of election or, for elections or changes of election made after the 10th day of a calendar month, on the first day of the second calendar month after the date of the election or change of election. In addition, based on our authority to establish requirements that can reduce the potential for retroactive transactions, we have developed guidelines for M+C organizations that include requirements for M+C organization verification of Medicare entitlement before submission of enrollment data (see OPL 99.100). The verification policy should minimize the potential for retroactive enrollment situations. Additionally, the new effective dates outlined in section 1851(f) of the Act have resulted in the need to clarify a number of operational issues. While the expansion of managed care provisions under the BBA has presented an extraordinary challenge to us, we have successfully implemented the necessary systems requirements to support this change in effective dates. Additionally, we have issued other guidelines to M+C organizations (OPL 98.074, our November 17, 1999 Systems Informational Letter, and OPL 2000.113) that outline how to identify the correct effective date and process the enrollments through our systems.

Comment: Several commenters were concerned that the new effective date requirements will not allow the M+C organization to receive our confirmation of the enrollment before the effective date, which could in turn increase beneficiary confusion.

Response: Section 1851(f) of the Act clearly outlines the effective dates of enrollment in M+C plans. If an eligible individual has elected an M+C plan, the M+C organization must cover the individual beginning on the effective date of coverage, even if the organization has not yet received final confirmation from us. An M+C organization can take several actions to reduce the chance of beneficiary confusion, including verifying Medicare entitlement before submission of enrollment data to us. This should increase the likelihood that we will confirm the individual's enrollment.

Comment: One commenter stated that original Medicare should pay M+C organizations for services furnished to individuals for whom retroactive disenrollments were processed.

Response: If a retroactive disenrollment is processed for a beneficiary, the M+C organization in which the beneficiary was enrolled can always bill for Medicare covered services rendered to the beneficiary.

Comment: One commenter stated that the effective date of coverage for individuals who enroll during an open enrollment period (the first day of the first calendar month following the month the election is made) is too rigid, and that delayed effective dates should be permitted.

Response: Again, section 501(b) of the BBRA provided for some relief in this regard by changing the effective dates for elections or changes in election made after the 10th day of a month. We also note that we have the authority under section 1851(f)(4) of the Act to establish effective dates for individuals who meet the condition for special election periods. We have provided for prospective effective dates for individuals electing benefits through their employer group health plans, and published this guidance on April 20, 1999 in OPL 99.087. We provided additional guidance on the effective dates of coverage for other special election periods authorized under § 422.62(b) in OPLs 99.098 and 99.100.

Comment: Two commenters questioned how M+C organizations will be expected to handle multiple transactions, given the new effective date requirements.

Response: As stated at § 422.50(b), an individual may not be enrolled in more than one M+C plan at any given time. Nevertheless, there are times when an individual will try to elect more than one plan for the same effective date, and it is not always clear with which plan the individual truly intends to be enrolled. On August 9, 1999, we issued OPL 99.100, which includes guidelines on what actions an M+C organization must take in the event of a multiple transaction in order to determine with which M+C plan the beneficiary should be enrolled.

Comment: One commenter stated that we should establish performance standards that take into account difficulties that we and M+C organizations will have in meeting effective date requirements.

Response: We recognize that section 1851 of the Act has resulted in significant changes to the Medicare program and that M+C organizations need time to prepare for the changes. We have provided additional guidance on implementation of M+C entitlement, eligibility, and elections to M+C organizations through various OPLs (98.072, 98.073, 99.083, 99.084, 99.087, 99.098, 99.100, 99.104, 99.105, 99.109, and 2000.113) and a November 17, 1998 Systems Informational Letter. These letters outline how to identify the correct effective date, how to process enrollments with the new effective dates, how to transition from section 1876 to M+C enrollment and disenrollment rules, and when grandfathered members must be disenrolled from M+C plans. As a result,

we believe we have given adequate time to modify operations and systems to implement the new M+C program. In addition, we continue to develop guidelines for M+C organizations on M+C entitlement, eligibility, and elections to M+C organizations. Any monitoring of performance will take into account the time M+C organizations have needed to implement the new program.

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

The general rule for disenrollment by the M+C organization is that an M+C organization may not disenroll an individual from any M+C plan it offers; or request or encourage (orally or in writing, or by any action or inaction) an individual to disenroll. However, § 422.74(b) describes the conditions under which the M+C organization may either be permitted or required to disenroll an individual. Under § 422.74(b)(1), the M+C organization may choose to disenroll an individual based on that individual's (1) failure to pay premiums, (2) disruptive behavior, (3) provision of fraudulent information on his or her election form, or (4) having permitted his or her enrollment card to be abused. Section 422.74(b)(2) requires the M+C organization to disenroll the individual if the individual no longer resides in the M+C plan's service area, the individual loses entitlement to Medicare Part A or Part B benefits, or the individual dies. The M+C organization must follow the procedures specified at § 422.74(c) and (d) when disenrolling an individual. The procedures to be followed and the consequences of the disenrollment vary depending upon the cause of the disenrollment.

Comment: One commenter believes that the 90-day grace period that must be afforded to an enrollee before a disenrollment for nonpayment of premium could be financially burdensome in 1999 since ACRs that did not necessarily reflect these costs were filed before the M+C regulations were published.

Response: We recognize that 1999 was a transition year with many new requirements. With respect to 2000, however, M+C organizations were fully aware of all regulatory requirements before filing their ACRs.

Comment: Several commenters believed that the 90-day grace period for nonpayment of premiums is too long. Two commenters recommended a 30-day grace period rather than the 90-day grace period. They noted that if an organization has to wait 90 days before disenrolling an individual, this potentially results in 4 months without the organization receiving payment, since organizations do not send notice to beneficiaries until the beginning of the month after payment is due. One commenter recommended that grace period extend until the last day of the third month following the date payment is due.

Response: Section 1851(g)(3)(B)(i) of the Act requires us to provide for a ''grace period'' before enrollment can be terminated for nonpayment of premiums. In determining the grace period, we adopted the grace period that Congress provided for in section 1836(b)(2) of the Act with respect to a termination for nonpayment of premiums for Supplementary Medical Insurance Benefits for the Aged and Disabled (that is, Part B). This results in consistent standards between the M+C program and the original Medicare program.

Comment: Several commenters believe that M+C organizations should be permitted to allow an enrollee to remain enrolled and eliminate only optional benefits if a member fails to pay premiums charged for such optional benefits. Some commenters believe that the option to disenroll for nonpayment of premiums implied that an organization could only disenroll the beneficiary from the plan, and could not simply eliminate the optional benefits. One commenter questioned whether under our rules, it might be necessary to disenroll the individual and re-enroll them as a ''standard option'' enrollee to accomplish this.

Response: We agree that providing the M+C organizations the option to retain an enrollee while eliminating an optional benefit for which premiums are not paid is a desirable and appropriate means of promoting continuity of care for beneficiaries. We are adding a provision to § 422.74(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.

Such an action would not affect the beneficiary's status as a member of the M+C plan, and would not constitute a new election. Therefore, the M+C organization does not have to formally disenroll and re-enroll the individual when downgrading the member's enrollment to the standard benefit package because the beneficiary fails to pay the plan premiums.

Comment: One commenter recommended that the M+C organization should be required to send notice to enrollees that premium payment is overdue within 10 days, rather than 20 days. Another commenter supported the 20-day time frame.

Response: Section 1856(b)(2) of the Act provides for the use of standards established under section 1876 to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Section 417.460(c)(1)(iii) requires section 1876 contractors to send notices of disenrollment for nonpayment of premiums to the enrollee before it notifies us. In addition, § 417.460(c)(1)(i) requires that the contractor demonstrate to us that it made reasonable efforts to collect the unpaid amount. Section 422.74(d)(1) of the M+C regulations carries over both of these requirements and clarifies that ''reasonable efforts'' include sending a notice of nonpayment to the beneficiary within 20 days after the date the payment was due. The notice advises the beneficiary that he or she has 90 days from the date of the notice to provide payment. We continue to support this policy and believe that 20 days is a reasonable maximum time frame within which to make an effort to collect unpaid premiums. We note that an M+C organization may notify the individual as soon as the premium payments are past due (that is, send a notice before 20 days have passed), in which case the 90-day grace period would begin on the day the M+C organization sends the notice.

Comment: One commenter requested clarification of the effective date of disenrollments for nonpayment of premiums following the 90-day grace period. The commenter asked that we clarify for how long the organization is obligated to provide benefits and we will continue to pay capitation.

Response: The effective date of disenrollment for nonpayment of premiums is the first day of the month after the 90-day grace period ends.

The M+C organization must continue to provide benefits and we will continue to pay capitation until the disenrollment is effective. We clarified this policy in OPL 99.100, issued on August 9, 1999. We note that § 422.74(d)(1) erroneously refers to the possibility of disenrollment for an individual who fails to pay any ''basic *or* supplementary premiums.'' Section 1851(g)(3)(B)(i) of the Act refers to ''basic *and* supplementary premiums'' and we are revising the regulations accordingly.

Comment: Two commenters requested clarification regarding the standards for disenrollment for disruptive behavior under the Health Insurance Portability and Accountability Act (HIPAA) and

BBA, unsure if the two statutes were in conflict in this area.

Response: For any issues for which there is a perceived conflict in the disenrollment standards established under the BBA (or the BBRA) and those established under HIPAA, the BBA standards (that is, the standards in § 422.74 pursuant to section 1851(e) of the Act) would control for M+C purposes.

Comment: One commenter recommended that disenrollments for fraud and abuse should include other fraudulent activities related to the delivery of health services, such as visiting multiple doctors for the purpose of obtaining specific drugs and/or using another enrollee's membership card when benefits have been exhausted.

Response: As noted above, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. The regulations in section 1876 of the Act addressing disenrollments for fraud and abuse at § 417.460(d) have been largely adopted in § 422.74(d)(3), which permits disenrollment of a beneficiary for providing fraudulent information that affects eligibility to enroll or for permitting others to use his or her enrollment card to obtain services. Manual instructions implementing § 417.460(d) further clarified that any abuse relating to a membership card was included as a ground for disenrollment. Thus, using another member's card would constitute grounds for disenrollment, just as would loaning someone else a card. With respect to the commenter's other example about multiple visits to physicians to obtain drugs, an M+C organization's utilization review system should be able to identify these abuses.

Comment: One commenter requested that we add clarification regarding when a disenrollment is effective in cases of fraudulent behavior.

Response: Disenrollment of an individual who has committed fraud or who permits the abuse of his/her enrollment card is effective the first day of the calendar month after the month in which the M+C organization gives the member the written notice of his/her termination.

Comment: One commenter is concerned that our process for making disenrollment decisions related to disruptive behavior would result in numerous retroactive disenrollment situations. The commenter suggested that we clarify or revise the regulation to assure that any effective dates for disenrollment be prospective in situations where an individual is being disenrolled for disruptive behavior.

Response: Section 422.74(d)(2)(v) establishes procedures for our review of an M+C organization's proposed disenrollment of an individual for disruptive behavior. Under these procedures, we review documentation submitted by the M+C organization within 20 working days, and notify the organization within 5 working days of whether it may disenroll the individual. Section 422.74(d)(2)(vi) then states that if we permit the disenrollment for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the M+C organization gives the individual written notice of the disenrollment. Since these procedures do not allow an M+C organization to disenroll an individual for disruptive behavior until after we have approved the disenrollment, we believe the process provides only for prospective disenrollments.

Comment: Several commenters believe that 12 months is too long to wait before disenrolling an individual for being permanently out of the service area. Many commenters are concerned that the beneficiary will be able to receive only urgent and emergency care during this time, and that 12 months is too long without routine and coordinated care. They made several recommendations. One commenter recommended that 6 months would be reasonable to cover those individuals who live in different parts of the country during the year, while still maintaining contact with the primary care physician for preventive care. Two commenters recommended maintaining past policy of disenrollment of members that move outside of service area for more than 90 days, unless the plan has an affiliate. Another commenter also supported a return to a 3-month time frame. One commenter requested clarification regarding the requirements for disenrolling members from M+C organizations if they move permanently before the 12 months have expired. The commenter believes that if the request to disenroll was written or other acceptable evidence was presented, the M+C organization may disenroll the individual from the plan.

Response: We must first clarify that if an M+C organization determines that an individual has *permanently* left the service area of the M+C plan, it must disenroll the individual from that plan regardless of whether 12 months have passed, unless the individual chooses a continuation of enrollment option. This is outlined at §§ 422.74(b)(2)(i) and 422.74(d)(4). However, we believe that this point may not be entirely clear in the existing regulations and thus we are revising § 422.74(d) to specify that an individual who has ''permanently'' moved out of a plan's service area must be disenrolled. Note that this disenrollment requirement also applies to individuals who are enrolled in a plan under the expanded seamless conversion option for former commercial plan enrollees that is now set forth at §§ 422.50(a)(3)(ii) and (a)(4). That is, should the individual change his or her residence, he or she would be treated the same as any other enrollee who moves to a residence outside of the service area.

The 12-month rule set forth under existing § 422.74(d)(4) establishes the time limit for how long an individual who has left the service area on a temporary basis may remain a member of the M+C plan. That is, an M+C organization must disenroll an individual who has not permanently changed his or her address but has been out of the service area for over 12 months.

After considering the comments on this provision, we agree that 12 months is too long for a beneficiary to have access only to emergency and urgently needed care (based on our operational policy that when a member is out of the service area, the M+C organization is required to cover only emergency and urgently needed care). Therefore, we are further revising § 422.74(d)(4) to state that the M+C organization must disenroll an individual, unless he or she chooses the continuation option, if the individual leaves the plan's service area on a nonpermanent basis for over 6 months. This change is within the parameters of the previous requirement under section 1876 of the Act which, as provided in § 417.460(f)(2), allowed an uninterrupted absence from the geographic area for more than 90 days but less than 1 year. However, we believe it is appropriate to extend the time frame from 90 days to 6 months to accommodate the many beneficiaries who leave the service area for seasonal periods each year, which often last more than 90 days, but rarely more than 6 months.

We note that on August 9, 1999, we issued OPL 99.100, specifying that: (1) If an M+C organization receives notice of a permanent change of address from the member (or member's legal representative) at any time, then it must disenroll that individual from the plan if that change of address is outside the M+C plan's service area unless the member chooses the continuation of enrollment option; and (2) if a member

leaves the service area of the plan, then the M+C organization must disenroll the member if the absence extends beyond 12 months (now, 6 months).

Comment: One commenter asked whether an M+C plan can provide out-of-area coverage in excess of that required by Medicare for only part of the 12-month period when a member is out of the M+C plan's service area.

Response: We allow M+C organizations the flexibility to develop programs to continue benefits for those members who temporarily leave the service area. We have developed operational policies regarding visitor programs. Again, note that revised § 422.74(d)(4) requires an M+C organization to disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area, for over 6 months.

Comment: One commenter asked for clarification of the effective date when an individual is disenrolled for being out of the area for over 12 months.

Response: Consistent with the change in § 422.74(d)(4), the effective date of disenrollment if a member is out of the area and has not informed the M+C organization that the move is permanent will be the first day of the calendar month after the 6 months has passed, and after appropriate written notice has been provided to the member. If the M+C organization is made aware of a permanent move out of the service area, disenrollment is effective the first day of the calendar month after the date the member begins residing outside of the M+C plan's service area, and after written notice has been provided to the member.

Comment: One commenter recommended that § 422.74(d)(7), which provides for disenrollment when a plan terminates services in the area in which the enrollee resides, explicitly states that disenrollment is automatic in this case.

Response: The effective date of a disenrollment based on an M+C plan termination or reduction in service area is the date that the M+C plan termination is effective, and disenrollment is automatic. Beneficiaries would have already received advance notice of such a termination as part of the nonrenewal requirements in § 422.506(a)(2). Accordingly, we have revised § 422.74(d)(7)(ii) to reference the time frames in § 422.506(a)(2).

Comment: One commenter recommended that notices for involuntary disenrollments should be mailed to individuals authorized to make elections on behalf of an enrollee as well as the enrollee.

Response: In general, and as indicated by our requirement that the beneficiary complete and sign the M+C enrollment form, we believe that an M+C-eligible individual should personally complete and sign any election form or disenrollment request whenever possible. If for some reason a beneficiary is unable to sign the election form and needs a surrogate, we defer to State law on who may sign for other persons. Legal representatives of such individuals who authorize the election of an individual must also sign the election form and specify their relationship with the enrollee. In instances of involuntary disenrollment, notifications of disenrollment occur before any action is taken, to ensure that the individual has adequate time to review his or her health care options. Since the legal representative has identified him/herself to the M+C organization, the M+C organization should ensure that both the legal representative and the enrollee subsequently receive, in a timely manner, any important information provided by the M+C organization related to the health care decisions of the beneficiary.

Comment: One commenter is concerned that the time frames for our review of an M+C organization's proposed disenrollment for disruptive behavior (20 working days for a determination and the subsequent 5 days to notify the M+C organization) are too long. The commenter believes that 5 days is reasonable for us to make our determination.

Response: Again, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Regulations at § 417.460(e)(5), which set forth the requirements for our review of an HMO's or CMP's proposed disenrollment for cause, addressed this issue. Under § 417.460(e)(5)(ii), we make this decision within 20 working days after receipt of the documentation material and notify the HMO or CMP within 5 working days after making our decision. We see no reason not to retain this standard under the M+C program, and have done so in § 422.74(d)(2)(v)(B). We believe that this period of time ensures that we can conduct a thorough review of all documentation submitted by the M+C organization and the beneficiary.

Comment: With respect to an M+C organization termination of an enrollee for disruptive behavior, one commenter asked for clarification of the process. For example, the commenter wanted to know who makes the determination, what appeal rights the beneficiary has, the time frame for a determination, and whether the beneficiary stays in the plan during the review of a determination. The commenter also asked if there is a possibility of coverage days lost while we are making the decision, and whether premiums would be refunded if the beneficiary is disenrolled.

Response: The M+C organization must make a serious effort to resolve the problems presented by the beneficiary, which includes the use of the M+C organization's grievance procedures. The M+C organization must notify the beneficiary of its intent to request such a disenrollment, as well as the beneficiary's rights under the M+C organization's grievance procedures. As described above, the final decision regarding the determination of disruptive behavior is made by us, as provided by § 422.74(d)(2)(v), which outlines our review authority of the M+C organization's proposed disenrollment. After reviewing the documentation submitted by the M+C organization and any information submitted by the beneficiary, we decide whether the M+C organization has met the disenrollment requirements. Until the disenrollment is effective, the beneficiary will continue to receive services from the M+C organization. Any premiums or other charges paid for coverage after the effective date would be refunded to the beneficiary; however, the beneficiary would be liable for the original Medicare cost-sharing and permitted balance billing in the case of any Medicare covered services provided by the M+C organization after the effective date of the disenrollment.

Comment: One commenter requested clarification regarding when to send out notices for disenrollments for cause.

Response: The basic requirement for notices is provided at § 422.74(c), which states that for any optional or required disenrollment (other than death or loss of entitlement), the organization must give the individual written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll. The notice must be mailed to the individual before submission of the disenrollment notice to us. Please note that we have amended §§ 422.74(c)(1) and (c)(2) to clarify that these notice provisions do not apply for disenrollments resulting from plan terminations or reduction of service or continuation areas, since there are no grievance rights provided in these

situations. The notice requirements for plan termination are outlined in §§ 422.74(d)(7) and 422.506(a)(2).

Comment: One commenter noted that § 422.74 only provides the opportunity for an individual to express a grievance to the M+C organization for an enrollment or disenrollment decision. The commenter believes that we should allow these decisions to be appealed because such decisions should not be left to the M+C organization.

Response: We agree with the commenter that decisions to disenroll for fraud or disruptive behavior should not be left solely to the M+C organization, which is why the regulations, at §§ 422.74(d)(2)(iv) and (3)(iii) provide for our role in these cases. However, in other cases, we believe that beneficiaries will be well-protected from a potentially wrongful disenrollment by the internal grievance procedures of the M+C organization. An M+C organization's decision to disenroll an individual does not meet the regulatory definition of an organization determination and thus, by definition, is not an issue that is eligible for the M+C reconsideration process.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

Section 1851(h) of the Act outlines the requirements related to marketing by M+C organizations. These provisions are implemented in § 422.80 of the interim final rule. Section 422.80(a) implements the requirements in section 1851(h)(1) that all marketing material and application forms be submitted to us for approval 45 days before distribution, and that such materials may be used only if we do not disapprove such use by the end of the 45-day period. Section 422.80(b) defines the ''marketing materials'' that must be submitted for approval. We note that we have made a minor revision to this regulation to reflect the fact that HCFA does not review newsletters as marketing material. The reference to newsletters was included in the interim final rule because it appeared in the part 417 regulations governing marketing by section 1876 contractors. In fact, HCFA did not treat newsletters as marketing materials in the case of section 1876 contractors, and there was no intent in the interim final rule to change HCFA's practice on this point. The interim final rule thus should not have included the reference to newsletters, and we are correcting our error in doing so.

Section 1851(h)(2) of the Act requires that the M+C standards include guidelines for review of marketing materials and requires that the guidelines provide that the Secretary will not approve materials that are inaccurate or misleading. Section 422.80(c) establishes the guidelines for our review of marketing materials. Consistent with the provision in section 1856(b)(2) of the Act for use of existing section 1876 standards, the guidelines in § 422.80(c) include existing marketing guidelines for HMOs and CMPs (from § 417.428), which have been in effect since the inception of the Medicare risk contract program.

Section 1851(h)(3) of the Act provides that if we have not disapproved the dissemination of marketing materials or forms with respect to an M+C plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the M+C plan and M+C organization except with regard to any portion of the material or form that is specific to the particular area. This ''deemed approval'' or ''one-stop shopping'' provision is implemented in § 422.80(d).

Section 1851(h)(4) of the Act provides that M+C organizations shall conform to ''fair marketing standards'' and requires that the fair marketing standards prohibit organizations from providing cash or other monetary inducements for enrollment. Section 422.80(e) outlines the fair marketing standards provided for under section 1851(h)(4) of the Act, and includes existing section 1876 standards as provided for in section 1856(b)(2) of the Act.

Finally, § 422.80(f) specifies that we may permit M+C organizations to develop and distribute marketing materials specifically designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization. Although these materials must be submitted for approval under § 422.80(a), we do not review portions of these materials that relate only to employer group benefits, rather than to M+C plan benefits.

The public comments that addressed marketing issues governed by § 422.80 are discussed below.

Comment: Two commenters suggested that we consider lengthening the review and approval processing time for marketing material from 45 days to either 60 or 90 days. The commenters believe that we need additional time to perform adequate review of marketing material submitted by M+C organizations. Another commenter suggested that the processing time be reduced to 14 days and the deemed approval time period be 30 days. The commenter asserted that M+C contractors must complete obligations within 14–30 days; therefore, we should be held to the same standard. The commenter also stated that 45 days for approval of marketing material is too long for effective marketing or to correct misinformation in the press.

Response: As noted above, section 1851(h)(1) of the Act establishes a 45-day limit for our review and approval of marketing materials. That is, absent our disapproval of such materials, the statute permits an M+C organization to distribute marketing materials 45 days after submitting the materials for review. Since any materials that are not affirmatively ''disapproved'' are effectively ''approved'' for distribution, we recognize the importance of completing our review of all marketing materials within 45 days. Accordingly, we are evaluating our marketing review procedures to identify ways we can promote greater efficiency in the marketing review process. We do not believe that reducing the marketing review and deemed approval periods would allow our staff adequate time to ensure that marketing material is accurate and not misleading to potential enrollees and beneficiaries.

Comment: Many commenters expressed concern regarding inconsistent review and treatment of marketing material by our different regional offices. A few commenters recommended that we consider centralized review of marketing material to promote greater consistency across the regions and central office. Several commenters also suggested that we require standard language and at a minimum, 12-point print, in all M+C marketing materials.

Response: We understand the concerns of M+C organizations regarding uniform application of marketing review and guidelines. To address these concerns, we have convened a team of representatives from our 10 regional offices and our central office that is responsible for addressing marketing issues which arise in policy and operationally. We recognize that centralized review may promote more consistent application of marketing review policy, and we are currently evaluating the feasibility of such review. Although we want to provide M+C organizations with the flexibility to develop marketing material that will distinguish their products and services from other organizations, we also believe that standardizing M+C marketing materials will facilitate beneficiary use and choice. Thus, we have taken steps to standardize beneficiary materials. Pursuant to our authority under § 422.80(c)(1) to require the use of ''a format * * * and * * * standard terminology * * * specified by HCFA,'' we required M+C

organizations to use a standardized Summary of Benefits format in describing their 2000 benefits, beginning in the fall of 1999. This Summary of Benefits provides beneficiaries with information on M+C plans that is standardized in terms of format, language, and content. We also plan to identify other beneficiary notification materials for which standardization will be required. The current marketing guide already directs M+C organizations to use 12-point print. M+C organizations can obtain the marketing guide from our website (www.hcfa.gov).

Comment: One commenter suggested that we clarify that documents developed by pharmacies to conduct pharmacy compliance programs are not marketing and promotional materials. Another commenter recommended that we clarify that marketing materials intended to promote the M+C organization (distinct from its Medicare contracting function) should not be subject to the marketing review process.

Response: To the extent that ''pharmacy compliance'' documents are directly related to health care or quality, we do not review them as marketing materials. On the other hand, if the ''pharmacy compliance'' materials are used to market the program in pre-enrollment marketing materials and advertisements, we treat them as marketing materials subject to our review and verification.

We do not review materials that are directed solely at an HMO's commercial population. However, we believe that any materials targeted at the Medicare population, and designed to inform beneficiaries about benefits, or encourage beneficiaries to enroll or remain enrolled, should be subject to our review on their behalf. Thus, we are retaining the provision under § 422.80(b)(1) that calls for review of materials that ''promote the M+C organization.''

Comment: A few commenters, particularly those providing services in rural areas, urged that we require M+C organizations to include a list of subcontracted providers in their pre-enrollment marketing material. Others suggested that we require organizations to include a list of participating providers in their marketing materials.

Response: We understand that provider directories are generally available at sales presentations or when a beneficiary visits the M+C organization. Thus, we do not think it is necessary or appropriate to mandate that an M+C organization identify subcontractors or furnish provider directories in general marketing materials or sales kits. We note that § 422.80(c)(1) directs M+C organizations to provide Medicare beneficiaries interested in enrolling in an M+C plan with a written description of plan rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges. M+C organizations also must meet the detailed disclosure requirements outlined in § 422.111, which include informing enrollees of the ''number, mix, and distribution (addresses)'' of available providers. We believe that these requirements adequately address beneficiary information needs.

Comment: Several commenters requested that we define ''significant non-English speaking population.'' One commenter recommended that 5 percent of the Medicare-eligible population be the standard, while another recommended a standard of 25 percent.

Response: Section 422.80(c)(5) of the interim final regulation requires, for markets with a significant non-English speaking population, that M+C organizations provide marketing materials in the language of these individuals. The term ''significant'' can refer to either the number or percentage of the affected population. We note that the Office for Civil Rights within the Department of Health and Human Services is responsible for implementing standards and providing guidance concerning the obligations of Federal fund recipients (such as M+C organizations) to provide language assistance to individuals who have limited English proficiency. As more information becomes available to HCFA, we will provide further guidance on M+C organizations' responsibility in this regard.

Comment: Some commenters asked that we clarify the role of physicians in the marketing of M+C products to their patients. The commenters also requested further guidance regarding whether physicians are allowed to counsel patients about their health insurance choices. Commenters both supported and opposed allowing physicians to advise potential enrollees and beneficiaries about M+C plan options.

Response: We agree that the role of physicians should be clarified. Accordingly, we are amending the standards for marketing to add a new § 422.80(e)(1)(vi) that permits provider groups and individual providers to distribute health plan brochures (exclusive of applications) at a health fair or in their own offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans. While this discussion is entirely appropriate within the doctor-patient relationship, M+C organizations may not use providers/provider groups to distribute printed information comparing the benefits of different health plans, unless the materials have the concurrence of all organizations involved and have received prior approval from us. Physicians and other providers may not accept plan applications. We also are adding a new § 422.80(e)(1)(vii) that prohibits M+C organization representatives from accepting applications in provider offices or other places where health care is delivered.

Comment: One commenter recommended that we revise § 422.80(c)(4) to reflect a statutory reference in section 1851(h)(2) of the Act to marketing material that is ''materially inaccurate or misleading or * * * makes a material misrepresentation.'' The commenter believed that the omission of the term ''material'' creates a more stringent standard of review than that intended by Congress.

Response: We concur with this recommendation. As noted, section 1851(h)(2) states that ''the Secretary shall disapprove * * * such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.'' Therefore, we are modifying § 422.80(c)(4) to read as follows: ''In reviewing marketing material or election forms under paragraph (a) of this section, HCFA determines that the marketing materials: * * *. (4) are not materially inaccurate or misleading or otherwise make material misrepresentations.'' This language is more consistent with the standard outlined in the statute, and we believe it can help avoid delays in the review and approval of marketing materials for immaterial or irrelevant errors.

Comment: Commenters also requested further guidance regarding the permissibility of offering ''value-added services'' to beneficiaries.

Response: In general, ''value-added items and services'' (VAIS) are items or services offered to beneficiaries by an M+C organization that do not meet the definition of a benefit as stated in § 422.2; that is, benefits are health care services for which the M+C organization incurs a cost under the M+C plan that are submitted and approved through the ACR process. Examples of VAIS may include but are not limited to discounts in restaurants, stores, entertainment, or travel; they could also include discounts on health club memberships and on insurance policy premiums.

Because VAIS do not constitute a benefit under the M+C program, neither the actual costs of the VAIS nor associated administrative costs may appear in the ACR, nor are they subject to the Medicare appeals process. Nonetheless, VAIS may be of value to some enrollees, and we do not wish to deprive M+C enrollees of access to items and services commonly available to commercial enrollees. Therefore, M+C organizations may offer VAIS to Medicare enrollees, but materials describing VAIS must clearly distinguish between VAIS and M+C benefits, including clarifying that VAIS are not subject to the M+C appeal procedures. VAIS may not appear in the Beneficiary Information Form or the Plan Benefit Package. Further, VAIS may not be described in Medicare Compare, the Medicare and You handbook, or the Standardized Summary of Benefits. We will provide further guidance regarding VAIS in a forthcoming OPL.

Comment: One commenter inquired if the prohibition of monetary rebates to induce enrollment applies to the distribution of coupons.

Response: Cash or monetary rebates, including coupons that have more than a nominal cash value (if converted to cash) are prohibited under § 422.80(e)(1)(i). This prohibition does not apply to items of nominal value ($10 or less). The coupons, or the combined value of the coupons, must not exceed the nominal value standard. Coupons that offer discounts on premiums or copayments are not permitted, because they would violate the ''uniform premium'' provisions of the statute, as outlined in § 422.304. If coupons are for VAIS in excess of nominal value, they cannot be distributed or advertised pre-enrollment. However, these coupons may be used after enrollment.

Comment: Commenters objected to the fact that the regulations are silent regarding the consequences if an M+C organization violates the marketing standards. Two commenters recommended that we begin retrospective review of marketing materials, and pull the advertising campaign for those found to be egregiously inaccurate. Similarly, another commenter suggested that we nonrenew or terminate contracts with organizations that are substantially out of compliance with the marketing regulations.

Response: We recognize that marketing material distributed by M+C organizations must be accurate and not misleading to potential enrollees, and that M+C organizations should be subject to sanction for a substantial failure to comply with marketing rules. We accordingly are adding a new § 422.510(a)(12) to specify that a substantial failure to comply with marketing guidelines is a ground for termination, and thus also a ground for nonrenewal or intermediate sanction (consistent with §§ 422.506(b)(1)(iii) and 422.572(b)).

Comment: Several commenters requested that we provide additional guidance regarding the documentation necessary to demonstrate that marketing resources are allocated for marketing to both the disabled and beneficiaries age 65 and over.

Response: Section 422.80(e)(2)(i) requires M+C organizations to demonstrate to our satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over. We plan to issue further guidance on this issue but, until then, we expect organizations to adopt their own procedures to implement these provisions. As a starting point, organizations may consider developing a formal marketing strategy that considers the needs of persons with disabilities and consulting with disability advocacy groups and outreach programs. We expect M+C organizations to avoid developing plans that could discourage the enrollment of persons with disabilities through the imposition of unusually large cost-sharing requirements for items and services frequently used by the disabled. M+C organizations are also expected to make their marketing materials accessible to persons with disabilities (including, for example, through use of alternative formats), and to establish mechanisms for making their marketing sessions accessible to the disabled Medicare population. Also, as discussed further in section II.C of this preamble, M+C organizations must comply with other applicable Federal statutes, including the Americans with Disabilities Act.

Comment: One commenter recommended that we revise or delete the heading ''Employer Group Retiree Marketing'' in § 422.80(f) to reflect marketing to Medicare-eligible employees of the employer.

Response: We believe that ''Employer Group Retiree Marketing'' is an appropriate heading. This provision addresses only marketing materials geared toward retirees of an employer group that reflect non-Medicare benefits offered to group members by that employer. These retirees generally would include individuals who have retired based on a disability rather than age. Thus, a reference to ''retirees'' is not necessarily limited to the over-65 Medicare market. Moreover, this provision in no way limits an M+C's obligation to market to both disabled and over-65 beneficiaries, both in a retiree group and otherwise.

Comment: Some commenters requested further clarification regarding the review of marketing material developed by employers for purposes of employer group marketing. One commenter inquired whether we will definitely permit M+C organizations to develop marketing materials for employer groups. Presently, § 422.80(f) states that we ''may'' permit M+C organizations to develop marketing materials for employer groups.

Response: Although we will not review all the specific benefits offered by the employer group, we will review those items that fall within the disclosure requirements of § 422.111. Further, we agree that the wording of § 422.80(f) may be unclear; thus we are revising the regulation to: (1) Specify that M+C organizations are permitted to develop marketing materials for employer groups; and (2) clarify that we will not review those portions of such marketing materials that relate solely to employer group benefits.

Comment: One commenter questioned whether it is appropriate to allow the term ''senior'' or the number ''65'' to appear in the name of an M+C plan. The commenter stated that including these terms could discourage some beneficiaries from enrolling in a particular M+C plan.

Response: We recognize that certain plan names may discourage enrollment by disabled beneficiaries. Accordingly, pursuant to our authority under section 1851(h)(4) of the Act to establish marketing standards, we have added a new § 422.80(e)(1)(viii) that will prohibit M+C plan names that suggest that a plan is available only to Medicare beneficiaries age 65 or over, rather than to all beneficiaries. This prohibition generally bars plan names involving terms such as ''seniors,'' ''65+,'' etc. In fairness to M+C organizations with an existing investment in a plan name, we are ''grandfathering'' existing M+C plan names, that is, plan names established before this final rule takes effect.

Comment: One commenter believes that tax dollars should not be spent on insurance counseling and assistance programs, such as State Health Insurance Assistance (SHIP) or Information Counseling and Assistance (ICA) programs. In the commenter's view, there are less expensive and better alternatives, such as licensed insurance agents. The commenter asserted that the licensure of these individuals assures public accountability, and that the

insurance professional is the best alternative for providing consumer information and expertise about the new M+C options. On the other hand, several commenters recommended that we not permit independent marketing agents to sell M+C products to potential enrollees.

Response: We believe that SHIPs and ICA programs are valuable, objective, and necessary resources for Medicare beneficiaries. These programs provide one-on-one counseling to beneficiaries on many complicated insurance issues and provide essential links to other important services and programs available to beneficiaries. SHIPs provide a service through a network of 10,000 trained volunteers. In addition, these programs effectively network with other key partners such as insurance carriers, departments of social services, and legal service agencies. SHIPs are able to provide assistance related to a broad spectrum of Medicare issues, and are required to conduct their programs with impartiality and confidentiality. While we strongly support these programs, which have been extremely valuable in educating beneficiaries on the new M+C provisions, we will continue to explore additional information mechanisms to ensure that beneficiaries receive information in the most efficient and effective manner.

We recognize that independent insurance agents may be able to provide a necessary service to Medicare beneficiaries who are considering enrolling in the M+C program. In the past, our position has been to strongly discourage, but not prohibit, Medicare managed care organizations from employing independent insurance agents to sell their products. Recently, we have engaged in extensive consultations on this issue with the DHHS Office of the Inspector General, and we intend to issue guidance to M+C organizations in the near future regarding the parameters for the participation of independent agents in marketing M+C plans.

C. Benefits and Beneficiary Protections

1. Introduction

Subpart C of these regulations details the scope of benefits a Medicare beneficiary is entitled to receive when electing coverage through an M+C plan, as well as establishing a number of beneficiary protections in areas related to access rules, enrollee notification requirements, confidentiality and others. The statutory authority for most of the provisions of subpart C is found in section 1852 of the Act, which outlines benefit requirements and provides authority for beneficiary protections under Medicare Part C. Many of the statutory provisions are the same as, or similar to, benefit provisions of section 1876 of the Act. Therefore, much of the regulatory language of part 417 is retained for purposes of establishing M+C standards, as provided for in section 1856(b)(2) of the Act (which provides for basing M+C standards on section 1876 standards implementing analogous provisions, where consistent with Part C).

All M+C organizations are required to cover the full range of Medicare benefits that are available under original Medicare to beneficiaries in the area who are not enrolled in an M+C plan, subject to certain rules regarding an accessible network of providers. M+C organizations are further required to cover Medicare preventive benefits with the same frequency that they are covered under original Medicare (for example, annual screening mammography examinations). Beneficiaries may be required to contribute to the cost of covered services in the form of cost sharing provided for under the M+C plan. Beneficiaries may have to cover all costs until a deductible is met (including the high deductible provided for under an MSA plan—see section III of this preamble), a percentage of costs in the form of coinsurance, or a fixed amount for services, in the form of a copayment. As discussed in section II.G below, there are limits that apply to the cost sharing that can be imposed on beneficiaries under M+C plans. For benefits that are covered under original Medicare, the benefits must be obtained through providers meeting the conditions of participation of the Medicare program.

This section of the preamble mainly discusses the requirements for network plans. Sections III and IV of the preamble provide more extensive information about benefit requirements applicable to non-network M+C MSA plans and to private fee-for-service plans, respectively. Organizations with network plans, which include coordinated care plans and network M+C MSA plans, are permitted to restrict enrollees to a specified network of providers in the case of non-emergency/urgent services if they have a network in place to provide these services directly or through arrangements (that is, written agreements with providers) that meet the availability and accessibility requirements of section 1852(d)(1) of the Act and § 422.112, discussed below.

2. Emergency, Urgently Needed, and Post-Stabilization Care Services (§§ 422.2, 422.100, 422.112, and new § 422.113)

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

- Emergency services;
- Urgently needed services;
- Renal dialysis services provided while the enrollee was temporarily outside the M+C plan's service area;
- Post-stabilization care services; and
- For both network and non-network plans, services denied by the M+C organization and found upon appeal (under subpart M of this part) to be services the enrollee was entitled to have furnished or paid for by the M+C organization.

The requirements that the M+C organization assume financial liability for renal dialysis services and post-stabilization care are new requirements introduced by the BBA that were not included in the requirements of section 1876 of the Act. The definitions of emergency services and urgently needed services in the M+C regulations are based on section 1852(d) of the Act, and thus differ from those used under the previous Medicare managed care program (see § 417.401). In accordance with section 1852(d)(3) of the statute, an ''emergency medical condition'' exists if a ''prudent layperson'' could reasonably expect the absence of immediate medical attention to result in serious jeopardy or harm to the individual. In addition, the new definition of ''emergency services'' includes emergency services provided both within and outside of the plan, while the definition of ''urgently needed services'' continues to encompass only services provided outside of the plan's service area (or continuation area, if applicable), except in extraordinary circumstances (as discussed below). Under section 1852(d)(1)(C)(i) of the Act, M+C organizations are required to pay for nonemergency services provided other than through the organization where the services are immediately required because of unforeseen illness, injury or condition, and it is not reasonable given the circumstances to obtain the services through the organization.

In the June 26, 1998 interim final rule, definitions of emergency services and

urgently needed services were provided at § 422.2; financial responsibility of the M+C organization for emergency, urgently needed, and post-stabilization care services provided outside of the organization was addressed at § 422.100; and special coverage rules for emergency services and urgently needed services were provided at § 422.112. In this final rule, general requirements for financial responsibility for services provided outside the M+C organization remain at § 422.100, while definitions and policies relating to all types of emergency episodes of care, including ambulance services, emergency services, urgently needed services, and post-stabilization care services, have been consolidated at § 422.113. Comments on these aspects of the subpart C regulations are discussed below.

a. Definitions (§ 422.2 and new § 422.113)

Comment: Two commenters requested that we specify in the definition of ''urgently needed services'' that these are not ''emergency services.''

Response: Section 1852(d)(1)(C)(i) of the Act specifies that urgently needed services are not emergency services. Thus, as the commenters suggested, we are revising the definition of urgently needed services to include the requested clarification.

Comment: One commenter expressed support for, while another commenter opposed, the inclusion of in-area unusual events in the definition of urgently needed services. The commenter opposing the inclusion of in-area urgently needed services suggested that if this provision is retained, M+C organizations should not be required to disclose it in member materials or that we give examples of circumstances in which this exception would apply. One commenter asked if this meant that beneficiaries could unilaterally obtain care out-of-plan if their M+C organization did not provide the care they requested. The commenter supporting our position provided the example of equipment failure as a case in which in-area services might not be available.

Response: As discussed in the preamble to the June 26, 1998 interim final rule (63 FR 34973), the inclusion of in-area unusual events in the definition of urgently needed services is based on the statutory language at section 1852(d)(1)(C)(i) of the Act, which does not specify that these services are covered only when the beneficiary is out-of-area. Rather, the statute provides for coverage of urgently needed services when ''it was not reasonable given the circumstances to obtain the services through the organization.'' As stated in the regulations, in-area coverage of urgently needed services applies only under unusual and extraordinary circumstances, for services provided when the enrollee is in the service or continuation area, but the organization's provider network is temporarily unavailable or inaccessible, and such services are medically necessary and immediately required. We believe that examples of when this could arise would include unusual events such as an earthquake or strike, if such events impede enrollee access to care through M+C plan providers. This regulatory definition of urgently needed services should be used in any materials that include a description of urgently needed services.

With regard to the request that the in-area exception in the definition of urgently needed services be interpreted to mean that beneficiaries could seek care out-of-plan if the particular services are not provided by an M+C organization, we believe that the commenter is asking about situations where an M+C organization has made a judgment that services are not necessary or not covered, rather than one in which the network is unavailable. There are other mechanisms in place to handle such situations. We may require a plan to take corrective action, where necessary, if a plan fails to provide services. In addition, services that the beneficiary believes he or she was entitled to receive from the M+C organization, but that the organization denied or otherwise did not provide, may be appealed under the regulations in subpart M of part 422. Whether situations involving equipment failures would be considered urgently needed services depends upon the clinical condition of the patient, and the M+C organization's ability to make services available notwithstanding the equipment failure.

We note that, inherent to the various requirements under § 422.112 relating to an M+C organization's responsibility to provide adequate access to covered services, is the obligation of an M+C organization to provide access to necessary care through out-of-network specialists when its network is inadequate or unavailable. That is, if in an individual case a plan's provider network is not adequate to meet an enrollee's health care needs (for example, the plan includes no specialist qualified to treat an enrollee's rare condition), the organization shall authorize the individual to go out of network to obtain the necessary care. We are revising § 422.112(a)(3) to make this requirement explicit. As discussed in detail in section II.M.9 of this preamble, failure to authorize such care constitutes an adverse organization determination, with concomitant appeal rights.

Comment: One commenter requested further elaboration on what is meant by ''prudent layperson'' within the definition of emergency services.

Response: Section 1852(d)(3) of the Act provides the definition of emergency services that includes the prudent layperson standard. Specifically, section 1852(d)(3)(B) of the Act states that an emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part. This entire definition should be considered when making a determination of whether a beneficiary acted appropriately in seeking emergency care. This definition is what the independent review entity under contract with us will consider when making determinations on beneficiary appeals of emergency services that an M+C organization has denied. With respect to the term ''prudent layperson,'' we believe that the term ''prudent'' has a commonly understood meaning, and would refer the reader to the general dictionary definition of this term. A layperson refers to an individual with an average knowledge of health and medicine, as the definition of ''emergency medical condition'' states. We do not believe that further elaboration of the term prudent layperson is necessary.

b. Enforcement of Emergency Requirements (§§ 422.80, 422.100, 422.113)

Comment: Commenters requested clarification of what steps we were taking to ensure that M+C organizations provide access to emergency services intended by law.

Response: One mechanism we use to ensure appropriate provision of covered services by M+C organizations is a review process of all organization materials provided to beneficiaries, including both pre-enrollment marketing materials provided to prospective enrollees and post-

enrollment member materials for enrollees. For example, § 422.80(b)(5)(v) lists examples of membership communication materials we review, including membership rules, subscriber agreements (evidence of coverage), and member handbooks. In considering our response to this comment, we have determined that ''wallet-sized'' instruction cards that might be used in the case of an emergency should also be expressly included as materials to be reviewed, because these cards may contain instructions to enrollees on how to access care, including instructions on what to do in an emergency. We, therefore, are adding wallet card instructions to the list of examples of marketing materials to be reviewed under § 422.80(b)(5)(v) to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services. We note that, as part of our monitoring of the ''prudent layperson'' standard, we have asked our independent review entity to report, on a quarterly basis, each instance in which it overturns a denial of a claim for emergency services.

Also in response to this comment, we have decided to specify at § 422.100(b)(1)(i) that M+C organizations are required to cover ambulance services provided other than through the organization that are dispatched through 911 or its local equivalent. Section 422.113 specifies that the M+C organization bears financial responsibility for ambulance services where other means of transportation would endanger the beneficiary's health. This policy is consistent with original Medicare's coverage of ambulance services where other means of transportation would endanger the health of the beneficiary as provided by section 1861(s)(7) of the Act, as well as with the emergency coverage provisions of section 1852(c)(1)(E) of part C of the Act. In particular, we believe that the law's reference to use of the 911 telephone system indicates statutory intent for coverage of ambulance services whether provided through the organization or other than through the organization. Ambulance services provided through the organization would also be considered part of basic benefits under §§ 422.100(a) and 422.101. We note that nonemergency ambulance services generally would be covered only when provided through the organization, to the same extent the services are covered under the general Medicare principles set forth in section 1861(s)(7) of the Act (that is, when use of other forms of transportation would endanger the health of the beneficiary.) Regulations on original Medicare coverage of ambulance services may be found at § 410.40.

c. Access to Emergency and Urgently Needed Services (§§ 422.112(c) and 422.113)

Comment: Commenters generally supported emergency services policies, such as the prudent layperson definition, the prohibition of prior authorizations, the requirement for out-of-plan coverage, and the requirement that the treating physician determine when the patient is stable. Commenters requested clarification of the prohibition on prior authorization.

Response: In considering our policy prohibiting prior authorization for emergency services as required under section 1852(d)(1)(E) of the Act, we have determined that the regulations should expressly reflect the fact that two parties are protected from prior authorization requirements, that is, the beneficiary and the emergency provider treating the beneficiary. We are clarifying at § 422.113(b)(2)(ii)(A) that prior authorization may not be required from the beneficiary in any materials furnished to enrollees (including wallet card instructions) and that, consistent with section 1852(c)(1)(E) of the Act, disclosure of an enrollee's right to coverage of services must include disclosure of the enrollee's right to use the 911 telephone system. Also, § 422.113(b)(2)(ii)(B) specifies that materials furnished to providers (including contracts with providers) may not include instructions to seek prior authorization before an enrollee has been stabilized.

We believe that these clarifications will promote compliance with the prohibition in section 1852(d)(1)(E) of the Act on prior authorization requirements for emergency services.

Comment: A commenter requested that we specify that retroactive denials should not be allowed based solely on a final diagnosis, and that the presenting condition from the perspective of the prudent layperson should determine coverage.

Response: As noted in our preamble discussion of the provisions of § 422.112 in the June 26, 1998 interim final rule, long-standing Medicare managed care manual policy (§ 2104) prohibited retrospective denial for services that appeared to be emergencies, but turned out not to be emergency in nature. This policy is consistent with the ''prudent layperson'' element of the definition of an emergency medical condition, in that the perspective of the enrollee is a significant factor in determining whether an enrollee acted appropriately in seeking emergency care. As explained in the preamble to the interim final rule, we believe that the current regulations already require such coverage. However, in light of the commenter's concern, we are including in new § 422.113(b)(2)(iii) the explicit requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson standard in the definition of emergency medical condition, regardless of final diagnosis.

Comment: We received a number of comments regarding the limit in § 422.112(c) on copayments for emergency services obtained outside the M+C plan's provider network (the lower of $50 or whatever the plan would charge for in-plan emergency care). Some commenters argued that significant copayments were necessary to deter unnecessary visits to the emergency room, and noted that commercial fee-for-service insurance plans have copayments for emergency care that may be higher than the $50 limit. Other commenters thought the $50 limit was a reasonable standard. Some commenters suggested that the copayment for an emergency room visit should be higher than that for a physician office visit. One commenter requested that a requirement for advance disclosure of the emergency room copayment amount be substituted for a dollar limit. One commenter requested clarification that the $50 limit be for the ''sum total'' for all care received for the emergency episode. Another commenter argued for a rule prohibiting copayments altogether, or at least for a reduced limit for low-income beneficiaries.

Response: We appreciate the commenters' responses to our request for public comment on the policy of limiting the amount that can be imposed as a copayment for emergency services. As we stated in the preamble to the June 26, 1998 interim final rule, our data showed that only 7 percent of Medicare managed care plans were charging more than $50 for emergency services. We believe that all of the above comments have some merit, but that, on balance, retaining the current policy (the lower of $50 or whatever the plan would charge for in-plan emergency care) is the best course of action. Although we agree that copayments can effectively deter unnecessary use of services, we believe that a $50 copayment accomplishes this objective, since 93 percent of M+C organizations do not exceed this amount. We also believe, however, that a copayment higher than this amount

could potentially deter an enrollee from receiving necessary emergency services. M+C organizations retain flexibility to set copayment amounts up to $50, including possible consideration for low-income beneficiaries, and organizations may provide for a substantial differential between copayments for physician office visits and emergency room visits. We believe that the difference between a $50 copayment for an emergency room visit and the typical $5 to $10 copayment for a physician's office visit is sufficient incentive to receive nonemergency services at a physician's office. With respect to the commenter who advocated disclosure of emergency room copayments, such copayments are already disclosed in the MedicareCompare database on the Internet at HCFA's website, www.hcfa.gov, and M+C organizations are required to disclose these amounts in membership materials provided to beneficiaries. Finally, we believe that the current language already conveys that $50 is the sum total limit for copayment for services defined as emergency services, and that further clarification beyond this response is not necessary.

Comment: One commenter suggested that beneficiaries be issued a single Medicare identification card that could be presented to their treating physicians and staffs, rather than one card issued by the M+C organization and one issued by Medicare. The commenter stated that beneficiaries frequently do not present the correct card denoting M+C plan coverage to their treating physicians. The commenters believe that the use of a single card would allow physicians and staffs to easily identify exact Medicare coverage and the appropriate administrative and billing procedures to be applied.

Response: The purpose of the Medicare card issued to the beneficiary is to serve as proof of entitlement to the Medicare program. We believe that the Medicare card and the M+C plan membership card serve two different purposes—to identify the individual as entitled to Medicare and to subsequently identify how the individual receives the services. Combining these elements into a single identification card would require the issuance of a new card each time the beneficiary chose a new plan or returned to original Medicare. Thus, although we welcome suggestions to improve the efficiency of our operations, we do not believe that a single card should be issued to the beneficiary.

d. Post-Stabilization Care Services (§§ 422.100 and 422.113)

Section 1852 (d)(2) of the Act gives the Secretary express authority to establish requirements needed to promote the ''efficient and timely coordination of appropriate maintenance and post-stabilization care'' (hereafter together referred to as ''post-stabilization care''). Section 1852(d)(1)(C)(iii) of the Act establishes an M+C organization's responsibility to provide reimbursement for these services. Implementing regulations at §§ 422.100(b)(1)(iii) and 422.113(c) specify that an M+C organization is financially responsible for post-stabilization care services obtained within or outside of the M+C organization. This requirement applies both to services pre-approved by the organization and services that were not pre-approved, under certain circumstances, including situations where an M+C organization fails to respond within 1 hour to a request for pre-approval from a provider of post-stabilization care services (as discussed in detail below). We received a number of comments regarding this section.

In this final rule, the special rules for post-stabilization care services are included under new § 422.113. The requirement for financial responsibility for post-stabilization care services provided outside the organization remains at § 422.100.

Comment: One commenter stated that after stabilization of the emergent medical condition, no immediate health risks should exist. This commenter asked why there is a need to change the time frame for obtaining approval of post-stabilization care, which the commenter apparently believed was 48 hours. Several commenters responded favorably to the 1-hour window for responding to a request for authorization of post-stabilization services, with one commenter suggesting that 30 minutes would be a better time frame.

Response: If no immediate health risks exist following an emergency episode, the patient would most likely be discharged. Post-stabilization care services are administered to ensure that the patient remains stabilized following an emergency episode. We agree with the majority of commenters who supported the 1-hour time frame. We believe that an untimely response to a request for post-stabilization care services would delay the delivery of these services, thereby compromising their effectiveness. We are not aware of the 48-hour time frame referenced by one commenter, as no such time frame exists under Medicare law.

Comment: Several commenters recommended that we require that the request for approval not be made until after the enrollee is stabilized, so that the organization will have the necessary information at its disposal. Commenters requested clarification as to what constitutes a response by the M+C organization to a call from the hospital. For instance, one commenter asked if an organization would be in compliance with the 1-hour rule if it calls back within the hour and states it needs more time to make a decision on post-stabilization care services. One of these commenters also stated that we should require that the emergency department treating the member contact the M+C organization within an hour of the point at which the member is stabilized. Another asked how the emergency provider would be held accountable for notification to the M+C organization once the patient is stable.

Response: Section 1852(d)(1)(E) of the Act states that the M+C organization must provide coverage for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the organization. Implicit in this requirement is the fact that the organization may not require the provider to call for approval of services prior to the point of stabilization. If the hospital chooses to notify the organization while the patient is still being stabilized, the organization will still need an update on the status of the patient at the point of stabilization, in order to make an informed decision. If the provider calls when the enrollee is stabilized, an organization which calls back within the hour should not need more time to make a decision. Therefore, we consider a response by the M+C organization to be when the M+C organization submits a decision to the provider about its request for post-stabilization care. While we believe it is reasonable to expect the emergency provider to contact the M+C organization within an hour of the point at which the member is stabilized, we do not believe that this final rule, which establishes and clarifies the requirements that M+C organizations must meet, is an appropriate vehicle to impose such a requirement on hospitals. (We are considering including such a requirement in future hospital provider agreements with Medicare, however.) It is clearly in the hospital's best interest to contact the organization as soon as a patient is stabilized in order to ensure plan coverage of post-stabilization services furnished by the hospital. In

addition, in order to be able to bill the beneficiary in circumstances where the plan is not liable for payment, the treating provider is expected to provide the stabilized patient with a notice of non-coverage, such as an Advance Beneficiary Notice.

Comment: A number of commenters asked for clarification of the definition of post-stabilization care services. The majority of these commenters requested that post-stabilization care services be linked to the emergency episode. Two commenters inquired if the term post-stabilization care replaces the pre-BBA term ''follow-up'' care, which includes only routine care following an out-of-area emergency medical episode.

Response: We agree that the concept of post-stabilization care services could be clarified further, and we have expanded on the definition, including the addition of language addressing services furnished while waiting for a response to a request for authorization from an M+C organization. We also agree with the commenter that post-stabilization services should be limited to services related to the emergency medical condition.

By post-stabilization care services, we generally mean covered services, related to an emergency episode, provided after the enrollee is considered to be stable (see new § 422.113(c)). Under the post-stabilization provisions set forth in the interim final rule, ''post-stabilization'' services were limited to services authorized by the M+C organization or services furnished when the organization cannot be reached, or fails to respond to a request for authorization within an hour. This definition did not address services that may be required during that hour to keep the patient stabilized. We believe that it is necessary to ensure that the patient continues to receive necessary treatment during the 1-hour time frame when the provider waits for the organization to respond. These services consist of those necessary to maintain the stable condition achieved through previously administered emergency services. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under § 422.113(b).

Section 422.113(c) also establishes that if the M+C organization does not respond within the 1-hour time frame, the M+C organization cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. When an M+C organization representative who is a non-physician and the treating physician cannot reach agreement on a course of treatment, the M+C organization must allow the treating physician to speak with a plan physician. By allowing the treating physician to proceed with care of the patient in these cases, we are ensuring that M+C enrollees receive the same standard of timely care as beneficiaries under original Medicare.

Accordingly, the revised definition of post-stabilization care services at § 422.113(c)(1) reads as follows:

''(c) Post-stabilization care services means covered services, related to an emergency medical condition, that are provided after the enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (2)(iii) below, to improve or resolve the enrollee's condition.''

Section 422.113(c)(2) then describes the M+C organization's financial responsibility for post-stabilization care services. Specifically, ''the M+C organization is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside of the M+C organization that are— (i) Pre-approved by a plan provider or other M+C organization representative; (ii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the stabilized condition, within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization services; or (iii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the treating physician may continue with the care of the patient until a M+C organization physician is reached or one of the criteria in § 422.113 (c)(3) is met.''

To further clarify the above requirements, consider the following example: A patient is brought to the emergency department with the preliminary diagnosis of a seizure. The patient is screened and receives services to stabilize his condition. Thus far, the services that the patient has received are emergency services under § 422.113(b). Once the emergency room physician considers the patient stabilized, the M+C organization is notified of the need to consult a neurologist in order to proceed with relevant diagnostic tests to determine the cause of the seizure, and to treat the cause of the seizure definitively. While the emergency provider waits 1 hour for a response from the organization, post-stabilization services necessary to maintain the stable condition achieved through previously administered emergency services are administered.

If the M+C organization responds within 1 hour, it can approve the request for additional post-stabilization services under § 422.113(c)(2)(i) or make other arrangements for additional services. If the organization did not respond within the 1-hour time frame, if the organization could not be contacted, or if the organization representative and the treating physician could not reach an agreement and a plan physician was not available for consultation during the hour, the treating physician can proceed with post-stabilization services administered not only to maintain the stabilized condition, but to improve or resolve the patient's condition. Again, if the organization representative and the treating physician cannot reach an agreement, the M+C organization must give the treating physician the opportunity to speak with a plan physician concerning the care of the patient. If a plan physician responds to a request for consultation outside the one hour time frame, the plan physician and the treating physician are expected to execute a plan for safe transfer of responsibility of the patient.

Comment: One commenter sought clarification as to when the M+C organization's liability to pay ends. This commenter does not believe that the M+C organization physician should have to ''arrive,'' as stated in the preamble of the June 26, 1998 interim final rule, in order to terminate the organization's responsibility to pay. This commenter also recommended that we explicitly state that even if the M+C organization does not respond within the hour, once it does respond, it should have the absolute right to control the care that is given to the member.

Response: We agree that the issue of when the M+C organization's financial responsibility ends needs further clarification. We also agree that the physician should not have to arrive in person at the hospital in order to assume responsibility for his or her patient. Therefore, we are incorporating the following language into § 422.113(c)(3): ''The M+C organization's financial responsibility

for post-stabilization care services it has not pre-approved ends when—(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care; (ii) A plan physician assumes responsibility for the enrollee through transfer; (iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or,(iv) The enrollee is discharged.''

We do not agree that the M+C organization should have the absolute right to control the care that is given to the member when it does eventually respond and the one hour time period has elapsed. For example, a late response could result in a scenario where post-stabilization care services may have already started, and in such a situation, we believe that interruption of a procedure in progress in order to transfer the enrollee to another facility could be harmful to the member. The M+C organization is financially responsible for post-stabilization services until the M+C organization and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Several commenters asked that HCFA clarify that only an M+C plan physician with privileges at the treating hospital may assume responsibility for the M+C plan enrollee's care.

Response: Generally, only an M+C plan physician may assume long-term responsibility for care furnished to an enrollee of that M+C plan. However, if there are no M+C plan physicians with privileges at the treating hospital, we would expect the treating physician and the M+C organization to make arrangements for appropriate care to be provided. Thus, we do not agree that an M+C plan physician with privileges at the treating hospital must necessarily assume responsibility for a plan enrollee's care.

Comment: Several commenters asked that we address how disputes between M+C organizations and providers would be resolved. One commenter asked that we develop guidelines for notification of organizations. Another commenter wanted to know how we will determine if a call was made, or responded to within 1 hour, if the provider's and M+C organization's records do not agree. Still another commenter suggested a provision holding the patient harmless for disputes between M+C organizations and the emergency provider regarding post-stabilization benefits and coverage.

Response: We believe that providers and M+C organizations will develop methods of documentation to ensure that calls are made and received in a timely manner, so that the 1-hour response requirement can be met and the possibility of disputes can be minimized. We do not believe the development of guidelines by HCFA to be necessary or appropriate. Complaints and disputes are addressed in the HCFA monitoring process, and resolution would depend on the circumstances encountered. Ultimately, if agreement cannot be reached, a dispute over whether the conditions for M+C coverage for post-stabilization care services under § 422.100 and § 422.113 have been met could be resolved in an enrollee's appeal of the M+C organization's denial of payment for post-stabilization services, or an appeal by a provider if the provider agrees not to charge the enrollee. (We note that the rules governing payment for services furnished by noncontracting providers would apply in post-stabilization cases, as set forth in § 422.214 and discussed in detail in section II.E of this preamble. We have made this explicit at § 422.113(c)(2).) Based on this comment, we agree that M+C enrollees should be protected from excessive charges for post-stabilization care services. Therefore, new § 422.113(c)(2)(iv) provides that cost-sharing for post-stabilization care services must not exceed cost-sharing amounts for services obtained through the organization.

Comment: One commenter stated that if an enrollee is admitted to a hospital for services that are later determined not to be emergency services, the M+C organization has no obligation to pay for services that a provider asserts are for post-stabilization care. In addition, a commenter asked whether, if there is a denial of post-stabilization care services, the treating physician can be given the right to speak with an M+C plan physician regarding the patient. Another commenter recommended we add protections against denials of post-stabilization care services.

Response: Section 1852(d)(3) of the statute states that the M+C organization is responsible for services required to treat an emergency medical condition under the prudent layperson standard. Organizations are not responsible for care sought by the enrollee when this standard is not met. Post-stabilization services are similarly covered only following treatment for an emergency (as noted above, we have revised the definition, at § 422.113(c)(1), to make this explicit.) If the patient did meet the prudent layperson standard, but the condition did not turn out to be an actual threat to the health of the patient, the M+C organization would not be responsible for any services beyond those services provided as part of the medical screening to determine whether an emergency medical condition existed. In such a nonemergency situation, the treating physician is expected to provide the patient with an Advanced Beneficiary Notice (ABN) to inform the patient that further services will not be covered.

With respect to the comment concerning denials, if the organization representative and the treating physician cannot reach an agreement concerning the enrollee's care, the M+C organization must give the emergency physician an opportunity to consult with an M+C organization physician.

With respect to the request for further patient protections, as noted above, the enrollee (or, the provider, if the provider agrees not to charge the enrollee) has the right to appeal any decision by an M+C organization to deny payment for post-stabilization services.

Comment: One commenter asked that post-stabilization care services be limited to services that can be furnished at the facility at which the emergency treatment was provided. Another commenter recommended that we require M+C organization staff, including plan providers, to defer to an emergency provider's preference to keep an enrollee in an emergency facility after stabilization to prevent any needless disruption in the patient's care.

Response: We disagree that treatment decisions should be limited by what services a facility can provide. If a treating physician or facility is prepared to provide additional needed treatment to a patient, and the M+C organization cannot be reached, or has not responded within an hour, we do not believe that the patient should have to wait for this treatment until the organization responds, simply because it would not be provided in the same physical location as the emergency services. Section 422.113(b)(3) specifies that 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. We would expect the M+C organization to allow the treating physician to speak with a plan physician if he or she is concerned about the care (for example, a transfer) planned for the patient.

Comment: One commenter asked which provider, the emergency provider

or the M+C plan provider, has the authority to establish a plan of care.

Response: In providing emergency services, the emergency provider has the authority to establish the plan of care. Once the enrollee has been stabilized, post-stabilization care services are provided in accordance with § 422.113(c). Thus, once the M+C provider assumes responsibility, then he or she has the authority to revise the plan of care or establish a new plan of care as long as the new plan of care is consistent with a safe transfer of responsibility.

Comment: One commenter recommended that the language in § 422.100(b)(iv)(A) be changed from ''Pre-approved by the organization'' to ''Pre-approved by a plan provider or other M+C organization representative.''

Response: In response to this comment, we have changed the language in question to read, ''Pre-approved by a plan provider or other organization representative.'' (See § 422.113(c)(2)(i).)

3. Service Area Requirements (§§ 422.2, 422.100, 422.304(b)(2))

In the June 26, 1998 interim final rule, we defined the term ''service area'' as a geographic area approved by us within which an M+C eligible individual may enroll in a particular M+C plan offered by an M+C organization. We specified that for coordinated care plans and network medical savings account (MSA) plans only, the service area also is the area within which a network of providers exists that meets the access standards in § 422.112. Existing regulations also require that an M+C plan's uniform benefit package must be available throughout a plan's service area (see the discussion below of modifications to this policy made by the BBRA). In deciding whether to approve a service area proposed by an M+C organization for an M+C plan, we consider the M+C organization's commercial service area for the type of plan in question (if applicable), community practices generally, whether the boundaries of the service area are discriminatory in effect, and, in the case of coordinated care and network MSA plans, the adequacy of the provider network in the proposed service area. As discussed in the interim final rule preamble, because of unique rules pertaining to the amount deposited in MSA plan accounts, we may approve single county M+C non-network MSA plans even if the M+C organization has a different commercial service area (63 FR 34971).

We note that since the publication of the interim final rule, we have issued further guidance implementing the definition of service area set forth in § 422.2, including an affirmation of our longstanding policy of not approving less than full county service areas unless circumstances justify an exception to this rule. This policy, which we refer to as the ''county integrity policy,'' is explained in detail in OPL 99.090 released April 23, 1999. The county integrity rule, which implements the reference in the service area definition to consideration of whether boundaries are discriminatory in effect, prevents the establishment of boundaries that could ''game'' the county-wide M+C payment system by excluding high cost areas of a county. (Note that M+C organizations are paid based on Medicare expenditures at the county level.) Under limited circumstances, as described in OPL 99.090, we will allow an M+C organization to establish a service area that includes a partial county. However, it is never acceptable for an M+C organization to devise an M+C plan service area that excludes portions of a county because it anticipates enrollees with higher health care needs.

Under § 422.100(f), an M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations for each M+C plan set forth in subpart C of the M+C regulations. For example, § 422.100(g) provides that we review and approve each M+C plan to ensure that the service area boundaries do not promote discrimination (for example, that they do not include partial counties unless justified), discourage enrollment, steer specific subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services.

We received about 20 letters commenting on various aspects of M+C service area policy and an M+C organization's ability to offer multiple M+C plans.

Comment: Several commenters objected to the requirement that each M+C plan offered by an M+C organization must be offered to beneficiaries with a uniform benefit package and cost-sharing structure that cannot vary throughout each M+C plan's service area. Some of these commenters expressed concern that this requirement will make it difficult for M+C organizations to serve multi-county areas due to the differences in Medicare payment rates across counties, and that this could result in beneficiaries in low-payment or rural counties having decreased access to M+C plans.

Response: As noted by the commenters, existing M+C regulations provide that each M+C plan offered by an M+C organization must be offered to all beneficiaries in an M+C plan's service area with a uniform benefit package and uniform cost-sharing arrangements. This requirement implemented the requirement of section 1854(c) of the Act for uniform premiums for all individuals enrolled in an M+C plan. Thus, under § 422.2, an M+C plan was defined as health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan. The BBA requirement that an M+C plan consist of a uniform benefit package that cannot vary in terms of benefits or price throughout the plan's HCFA-approved service area contrasted with our previous ''flexible benefits'' policy, which permitted HMOs and CMPs under section 1876 to vary premium and benefit offerings by county within a service area. As discussed in the preamble to the interim final rule, however, an M+C organization was able to achieve the same result as the flexible benefits policy by offering multiple M+C plans, either in the same or in different service areas. This administrative policy allowed an M+C organization great flexibility to offer M+C plans that take into account varying county payment rates and preferences of the Medicare population. (Each M+C plan offered by an M+C organization must have a HCFA-approved service area and meet access standards for health care services as described in our regulations at § 422.112.)

As noted in section I.C of this preamble, section 515 of the BBRA amended section 1854 of the Act by adding a new paragraph (h) to permit, effective for contract years beginning on or after January 1, 2001, the application of the uniformity rule to individual ''segments'' of an M+C plan service area, provided that each segment is composed of one or more M+C payment areas (that is, one or more counties), and a separate complete ACR is submitted for each such segment. The practical implications of this option are similar to our existing administrative policy, under which M+C organizations have the flexibility, by offering multiple plans in a given area or areas, to tailor the benefits offered under their M+C plans to the areas where the plans are offered. In practice, we anticipate that organizations will likely continue to offer multiple M+C plans, since they have already established such separate

plans, and they would have to submit the ACR information required under section 1854(a)(2) of the Act for each segment under the BBRA option, just as they do for each M+C plan now. However, the statute gives M+C organizations the alternative of choosing instead to establish a single M+C plan consisting of segmented service areas, with a separate ACR submission for each segment of the service area. In this final rule, we are adding a new § 422.304(b)(2) which reflects section 515 of the BBRA. We also are making needed conforming changes to the definitions of ''service area'' and ''M+C plan'' in § 422.2, and to § 422.100(d) concerning the structure of M+C plans.

Comment: A commenter asked that we clarify our requirements for approving the service area of M+C plans. The commenter stated that the discussion of service area in the preamble and the definition at § 422.2 did not provide specific guidance on what constitutes an acceptable service area for an M+C plan offered by an M+C organization.

Response: Although we believe that the service area definition in § 422.2 is fairly detailed and specific, we agree that some additional guidance and reorganization of the definition could be of value. Specifically, while our county integrity policy discussed above implements language in the current definition with regard to discriminatory boundaries, the current regulation text does not expressly reflect our longstanding county integrity policy. In response to this comment, and under our authority in section 1856(b)(1) of the Act to establish M+C standards, we are revising the service area definition to specify that in deciding whether to approve an M+C plan's proposed service area, we consider the following criteria:

(1) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties. However, we may approve a service area that includes a portion of a county if we determine that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed service area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, HCFA must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, we may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

We believe that these revisions to the service area definition, although they do not constitute policy changes, should help to clarify for M+C organizations our method for determining whether a service area is acceptable.

Comment: A commenter supported the M+C standard that the delineation of an M+C plan's service area should not discriminate against beneficiaries through ''gerrymandering'' or ''red-lining'' to deliberately avoid particular areas (for example, to prevent the enrollment of poorer Medicare beneficiaries, or those known to be in poor health). The commenter asked that we also include cultural accommodations (for example, language access) as part of the requirements for service area designation.

Response: We are very concerned that the service areas for M+C plans be drawn in a manner that avoids discriminating against certain groups of beneficiaries who may be perceived as having higher than average health care needs. The general requirement that M+C plan service areas be made up of whole counties, as discussed in OPL 99.090, is intended in part to preclude any incentive to create M+C service areas that serve only the lowest cost population of a particular county. We believe that the revised service area definition, which continues to provide for our consideration of discriminatory effects, already provides sufficient authority to disapprove a service area if there is evidence that an M+C organization attempted to establish boundaries based upon cultural discrimination, or discrimination against non-English speaking beneficiaries.

Comment: A commenter pointed out that the definition of service area states that the service area also is ''the area within which a network of providers exists that meets the access standards in § 422.112.'' The commenter believes that this wording implies that all services must be provided in the service area itself, and that this requirement conflicts with § 422.101(a), which states that services obtained outside the geographic area are acceptable if it is common practice to refer patients to sources outside the geographic area. The commenter asked that we allow some services to be furnished outside of an M+C plan's service area if patients traditionally go outside the service area to receive such services. Another commenter stated that the M+C organizations should be permitted the flexibility of structuring plan benefits and provider networks in accordance with local patterns of care regardless of political boundaries. The commenter believes this would afford a broader choice of health care options to beneficiaries.

Response: The intent of the cited language from the service area definition is to require that services are available to a plan's enrollees through an M+C plan provider network that is accessible from the service area. We have not interpreted this language to prohibit the inclusion in a plan's network of providers physically located outside the area. In fact, as noted above, we allow M+C coordinated care and network MSA plans to establish a provider network with contracting providers located outside of the M+C plan service area, provided that we determine that the M+C organization's contracted provider network meets Medicare access and availability standards at § 422.112. We believe that the revised service area definition described above should eliminate any implication that all network providers must be located within the service area.

Under both the former risk contracting program and the M+C program, we generally have required that M+C organizations make health care services available through a network of contracting providers located within the boundaries of the M+C plan service area. Under certain circumstances, however, we have always allowed exceptions to this policy, such as in rural areas when providers were not available in a plan's service area, when traveling outside the service area to obtain health care is not uncommon, and also when the services are still reasonably accessible and available. We have also allowed plans to provide certain specialist services outside of a plan's service area if the specialist services were not available in the plan's service area and if the specialist was reasonably accessible.

Another reason that we do not require an M+C plan's provider network to be located entirely within the plan's service area is to allow for multiple M+C plans in the same or close geographic areas that share the same provider network, as discussed in the next comment and response. However, we will continue to employ the same criteria in evaluating whether beneficiaries enrolling in an M+C plan are provided with the required access and availability to health care services. Generally, we will evaluate the provider

network supporting an M+C plan by considering the prevailing community patterns of care in obtaining health care services (for example, where people obtain care, the types of providers available in the community, reasonable travel times to obtain care) and the access standards at § 422.112.

Comment: A commenter notes that an M+C organization can offer multiple M+C plans under a single M+C contract with us. The commenter asks how multiple plans would work, and whether each would be required to have a separate health services delivery system.

Response: In order to respond to the commenter's question, we will briefly review the principal requirements that each M+C plan offered by an M+C organization must independently meet. We note that these M+C plan requirements also are discussed in greater detail in other parts of this preamble. Each M+C plan must be approved by us through the adjusted community rate (ACR) process, and each M+C plan must be offered to all beneficiaries in the given M+C plan's service area. An M+C organization can offer multiple M+C plans. Each M+C plan offered by an M+C organization must have a HCFA-approved service area that is generally made up of whole counties consistent with our county integrity policy discussed above, and reflected in OPL 99.090. The M+C plans offered by an M+C organization can have the same or different service areas. For example, an M+C organization may choose to offer more than one M+C plan in the same service area in order to provide beneficiaries with a choice of plan benefit packages and cost-sharing structures, including differing basic premium amounts. Also, each M+C coordinated care plan must provide enrolled beneficiaries access to health care service through a network of contracting providers. M+C plans may share the same provider network and portions of the provider network may be located outside of the plan's service area. However, the provider network supporting an M+C plan must meet M+C access standards with respect to all enrollees in that plan's service area (see § 422.112) as determined by HCFA. We note that under § 422.501(e), when an M+C organization includes several M+C plans under a single contract, the contract must provide for an amendment upon our request to remove an individual M+C plan from the contract, so that we have the flexibility to nonrenew or terminate only a single M+C plan if a problem is confined to one such plan.

4. Benefits (§§ 422.2, 422.100, 422.101, 422.106)

The regulations contained in subpart C describe the requirements for M+C organizations' benefit offerings. The statutory basis for these provisions generally can be found in section 1852 of the Act. The basic categories of benefits parallel those that applied under the section 1876 risk contracting program with the exception of the use of the term ''basic benefits,'' which we now define as both original Medicare benefits and additional benefits. Despite the limited changes, we believe it is important to carefully define the different benefit categories, because, historically, organizations participating in the risk-contracting program often used different terminology in describing their benefit packages to beneficiaries and in structuring benefits under Medicare risk contracts.

Thus, in order to promote consistency, M+C organizations must use the benefit terminology specified in the M+C regulations and in instructions and operational policy letters. We intend to provide further instructions over the next several years to assist organizations in standardizing the structure and terminology used in describing their benefit offerings. In addition to issuing instructions, we will be reviewing benefit design closely to provide feedback to M+C organizations on ways they can improve their benefit descriptions and ensure that the benefits comply with our requirements. The use of consistent terminology in describing benefit categories will result in better information for Medicare beneficiaries to compare their Medicare options as well as help us to review both benefits paid for with Medicare capitation payments and benefits for which Medicare beneficiaries are charged a premium.

Comment: Several commenters asked for additional clarification regarding the new definitions of the benefit categories under the M+C program.

Response: We have been aware of confusion about the benefit terminology used in the Medicare risk contracting program, and have attempted to clarify the terminology in the M+C regulations. As noted above, a significant change under the M+C program involves the definition of the term ''basic benefits.'' Under the M+C program, basic benefits means both benefits covered under original Medicare and additional benefits, not otherwise covered under original Medicare, that are paid for with Medicare payments. Additional benefits are grouped with original Medicare benefits because they are part of the package of basic benefits for which beneficiaries are not charged a premium, beyond any premium the M+C organization is permitted to charge for original Medicare benefits. As discussed more fully below in section II. D, the costs of additional benefits are funded by the difference between an organization's ACR for the original Medicare benefit package, and the M+C payment plus any approved enrollee cost sharing.

Mandatory supplemental benefits are M+C plan benefits not otherwise covered under original Medicare for which anyone who enrolls in an M+C plan is charged a premium. Thus, additional benefits (included in the basic benefit package) and mandatory supplemental benefits are similar in that they are not covered by original Medicare, and *all* M+C enrollees receive them as part of their M+C plan. The difference is in the way these benefits are funded: additional benefits are funded with Medicare payments through the M+C payment rate, and mandatory supplemental benefits are fully paid for by M+C enrollees through a separate premium or cost sharing.

Like additional benefits and mandatory supplemental benefits, optional supplemental benefits are not covered by original Medicare. However, plan enrollees may choose whether to elect and pay for optional supplemental benefits. M+C organizations may offer M+C plans that have individual items or groups of items and services as optional supplemental benefits.

We are making several minor technical changes to improve the accuracy and consistency of the benefit-related definitions set forth in § 422.2. For example, we are clarifying under the definitions of ''mandatory supplemental benefits'' and ''optional supplemental benefits'' that these categories of benefits consist of ''health care services'' that may be paid through premiums ''and/or'' cost sharing. Also, we are clarifying in the definition of ''benefits'' that the costs an M+C organization incurs in providing benefits may not be solely an administrative processing cost and that benefits must be ''submitted and approved through the ACR process.''

Comment: Commenters suggested that we consider developing standardized definitions or descriptions for the individual items and services that make up a benefit package.

Response: The intent of the regulations is to clarify the meaning of the terms used in the statute, which reflect the funding source for various groups of benefits. We recognize the value of standardizing the definitions of

individual items and services that might be included as additional or supplemental benefits, such as a drug benefit. Both the annual Summary of Benefits and the Plan Benefit Package are important parts of our standardization efforts. As noted above, we intend to provide further instructions over the next several years to assist organizations in standardizing the terminology used in describing their benefit offerings. Work on defining individual items and services so that beneficiaries may compare benefit offerings is taking place predominantly within the context of our information campaign. We are not including standardized definitions in this final rule.

Comment: Several commenters asked for further clarification of the meaning of the requirement in § 422.101(a) that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in a plan's geographic area, including services obtained outside of the area if it is common practice to refer patients to sources outside the area. Two commenters noted that the term ''common practice'' might be misleading, and recommended that we revise the regulations to state that services may need to be provided outside the area, provided that the services are reasonably accessible to enrollees and such use is consistent with community practice patterns. One commenter recommended that we confirm in the final rule the basic premise that M+C organizations must provide all their enrollees with all services covered under original Medicare, including any needed out-of-area care. Another commenter questioned whether the requirement that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in the service area implies that the M+C organization's health care delivery patterns must mirror care delivery patterns in original Medicare.

Response: Consistent with section 1852(a)(1)(A) of the Act, § 422.101(a) establishes the principle that an M+C organization must provide its plan enrollees with all the Medicare-covered services available to other Medicare beneficiaries in the area served by the plan. We recognize that the existing regulatory language in this section creates some potential for confusion and are making several changes along the lines suggested by commenters in order to clarify the regulations. Revised § 422.101(a) continues to specify that an M+C organization must provide coverage of all Medicare-covered services available to beneficiaries residing in a plan's service area. We are adding a provision to state explicitly that services may be provided outside of the service area of the plan if the services ''are accessible and available to enrollees in the same area.''

When we assess the capability of any proposed plan to serve an M+C service area, we consider the numbers, types, and locations of all providers needed to provide all Medicare-covered services or, in regulation terms, the access and availability of Medicare-covered services. We continue to believe that it is in the best interest of the Medicare program and Medicare beneficiaries to evaluate proposed M+C plan networks on a case-by-case basis taking into account the patterns of care and access to care in particular geographic areas. It is not unusual for services such as a dialysis center or transplant center not to be available in a county. If, for example, a Medicare beneficiary would normally have to travel to a different county for renal dialysis or a transplant, we believe it would not be unreasonable for an M+C plan enrollee to be required similarly to travel outside of a service area for access to such services. Such exceptions to in-area care access should, however, be limited in order to have a viable M+C plan.

The fundamental requirement under § 422.101(a) that an M+C organization provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. For example, M+C organizations may furnish a given service using a defined network of providers, some of whom may not see patients in original Medicare. M+C organizations may also encourage patients to see more cost-effective provider types than would be the typical pattern in original Medicare (as long as those providers are working within the scope of care they are licensed to provide, and the M+C organization complies with the provider antidiscrimination rules now set forth under new § 422.205).

M+C organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the M+C program. If original Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Medicare benefits component of an M+C plan. M+C plans may cover the same service when the conditions are not met, but these benefits would then be defined as additional or supplemental.

In summary, each M+C plan must include all Medicare-covered services available in the service area served by the M+C plan, with the exception of hospice services. Our longstanding policy of allowing organizations flexibility in the provision of services (for example, in terms of who provides the service, what equipment is used, where the service is provided, and what procedure is used) has not been affected by the BBA. Organizations are required to provide services within the guidelines of Medicare national coverage policy and other Medicare rules and requirements that apply to the traditional Medicare fee-for-service system. When a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, we continue to recognize a managed care organization's right to choose how services will be provided. These decisions have been left to managed care organizations to allow them to maximize their value purchasing power, and use resulting savings to provide services not covered by the Medicare program.

Comment: Several commenters raised questions about the requirements in § 422.101(b) that M+C organizations comply with our national coverage decisions and with the coverage decisions of local carriers and intermediaries with jurisdiction for claims in an M+C plan's geographic area. Among the issues raised were the following.

- The national requirements which must be followed, and the meaning of ''HCFA's national coverage decisions''.
- General confusion about the relationship between national coverage decisions and local medical review policy.
- Need for additional guidance in situations when plan service areas extend over a geographic area involving multiple carriers or intermediaries, and thus potentially conflicting medical review policies.
- Difficulties in obtaining coverage decisions by local carriers and intermediaries, and the unwillingness of some carriers to permit M+C organizations to be represented on carrier advisory boards.

Response: As discussed in detail above, M+C organizations must provide their plan enrollees access to all Medicare covered services. However, there is a distinction between the general rule that a health care service is covered under Medicare and the decision that an individual patient fits the clinical criteria necessary for receipt of the service. National coverage determinations and local medical

review policies establish what could be a covered benefit under Medicare and the clinical criteria under which the benefit must be provided. The M+C organization must determine whether or not an individual patient fits this clinical criteria. This process at the plan level constitutes an organization determination. In making organization determinations, M+C organizations are required to follow all national coverage determinations and relevant local medical review policies.

It is important to note, that all M+C organization determinations must be made based on the individual circumstances of a given case, using the best and most relevant information available. All organization determinations are subject to enrollee appeals to the M+C organization and subsequently to an independent review entity. The fact that an M+C organization determination was applying a local medical review policy does not in itself ensure that an appeal to the independent review entity might not result in a determination that the service in question was medically necessary for the individual enrollee and therefore should be covered.

In this final rule, we are revising § 422.101(b)(1) to clarify that the requirement that M+C organizations comply with national coverage decisions includes following the general coverage guidelines included in original Medicare's manuals and instructions to contractors, unless superseded by the M+C regulations or operational policy letters. The Coverage Issues Manual is the primary resource for national coverage decisions. Additional guidance on coverage of hospital and skilled nursing services, home health services, physician services, and other Medicare services can be found in the instructions in the Carriers, Intermediaries, and other HCFA manuals. In the absence of a national standard, M+C organizations should follow local medical review policies in making medical necessity decisions.

We recognize the potential for conflicting local medical review policies when an M+C plan's service area extends across the jurisdictions of more than one carrier, for example. Our general rule under OPL 46 continues to be that the M+C organization should apply the medical review policy of the Medicare carrier in the area where the services are furnished, since that is the policy that would apply to those services under original Medicare. However, as one commenter pointed out, an M+C organization is not precluded from covering services that a local carrier may have determined are not covered, if the organization's own utilization and quality management standards support the medical necessity of the service. Similarly, an organization may occasionally need to make a coverage determination in a situation when there is neither national coverage policy or relevant local review guidelines. In all such cases, an M+C organization's fundamental responsibility is to use the best information available to make an informed decision on the medical necessity of a given service, and then to provide the medically necessary service, even if doing so may conflict with local medical review policies.

One way for an M+C organization to attempt to pursue consistency in medical review policies is to participate on the review boards of local carriers or intermediaries. We are aware of the difficulties M+C organizations are encountering in some areas of the country in participating on these boards, and are actively working to address this issue. We remain committed to establishing more standardized procedures for developing medical review policies, and for increasing M+C representation in formulating these policies.

Comment: Several commenters requested clarification of our policy regarding employer groups and the coordination of benefits with employer group health plans (EGHPs). They asked for clarification as to whether members of an EGHP had to be offered the same benefits as other Medicare enrollees, and whether it would be acceptable to offer an actuarial equivalent package. Another commenter asked that § 422.106 be amended to address coordination of Medicaid benefits, as well as EGHP benefits.

Response: EGHPs that are offered by an M+C organization must provide Medicare-eligible EGHP members the same benefits provided to all other Medicare enrollees under the M+C plan in which the beneficiary is enrolled. The benefits in the M+C plan may not be reduced or otherwise changed, and actuarially equivalent benefits may not be substituted in place of the M+C plan benefits. As noted below in the next response, EGHP benefits beyond those benefits offered under the M+C plan are considered outside the purview of our regulatory authority under the M+C program. However, we retain the authority and responsibility to assure that all Medicare beneficiaries enrolled in organizations that have a contract with Medicare (even if they are dually entitled to coverage under another plan) receive the same benefits and protections as other Medicare beneficiaries enrolled in the plan.

We recognize that the existing regulations describing these situations are somewhat unclear. Therefore, we are revising the language at § 422.106 by reorganizing its requirements for clarity. Revised § 422.106(a)(1) clarifies that if an M+C organization contracts with an EGHP that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits supplementing the M+C plan benefits. Section 422.106(a)(1) states that all M+C program requirements apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract. We also are revising § 422.106 to delineate clearly that our review authority extends only to the M+C plan benefits provided to members of the EGHP, and the associated marketing materials, rather than to any other complementary benefits provided only under the EGHP. The rules contained in this regulation and the corresponding instructions and operational policy letters take precedence for benefits included in the M+C plan.

We are also adopting the commenter's suggestion that § 422.106 incorporate our requirements concerning the coordination of M+C and Medicaid benefits. These rules are conceptually identical to those governing EGHPs. Thus, for individuals dually eligible under Medicare and Medicaid who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the Medicaid benefits supplementing the M+C plan benefits.

Comment: One commenter questioned whether group health benefits offered by employers were considered to be supplemental benefits under the M+C program.

Response: Employer group health plan benefits paid by an employer on behalf of an employee or retiree, as well as Medicaid benefits furnished under a Medicaid State plan, are neither basic nor supplemental benefits. They are therefore outside the scope of M+C plan benefits regulated by the Medicare program. Other laws and regulations may apply to these benefits (such as ERISA requirements for EGHPs). We recognize in § 422.106 that M+C organizations may contract with employers to furnish benefits that complement those that an employee or

retiree receives under an M+C plan. Such benefits may include M+C plan premiums, cost sharing, and additional services. M+C organizations may design an M+C plan with the expectation that an employer group will offer a particular set of complementary benefits. In such a case, however, the M+C plan must be offered to all Medicare beneficiaries in the service area, regardless of whether they are eligible for the employer group benefits, and meet all other M+C plan requirements.

Comment: Several commenters expressed confusion regarding the benefit-related implications of the ''conscience protection'' provision contained in section 1852(j)(3) of the Act, which is a new provision giving enrollees rights to unrestricted physician counseling and advice. Under the conscience protection provision in section 1852(j)(3)(B) of the Act, implemented in § 422.206(b), the prohibition on interference with provider advice to enrollees in section 1852(j)(3)(A) of the Act (reflected in § 422.206(a)) may not be construed to require an M+C organization to provide or pay for counseling or referrals if the organization objects on moral or religious grounds and notifies enrollees of its policies in this regard. Some commenters asked whether the conscience clause in section 1852(j)(3)(B) of the Act and § 422.206(b) would permit an M+C organization to refuse to include a Medicare-covered service in its M+C plan, as otherwise required under § 422.101.

Response: The conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A) of the Act, not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) of the Act to cover all Medicare-covered services available in the area served by the M+C plan. To the extent the operation of the right to advice and counseling under section 1852(j)(3)(A) of the Act would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) of the Act allows the organization to decline to provide such service on conscience grounds if appropriate notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A) of the Act, it could not be affected by a provision that by its own terms affects only the way that ''[s]ubparagraph (A) [of section 1852(j)(3)] shall * * * be construed.'' It in no way affects obligations that arise elsewhere in the statute. Therefore, an M+C organization could not rely upon section 1852(j)(3)(B) of the Act or § 422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover.

We note, however, that in the case of abortion-related services, Congress has provided M+C organizations with conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 211 of the fiscal year 2000 Department of Health and Human Services Appropriations Act, Pub. L. 106–113, we are prohibited from denying a M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. We are required, however, to make appropriate adjustments to such an entity's M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

Comment: Commenters requested that copayments for outpatient psychiatric services be limited to the same percentages of copayments allowed for other services.

Response: With the sole exception of out-of-area emergency services, we have not prescribed limitations on copayments for individual Medicare services in the M+C regulations. In this case, the commenter's suggestion would impose a requirement on M+C organizations that is inconsistent with the cost-sharing structure of original Medicare. We do not believe this would be appropriate.

5. Special Rules for Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine (§ 422.100(h))

Section 422.100(h) establishes special rules for screening mammography, influenza vaccine, and pneumococcal vaccine. Enrollees of M+C organizations may directly access, through self-referral, screening mammography and influenza vaccine. In addition, M+C organizations may not impose cost sharing for influenza vaccine and pneumococcal vaccine.

Comment: Several commenters expressed concern that enrollees may directly access out-of-network providers through self-referral. They believe that self-referrals should be limited to in-network providers. Furthermore, they feared that an enrollee may self-refer to noncertified facilities or noncredentialed providers.

Response: The right to directly access screening mammography services and flu vaccines does not include accessing these services out of network. Section 422.112(a) specifies that an M+C organization ''may specify the networks of providers from whom enrollees may obtain services'' if the organization meets a number of specified conditions. M+C organizations thus have the discretion under § 422.100(h)(1) to require that self-referrals be made to a provider within the M+C plan's network, as long as sufficient access is provided in that network. We note that if an M+C organization offers a point-of-service (POS) option under its M+C plan, an enrollee selecting this option could self-refer to an out-of-network provider, consistent with the payment rules established by the M+C organization.

Comment: One commenter stated that we should prohibit cost sharing for mammography as well as vaccines, noting that both health care services are preventive in nature and would be cost-effective measures for the Medicare program in the long term. The commenter pointed out that women constitute a substantial portion of the Medicare population, and asserted that allowing cost sharing for screening mammographies could be perceived as both gender-specific and discriminatory in nature.

Response: Various provisions of Title XVIII of the Social Security Act specify the coverage of mammography, influenza vaccine, and pneumococcal vaccine. The Act provides that there should be no deductible for any of these services. Further, while the Act indicates that there be no copayment for influenza and pneumococcal vaccine, it provides for a 20 percent coinsurance for mammography. (See, for example, section 1834(c) of Title XVIII and 42 CFR 410.152(h).) These are policies established by statute for the original Medicare program, and we see no basis for requiring M+C organizations to provide more favorable treatment to M+C enrollees than that provided to original Medicare beneficiaries.

Comment: A commenter requested that we clarify in the regulations that the prohibition on cost-sharing for influenza and pneumococcal vaccine applies to the imposition of cost-sharing on M+C plan enrollees.

Response: As requested by the commenter, we have added language to the regulation text to clarify that M+C organizations are prohibited from imposing cost sharing ''on their M+C plan enrollees'' for influenza and pneumococcal vaccines.

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

A POS benefit is an option that an M+C organization may offer under an M+C coordinated care plan, or network M+C MSA plan, to provide enrollees in

such plans with additional choice in obtaining specified health care services. A coordinated care plan may include a POS option as an additional benefit, a mandatory supplemental benefit, or an optional supplemental benefit. A network MSA plan may include a POS option only as a supplemental benefit.

Under a POS option, the M+C organization generally permits enrollees to obtain specified items and services outside of the M+C plan's normal prior authorization rules, but provides that enrollees will incur higher financial liability for such services. The enrollee may be required to pay a premium for the benefit unless the benefit is offered as an additional benefit. M+C organizations can establish what services are available under a POS benefit and the amount of member cost sharing subject to ACR limits. M+C organizations may also place other limits on the benefit; for example, a plan could offer a POS benefit as a travel benefit allowing members to access specified services when the member is traveling outside of the plan's service area.

Comment: Several commenters objected to the restriction in the interim final regulation at § 422.105(a) stating that a POS benefit can be used only to obtain services from providers that do not have a contract with the M+C organization. The commenters maintained that an important aspect of a POS benefit is that it allows beneficiaries who have reservations about joining a managed care plan the opportunity to enroll without following strict prior authorization requirements to access services, and that this consideration applies without regard to whether the provider is part of the M+C plan network. Some commenters also noted that the restriction against in-network use of a POS benefit was particularly unfair to M+C plans with large provider networks, since the likelihood of an in-network referral was much greater. Several commenters stated that if we are concerned about in-plan use of a POS benefit, the solution is monitoring rather than prohibiting beneficiary choice.

Response: In the interim final M+C regulations, we specified that an M+C POS benefit could be used by plan members only to obtain health care services from providers outside of the plan's contracted provider network (non-network providers). The intent of this restriction was to ensure that plan enrollees were not inappropriately induced to use a POS benefit to obtain services at higher cost from plan contracting providers that they could otherwise receive at lower cost by following the plan authorization rules for obtaining health care services. However, we have reconsidered this position in response to the above comments, and in recognition of the fact that a number of organizations withdrew their POS benefit due to this restriction. We recognize that for some beneficiaries the ability to obtain health care services directly from providers without obtaining advance authorization is an important choice. Accordingly, in order to ensure that beneficiaries have the widest possible array of choices, we have decided to allow plans the option of offering a POS benefit that can be used by plan members to receive services from plan contracting providers.

We remain concerned about the potential for inappropriate cost-shifting to beneficiaries. To help guard against this possibility, we have revised § 422.105 to require that M+C organizations offering a POS benefit must track, and report to us upon request, POS utilization at the M+C plan level by both contracting providers and noncontracting providers. In monitoring use of the POS benefit, we will pay particular attention to potential over-utilization of the POS benefit by plan enrollees in obtaining services from the plan contracting provider network. We will attempt to verify that it is a matter of choice when a plan member uses a POS benefit to obtain services, rather than due to the member being inappropriately denied prompt access to the service by the plan. We note that an M+C organization still has the option of offering a POS benefit through an M+C plan that can be used by plan members only to obtain health care services from providers who do not contract with the plan.

Comment: A commenter asked if the POS regulations apply to POS benefits that are offered only for employer group members. The commenter noted that under § 422.106, employer group benefits that are designed to complement the Medicare benefits are exempted from our review.

Response: An employer may through negotiation with an M+C organization provide a POS benefit for members of an employer group who elect to join an M+C plan. As described in the regulations at § 422.106, such enhancements to the Medicare-approved benefit package are not subject to our review or approval.

Comment: A commenter expressed concern about the requirement at § 422.105(d)(2)(iv) that a POS benefit must have a maximum annual out-of-pocket cap on enrollee liability. The commenter questioned whether capping enrollee out-of-pocket expenses would leave the plan at risk for all out-of-network care received by the enrollee once the cap was exceeded.

Response: As the commenter stated, M+C plans offering a POS benefit must place an annual maximum cap on an enrollee's financial liability in using a POS benefit. The reason for requiring a cap on beneficiary financial liability is to ensure that beneficiaries understand in advance what their maximum financial risk is in using a POS benefit. However, once the annual maximum for a POS benefit is reached (including the beneficiary cap), the plan does not have to continue paying for health care service under a POS benefit. For example, consider a plan that offers a POS benefit with a $5,000 annual maximum, and requires 20 percent coinsurance from the beneficiary using the POS benefit. In this example, the member's annual maximum financial liability under POS is $1,000 (20 percent of $5,000). Once the $5,000 overall POS annual maximum is reached, the beneficiary has paid the out-of-pocket maximum of $1,000 and the plan has contributed $4,000 of the $5,000 annual maximum for the POS benefit. At this point, the plan has no further obligation to cover services for the beneficiary under the POS benefit. Thus, any use of the POS benefit beyond this maximum would be at the enrollee's financial liability. We note that § 422.105(d)(2)(iii) specifies that an M+C organization must explain in the Evidence of Coverage the enrollee's financial responsibility for services that are not covered under the POS benefit or services beyond the maximum POS limit.

In general, we expect that organizations offering a POS benefit will be able to provide enrollees with timely information on the POS financial limits, coverage rules, and enrollee cost-sharing for a given service, including the capacity to provide enrollees with advance coverage information over the phone. For example, if the POS benefit has an annual dollar cap, enrollees should be able to phone the organization offering the POS benefit and be informed of how close they are to reaching the financial cap on the benefit. In addition, the plan should be able to advise an enrollee whether a particular service will be paid for under a POS benefit, how much the member will pay out-of-pocket, and how much the plan will contribute under the POS benefit.

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

As stated in the June 26, 1998 interim final rule, Medicare does not pay for services to the extent that there is a third party that is to be the primary payer under the provisions in section 1862(b) of the Act and 42 CFR Part 411. The M+C organization must, for each M+C plan, identify payers that are primary to Medicare under section 1862(b) of the Act and part 411; determine the amounts payable by those payers; and coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

The M+C organization may charge, or authorize a provider to charge, other individuals or entities for covered Medicare services for which Medicare is not the primary payer. If an enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may charge, or authorize a provider to charge the insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter, or the M+C enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

Where Medicare is a secondary payer to employer coverage in the case of certain working Medicare beneficiaries, an M+C organization may charge a group health plan (GHP) or large group health plan (LGHP) for services it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Comment: Two commenters requested that the M+C regulations provide that Medicare secondary payer regulations apply generally to M+C organizations. One of these commenters also favored a cross reference to the Medicare overpayment regulations.

Response: M+C organizations are to apply only the Medicare secondary payer (MSP) rules as found in section 1852(a)(4) of the Act and in § 422.108. Other MSP provisions do not apply to M+C organizations, and they do not have recourse to them. However, M+C organizations are expected, as provided under § 422.108(a), to look to section 1862(b) of the Act and 42 CFR Part 411 to determine whether Medicare or some other party is the primary payer.

Since section 1852(a)(4) of the Act and § 422.108 are the only MSP provisions that apply in the M+C context, M+C organizations would pursue their Federally authorized claims under State law. Federal preemption of State laws in the MSP context would occur only to the extent a State law would prohibit an M+C organization from complying with what the Federal rules authorize (that is, from billing and recovering from specified third parties, and from beneficiaries to the extent they have received third party payments that are primary to Medicare under MSP rules). These recoveries are not made on behalf of the United States and, therefore, the Federal overpayment rules cited by the commenter do not apply.

Comment: One commenter requested that enrollees be given written notice of their right to appeal an M+C organization decision to withhold payment under MSP rules, or file a request for a waiver of recovery of the overpayment.

Response: Section 422.568 requires an M+C organization to give an enrollee written notice of any denial, in whole or in part, which includes a description of the enrollee's appeal rights. It is not necessary to create a separate requirement in the MSP context. With respect to a request for waiver of recovery of the overpayment, since any recoveries are not obtained on behalf of the United States, State laws rather than Federal overpayment rules would apply.

Comment: One commenter believes that if an M+C plan enrollee with coverage primary to Medicare obtained services from providers not participating in the M+C plan, the M+C organization should pay for the services. By paying nonplan providers first, and then seeking recovery from the primary payer, the beneficiary would not be held responsible for the bill.

Response: There is no statutory authority to require M+C organizations to make payments to nonplan providers, except in the circumstances set forth in § 422.100(b)(1) (for example, emergency or urgently needed services, out-of-area dialysis) and § 422.114(b) (for example, access to services under an M+C private fee-for-service plan).

Comment: Three commenters recommended that since some States have laws that do not allow HMOs and health insurers to seek payment from primary payers, the regulations should be clarified to indicate that MSP rules preempt any State laws that would prevent an M+C organization from complying with the Federal law and regulations.

Response: We are adding a new paragraph ''f'' to § 422.108 to clarify that a State cannot take away an M+C organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer. However, nothing in section 1852(a)(4) of the Act would prohibit a State from limiting the amount of the recovery; therefore, State law could modify an M+C organization's rights in this regard, but could not deny them entirely.

Comment: One commenter believes that the use of the term ''charge'' in this section is not appropriate. The commenter pointed out that ''charge'' has a specific meaning in the Medicare context (as in ''reasonable charge''), and the use of ''charge'' in this section is not consistent with the commenter's understanding of the common meaning of this term. The commenter recommended revising the regulations to use the term ''bill'' or ''collect from.'' The same commenter also suggested that there was ambiguity in the use of the word ''determine'' in § 422.108(b)(2), because ''determine'' and ''determinations'' also have different specific meanings under Medicare. ''Calculate'' or ''identify'' was suggested as a replacement.

Response: The intended meaning of ''charge'' as used in this section is ''the imposing of a pecuniary obligation on another entity.'' Although this usage is technically correct and consistent with statutory language, in the interest of clarity, we are adopting the commenter's request, and changing ''charge'' to ''collect from'' in the regulation headings, and to ''bill'' in the body of the regulation text. We also have changed ''determining'' to ''identify'' in subsection (b)(2).

8. National Coverage Determinations (§ 422.109)

Section 422.109 addresses how M+C organizations are paid when a new Medicare benefit is required under a national coverage determination, but payment for this benefit is not yet included in the organization's capitation rate. Frequently, we develop coverage policy on new procedures or technology during the year. M+C organizations must provide these benefits as soon as they are covered by Medicare, even if this occurs during the middle of a contract year. If the cost of such new benefits exceeds a specified threshold, we pay the M+C organization on a fee-for-service basis under original Medicare payment rules to cover the services in question.

Comment: Commenters requested that we include a definition of ''national coverage determination'' in the M+C regulations, and objected to the fact that beneficiaries would be liable for paying

the Part A deductible, when the beneficiary in most cases has already been charged premium or cost-sharing amounts based on the actuarial value of this deductible.

Response: The definition of ''national coverage determination'' was not included in the M+C regulations because it is already set forth in § 400.202 of title 42 of the CFR; however, for the convenience of users of the M+C regulations, we have now repeated this definition in § 422.2. With respect to the issue of the Part A deductible, section 1852(a)(5)(A) of the Act provides that services covered by a national coverage determination involving significant costs not included in M+C capitation payments are not covered as a service that must be provided under the M+C contract in exchange for capitation payments. Section 1852(a)(5)(B) of the Act provides that the normal rule that capitation payments are made in lieu of regular Medicare payments (section 1851(i)(1) of the Act) does not apply in the case of additional services covered under a national coverage determination. Thus, the services would be covered under original Medicare's coverage rules. Congress did not provide for a similar exception, however, to the rule in section 1851(i)(2) of the Act providing that ''only the M+C organization shall be entitled to receive payments from the Secretary under this title for services furnished to [an M+C enrollee of that organization].'' Read together, these provisions mean that the M+C organization will receive Medicare payment under original Medicare's payment rules for services covered by a national coverage determination that triggers the procedures in § 422.109.

Under these payment rules, a beneficiary is liable for deductible and cost-sharing amounts, which is why § 422.109(b)(5) provides that enrollees would pay these amounts. Although the enrollee has in most cases paid a premium and other cost sharing based on the actuarial value of Part A and Part B deductibles and cost sharing, this amount is for services covered under the contract. These services are covered outside the contract under original Medicare payment rules. However, since the general Part A deductible arguably would already have been satisfied for the beneficiary through M+C plan premiums and cost sharing, we are revising § 422.109(b)(5) in response to this comment to provide that M+C enrollees are responsible only for coinsurance amounts. Medicare payments will thus be made without regard to satisfaction of the Part A deductible.

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

Consistent with section 1852(b)(1) of the Act, § 422.110 establishes that an M+C organization may not discriminate among Medicare beneficiaries based on any factor that is related to health status, including, but not limited to the following factors: medical condition (including mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), or disability. The only exception to this rule is that an M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease (unless the individual is already enrolled with the organization under a different plan). M+C organizations are required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act.

Comment: One commenter suggested that we require M+C organizations to provide handicapped-accessible facilities for marketing presentations, full access to plan information and plan providers, as well as access to the M+C organization itself.

Response: This comment speaks to the practice of health screening and the allocation of marketing resources with respect to disabled populations. Section 422.110(c) requires M+C organizations to meet the requirements of the Americans with Disabilities Act (ADA). Consistent with ADA, an M+C organization must ensure that its providers and marketing presentations accommodate persons with disabilities, both in terms of physical accessibility and communication of information. Thus, the organization and providers must afford the same freedom of choice with respect to providers to all enrollees. Further, access to information must be provided in appropriate alternative formats upon request, such as Braille, enlarged font (at least 14 point), audio cassette, closed or open captioning, or formats that accommodate low-literacy beneficiaries. In providing information access to hearing-impaired individuals, M+C organizations must not rely on relay services but must make available TTY/TDD service as well. Again, these requirements are consistent both with the Americans with Disabilities Act and with the M+C provisions in § 422.80(e)(2) regarding marketing to the disabled population.

10. Disclosure Requirements (§ 422.111)

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 disclosure requirements are set forth in § 422.111 of the regulation. M+C organizations are required to provide to each M+C plan enrollee, at the time of enrollment and at least annually thereafter, in a clear, accurate, and standardized form (that is, through the Evidence of Coverage), the following information regarding the enrollee's M+C plan: Service area, benefits offered under the plan and under original Medicare, access to providers, out-of-area coverage, emergency coverage, supplemental benefits, prior authorization rules, grievance and appeals rights and procedures, quality assurance programs, and disenrollment rights and responsibilities.

M+C organizations are also required to provide additional information upon request of a beneficiary, including: General coverage and comparative plan information, information on the number and disposition of grievances and appeals, information on the financial condition of the M+C organization, the procedures the organization uses to control utilization of services and expenditures, and a summary of physician compensation arrangements. Section 422.111 also includes procedures for an M+C organization to follow when it intends to change its rules for an M+C plan, and describes the enrollee notification requirements when there are changes in a plan's provider network.

Finally, as discussed in section II.B of this preamble, § 422.64 no longer lists the information that we must provide to beneficiaries. However, because § 422.111 referred to this material in several places, we are revising § 422.111 to incorporate the necessary specifications into a new paragraph (f).

Comment: Several commenters acknowledged the importance of providing beneficiaries with information on their range of health care choices, so that they can make informed decisions about their Medicare coverage. However, they were concerned that duplication of efforts will result from our responsibilities to provide beneficiaries with the information formerly specified in § 422.64(c) (now set forth in § 422.111(f)) combined with the requirements in § 422.111 concerning information that an M+C organization must disclose to its enrollees. The commenters viewed these requirements

as an unnecessary overlap of information.

Response: We have no intention of burdening M+C organizations with unnecessary disclosure requirements that duplicate our efforts. However, just as section 1851(d) of the Act mandates our responsibilities for distributing information to all beneficiaries (including the requirement at section 1851(d)(7) of the Act that M+C organizations provide us with the information needed to carry out these responsibilities), section 1852(c) of the Act establishes several specific requirements for M+C organizations to disclose plan information to their enrollees, and to individuals eligible to enroll in their plans. The M+C regulations do not expand upon the disclosure requirements set forth in the M+C statute. In general, the plan-specific information that we collect from M+C organizations for Medicare Compare (our database of comparative plan information) can also be used by M+C organizations to meet their statutory information disclosure responsibilities. Thus, although the statute does mandate that M+C organizations report similar information both to us and to their plan enrollees, we do not believe that the M+C disclosure requirements should result in significant additional burdens for M+C organizations.

Comment: Commenters discussed the importance of conveying required information to beneficiaries in a culturally competent manner. They suggested that criteria be developed by us for use by M+C organizations.

Response: We agree that plan information needs to be provided to beneficiaries in a culturally competent manner, so that beneficiaries are provided with the opportunity to make fully informed health care choices. We note that § 422.80(c)(5) addresses this concern by specifying that, for markets with a significant non-English speaking population, marketing materials and election forms must be provided in the language of those individuals. In order for M+C organizations to provide beneficiaries with plan information in a culturally competent manner, we provide guidance for both developing and reviewing marketing materials through our managed care manual, marketing guidelines, and operational policy letters. M+C organizations are required to submit their marketing materials and election forms to us for review prior to distribution to Medicare beneficiaries. The Regional Offices (RO), with direction from Central Office, are involved in reviewing and approving plans' marketing materials. In carrying out these efforts, the ROs balance the M+C organizations' needs for flexibility in developing beneficiary information with our responsibility to assure that materials are compliant with the regulation and are consistent nationwide. The ROs require that information be changed if it is inaccurate, misleading, or unclear.

Our plans for standardizing beneficiary enrollment and appeals notices, including the Evidence of Coverage (EOC), involve consulting with interested parties, including beneficiary advocacy groups. We are now in the process of consumer testing the enrollment and appeals notices to ensure that the message of each notice is clearly understood by beneficiaries. (For a further discussion of cultural competency issues as they pertain to the delivery of services, see section II.C.11 below.)

Comment: Commenters suggested that information should be disclosed in a standard format or model notice, including information that must be provided upon request of the beneficiary.

Response: We agree that standardized formats for M+C beneficiary notification materials are needed. Health care information that is provided in a well-designed standardized format, using consistent, descriptive terminology, assists beneficiaries in making important decisions about their health care.

We have initiated a two-phase Marketing Material Standardization Project that includes input from the managed care industry and beneficiary advocacy groups. In Phase I, we have implemented, beginning October 15, 1999, a standardized Summary of Benefits (SB), the key pre-enrollment marketing document provided to beneficiaries, so that they can compare the same benefits and costs across several M+C plans and original Medicare. Phase II will involve standardizing beneficiary enrollment and appeals notices. We are conducting consumer testing of these notices in preparation for the final phase of the standardization initiative.

Phase II of our standardization project includes the EOC, also known as the Subscriber Agreement and Member Contract. The EOC contains an explanation of plan benefits (covered services), member rights, and member/M+C plan contractual responsibilities and obligations. The EOC is provided to beneficiaries when they join the M+C plan and annually thereafter. As part of the standardization process for the EOC, we released a model EOC on December 1, 1999, for use in contract year 2000, that M+C organizations are required to distribute to all enrolled members by May 15, 2000. In developing the model EOC, we consulted with managed care industry representatives and beneficiary advocacy groups, and we intend to use this model as a baseline for developing the standardized EOC. The process for standardizing a document as important and comprehensive as the EOC requires adequate time for input from the industry and beneficiary advocacy groups, for public review and comment, and for implementation of the standardized document. We plan to begin standardization of the EOC in the Spring of 2000 and to complete the process in time for the November 2001 annual election period for contract year 2002.

We also have provided guidance to M+C organizations on the manner and form for disclosing the information required under § 422.111(c) upon a beneficiary's request. For example, OPL 099.081, issued on February 10, 1999, addresses appeal and grievance data disclosure requirements, and further clarifying instructions were issued in OPL 2000.114. These disclosure requirements are consistent with the reporting units for the Health Plan Employer Data and Information Set (HEDIS), the Medicare Consumer Assessment of Health Plans Study (CAHPS), and the Medicare Health Outcomes Survey (HOS). We have also issued guidance on how M+C organizations can best provide information relating to compensation for physicians, specifically incentive arrangements. The guidance includes suggested language for marketing materials as well as suggested responses for requests from beneficiaries. Again, our ROs will review these materials as part of their usual responsibilities for pre-approving beneficiary materials.

Comment: Commenters expressed concern that information concerning the number and disposition of appeals and grievances from M+C plans with low enrollment may not be statistically valid, and suggested that reporting such data could be misleading to beneficiaries. They recommended that, if an M+C organization offers a number of different M+C plans in a single service area, the organization should report appeals and grievance data on an aggregate basis, rather than on a plan-specific basis.

Response: We assessed alternative ways to report this information and decided that the most meaningful way to report this information would be to make it consistent with the reporting unit for HEDIS, CAHPS, and the Medicare HOS. The reporting unit for

these instruments is the ''contract market,'' which implies either reporting by contract or by a market area within a contract. M+C organizations must report for each contract unless we divide the contract service area into ''market areas.'' We will assess all contract service areas to determine whether M+C organizations must report by market area, and will notify plans as soon as possible whether they must report by market area. Further details on subdividing the contract service area into market areas can be found in OPL 099–081. The OPL also describes the data collection periods and reporting periods that have been established in order for M+C organizations to report data consistently. We and our contractors are working with M+C organizations and consumer groups to determine additional information needed to develop a national managed care appeal and grievance data collection and reporting system, with data disclosure requirements to be built into this system.

Comment: Several commenters expressed concerns over the requirement for public reporting of quality improvement results. They feared that this reporting could result in: (1) M+C organizations altering their decision making to produce competitively attractive numbers'' at the expense of good patient care, or (2) the dissemination of data that could easily be misinterpreted by Medicare beneficiaries, rather than of value in facilitating informed beneficiary choice.

Response: The reporting of plan-specific quality and performance indicators is based directly on the requirements of section 1851(d)(4)(D) of the Act. Moreover, we believe that it is essential for plan comparison purposes that M+C organizations report on standardized quality measures. The standardized measures that we are requiring, as discussed in detail in section II.D of this preamble, are largely those of HEDIS. These measures are predictive of health care outcomes, well-defined, and well-established in the private sector. Thus, we do not believe that the commenters' concerns that the reporting of these measures will negatively affect M+C organizations' decision making and lead to widespread public misinterpretation are justified.

Comment: We received several comments regarding notification of beneficiaries of changes in an M+C plan's provider network. Three commenters suggested that the requirement that written notification to the enrollee occur within 15 working days of the receipt or issuance of a notice of provider termination would be confusing for enrollees and an administrative burden for M+C organizations. Another commenter suggested that the 15 working days be converted to calendar days to be consistent with the appeals requirements under Subpart M.

Response: We recognize that the requirement that written notice be provided ''within 15 working days of receipt or issuance of a notice of termination'' has the potential in some situations to cause confusion for beneficiaries and impose an unnecessary administrative burden on M+C organizations. For example, because contract negotiations with providers often extend beyond a 15-day period after initial notice of termination, an M+C organization may be unable to furnish definitive network information to its enrollees within the 15-day time frame. Therefore, we are revising § 422.111(e) to decouple the enrollee notice time frame from the ''issuance or receipt'' of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date. (As the commenter suggested, we agree that measuring this time frame by using calendar days, rather than working days, would improve the internal consistency of the M+C regulations, as well as eliminating any possible confusion over what constitutes a ''working day.'')

Comment: Two commenters suggested defining ''regular basis'' for purposes of § 422.111(e). Under this requirement, a M+C organization must notify ''all enrollees who are patients seen on a regular basis by the provider whose contract is terminating.'' One commenter suggested that ''regular basis'' be defined as seeing a provider within the last 180 days or 6 months.

Response: Section 422.111(e) is clear that all enrollees who are patients of a primary care professional (PCP) must be notified by the M+C organization when a PCP's contract is terminated. We are not making any change in this regard. For other providers, the regulations establish the ''regular basis'' standard. Generally, we would interpret this standard to require the notification of all enrollees who have a referral to a specialist for an ongoing course of treatment, or of all regular patients of an OB/GYN, for example. In combination with the explicit requirement for notification of all patients of a PCP, we believe that the ''regular basis'' standard is sufficient for accomplishing the objective of notifying all enrollees who are likely to be affected by a provider termination. We note that this requirement does not preclude the providers themselves from notifying M+C enrollees of the termination of their participation in an M+C plan's provider network.

11. General Access Requirements (§ 422.112)

a. Introduction

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, and reflecting standards from the Quality Improvement System for Managed Care (QISMC).

On February 17, 1999, we published a final rule (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. In the February 17, 1999 final rule, we made changes to several of the access provisions of this section. These changes involved the coordination of care requirements, provisions related to complex or serious medical conditions, notification requirements when specialists are terminated from an M+C plan, and initial care assessment requirements.

More specifically, for serious and complex conditions, the treatment plan may be updated by a health care professional other than the primary care provider. Furthermore, this section now requires that the M+C organization ensure adequate coordination of providers for persons with serious or complex medical conditions. Under the general coordination of care requirements, the responsibility for ensuring coordination of care is not limited to an individual provider. Instead, the organization must: (1) Establish policies to ensure coordination; and (2) offer each enrollee a primary source of care. Further, as to the initial assessment, each organization will be expected only to demonstrate a ''best effort'' attempt to complete the assessment of health care needs within 90 days of enrollment. Finally, we no longer require, when a specialist is involuntarily terminated from an M+C plan, that the M+C organization offer to provide enrollees with the names of other plans in the area that contract with the specialist. However, as discussed above, the general requirements regarding notification of affected patients upon provider

termination remain in effect. Comments on aspects of the access requirements that were not addressed in our February 17, 1999 final rule are discussed below.

b. Provider Network (§ 422.112(a)(1))

Section 422.112(a)(1) requires M+C organizations that wish to limit an enrollee's choice of providers to 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. We received several comments regarding access standards and one comment regarding contracting with community pharmacies.

Comment: Several commenters asked us to elaborate on access standards by including time and distance travel standards, such as specifying a 30-mile standard except where travel is difficult.

Response: Both the Medicare managed care manual and the QISMC guidelines issued on September 28, 1998 specify that a 30-mile standard must be satisfied in order to meet access requirements, except where a different standard is justified by geographic factors. We believe the inclusion of this requirement in these documents provides sufficient guidance on this subject. Furthermore, because the community pattern of care in some rural areas is to travel further than 30 miles for care, we do not believe it would be appropriate to establish an absolute 30-mile standard in the regulations.

Comment: One commenter requested that we require M+C organizations to contract with community pharmacies that are easily accessible.

Response: Community pharmacies have a number of advantages, and thus, M+C organizations should consider this as an option in providing pharmacy services. However, other options, such as pharmacy benefit management companies or mail order pharmacies, may have other advantages that are appropriate for M+C organizations to consider, such as lower cost. In choosing among these options, the M+C organizations must ensure that the providers of pharmacy services meet the various access and quality standards required by these regulations, implementing manuals and guidelines. Given these criteria, we do not believe it appropriate to require that community pharmacies be mandated as the source of pharmacy services.

c. Primary Care Provider Panel (§ 422.112(a)(2))

Section 422.112(a)(2) requires an M+C organization that wishes to limit an enrollee's choice of providers to establish a panel of PCPs from which an enrollee may choose. We received two comments regarding the PCP panel.

Comment: One commenter specified that all PCPs should be licensed physicians or Doctors of Osteopathy.

Response: QISMC Standard 3.2.1.2 provides additional guidance with respect to our policies regarding PCPs. The guideline states:

> An organization may permit licensed practitioners other than physicians to serve as primary care providers, consistent with requirements of applicable State laws. (Qualifications of such practitioners, and the degree of supervision required, are generally established under State law). If an organization designates nonphysician practitioners as primary care providers, it must still ensure that each enrollee has a right to direct access to a physician for primary medical care. This right may be ensured in either of two ways: (a) the enrollee may choose between a physician and nonphysician primary care provider, and may change this choice at any time; or (b) when the enrollee is not allowed such a choice, an enrollee with a nonphysician primary care provider may have timely access to a physician upon request.

The guideline further states: ''An organization may allow an enrollee to select a physician group, clinic, federally qualified health center, or other facility with multiple practitioners as his or her primary source of care. To the extent feasible, the enrollee must be allowed to choose an individual primary care provider within the group or facility.''

Thus, the QISMC guidelines do not limit enrollees to the use of physicians or Doctors of Osteopathy as PCPs. However, as indicated, an M+C organization must provide enrollees with access to physicians or Doctors of Osteopathy upon request. Furthermore, § 422.112(a)(1) requires that the M+C organization have an adequate network of providers and § 422.112(b)(2) requires the organization to offer each enrollee a source of primary care. In addition, consistent with the BBA provisions regarding antidiscrimination, and the Consumer Bill of Rights and Responsibilities, we intend to provide enrollees with freedom of choice in the selection of providers subject to the above constraints. Therefore, we are not adopting the commenter's suggestion. We note that an M+C organization's use of nonphysicians to deliver Medicare benefits must be consistent with Medicare coverage requirements, such as ''incident to'' supervision requirements. To the extent nonphysicians are providing non-Medicare covered services as an additional or supplemental benefit, these requirements do not apply.

d. Specialty Care (§ 422.112(a)(3))

This section requires an M+C organization to provide or arrange for necessary specialty care, and gives 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, notwithstanding that the M+C organization maintains a PCP or some other means for continuity of care.

Comment: One commenter expressed concern that an M+C organization may prohibit enrollee access to a specialist without a referral from a PCP, even when not all enrollees will choose to select, or be provided, a PCP. This would effectively deny access to specialist care to such individuals.

Response: Again, all M+C organizations must provide an adequate network of providers (§ 422.112(a)(1)), offer to provide each enrollee with an ongoing source of primary care (§ 422.112(b)(2)), and provide a primary source of care to each enrollee who requests one. In addition, § 422.112(a)(3) requires an M+C organization to provide or arrange for necessary specialty care. (As discussed above in section II.C.1, we are revising § 422.112(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.) If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, specialty care is medically necessary, and the enrollee has not selected a PCP, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to provide the necessary care. Accordingly, we have revised § 422.112(a)(2) to specify that the M+C organization must make specialty care available even if a plan enrollee has not selected a PCP.

Comments: Several commenters asked for clarification of the terms ''routine'' and ''preventive'' as they apply to women's health services. They asserted that routine services should include more than just preventive services, while the examples offered in the preamble to the June 26, 1998 interim final rule only were limited to preventive services. One commenter noted that there are many services that OB/GYNs are most appropriately qualified to provide that should not require a referral from another physician, such as hormonal replacement therapy, and treatment of osteoporosis, genital relaxation disorders, incontinence, abnormal uterine bleeding, urinary tract infections

(UTI), and sexual dysfunction. Another commenter suggested that we clarify that even though women have direct access to women's health specialists, it was not intended that the PCP be bypassed.

Response: We consider routine and preventive women's health care services to mean: an exam that is provided on a regular, periodic basis, in the absence of presenting symptoms, diagnosis or complaints, for disease prevention and health maintenance. The examples from the commenter, therefore, are not routine and preventive.

In the setting of such an exam, abnormalities may be found, such as incidental vaginitis or UTI, or abnormal Pap smear. We would consider routine services to follow up on such gynecologic abnormalities to be included under this definition.

We agree that the provision is unclear about the role of PCPs, and have deleted from § 422.112(a)(3) the reference to ''while the plan maintains a PCP or some other means for continuity of care.''

Although the regulations require that M+C organizations allow women direct access (that is, without referrals or preauthorization) to a women's health care specialist within the network for women's routine and preventive services, if there is a PCP, he or she needs to be kept informed of the health care provided by such specialists. It is up to the M+C organization to develop appropriate strategies for assuring such an outcome.

We note that an M+C organization may place restrictions on enrollees as to the eligible universe of providers to whom they may ''self-refer'' for women's health services. Thus, QISMC guideline 2.2.3.2 provides for M+C organizations to create formal subnetworks. In these cases, an organization can require an enrollee at the time of initial selection of a PCP, to choose an entire subnetwork that may also include specialists, hospitals, or other providers. The enrollee may be required to obtain covered services, including routine and preventive women's health services through providers affiliated with the system. Under the QISMC guideline, an enrollee could change his or her choice of subnetwork at any time. (See the guidelines for further details, including an M+C organization's responsibilities to ensure that enrollees are aware of the implications of their choice of a PCP in terms of the available subnetworks associated with a given PCP.)

Comment: One commenter suggested that we allow OB/GYN specialists to serve as PCPs.

Response: Although such a practice is permissible under the M+C regulations, we believe that this is a decision that should be made by the M+C organizations, based upon the needs of their enrollees and available resources. This position is consistent with that adopted regarding use of specialists with respect to ''serious and complex'' medical conditions, as stated in the February 17, 1999 final rule.

e. Serious Medical Conditions (§ 422.112(a)(4))

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.

Comment: Several commenters asked for clarification of what is meant by ''serious or complex medical conditions.''

Response: On August 31, 1999, the Institute of Medicine (IOM) submitted a final report to us, entitled ''Definition of Serious and Complex Medical Conditions.'' This report is available through the Internet at ''www.nas.edu''.

A key recommendation made in the report is: ''The committee recommends that the Health Care Financing Administration should provide guidance [emphasis added] to health plans to assist their efforts to identify patients with serious and complex medical conditions. Specifically, the committee recommends the following language be used to facilitate efforts of plans to identify their enrollees with ''serious and complex conditions'': A serious and complex condition is one that is persistent and substantially disabling or life-threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member.''

In view of the committee's recommendation that it is premature to establish an administrative definition of these terms, we have decided not to make any changes at this time to the regulations regarding serious medical conditions. We will provide further policy guidance on the meaning of this definition through a future OPL. For now, M+C organizations have the option of adopting the IOM definition or developing an alternative definition.

The committee also recommended that rather than focus on access to specialists, the treatment plans that M+C organizations develop should address access to specialty care. Furthermore, the committee recommended that M+C organizations develop a care management strategy that integrates the participation of all those involved in the care of the patient, including primary care physicians; medical and surgical specialists; nurses and nurse specialists; behavioral and mental health specialists; physical, occupational, and speech therapists; social workers; allied health professionals; and community-based service providers. The forthcoming OPL will address these strategies, as well as provide guidance on implementation and monitoring procedures.

f. Written Standards (§ 422.112(a)(7))

Section 422.112(a)(7) (as recodified in the February 17, 1999 final rule) requires the establishment of written standards for specified areas of policy and procedures (coverage rules, practice guidelines, payment policies, and utilization management). This section is based on existing regulations and policies under part 417. We received two comments regarding this requirement.

Comment: In a comment cosigned by one hundred and fifty advocacy organizations, it was suggested that we amend the regulations regarding use of practice guidelines to specifically encourage or require contracting managed care plans to use Federally-developed practice guidelines, where appropriate.

Response: In general, we concur with the commenters that the use of Federally-developed practice guidelines, such as those produced by the Department of Health and Human Services, in the provision of services is a desirable objective. However, we believe that the commenter's suggestion that use of these guidelines be mandated by regulation would be inconsistent with section 1801 of the Act, which provides that the Medicare statute ''shall [not] be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided. * * *'' While we thus do not believe that mandating use of Federal guidelines is appropriate, we do encourage M+C organization health provider committees to explicitly consider such recommendations, particularly as they relate to care of enrollees with high-risk, complex care needs (such as those with HIV disease, cancer, *etc.*).

Comment: One commenter requested that we specify that the ''responsible health professionals'' be included in the development of practice guidelines and medical review criteria.

Response: We encourage M+C organizations to include the responsible health professionals in the development of such written standards. In some cases, however, a physician may be qualified to develop standards that apply to other health professionals, and it could impose an undue burden on M+C organizations to require that all responsible health care professionals always be consulted about standards. We therefore do not believe it would be appropriate to impose an absolute requirement that all health professionals always be included in developing written practice guidelines. We believe, however, that as a general matter, it is important that health care professionals such as physician assistants, advanced practice nurses, clinical psychologists and others integrally involved and knowledgeable regarding treatment planning and delivery, contribute to the process of standard development. We would thus expect that M+C organizations generally will consult with such professionals in developing guidelines in their areas, even though we are not imposing an absolute requirement for such consultation in all cases. For a further discussion of this issue, see the portion of the February 17, 1999 final rule dealing with provider participation rules.

g. Cultural Considerations (§ 422.112(a)(9))

Section 422.112(a)(9) (as recodified in the February 17, 1999 final rule) requires that services be 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. We received many comments regarding this section.

Comment: Many commenters asked for clarification regarding the term ''culturally competent'' and our expectations with respect to the implementation and monitoring of this requirement. While some commenters asserted that the cultural competence requirement would be too burdensome and should be deleted, most supported the requirement, but requested additional detail and guidance regarding its interpretation.

Response: In reviewing the comments received, there were several recurrent themes: (1) Widespread support of the general requirement that all health care services be provided in a culturally competent fashion; and (2) a need for us to clarify our expectations with respect to acceptable activities undertaken to achieve that goal.

We do not believe that changes to the regulation text regarding the definition of cultural competence are needed, other than to delete the reference in the regulations to mental and physical disabilities (as discussed below). However, in this preamble, we will attempt to provide further guidance on this issue. We also intend to incorporate the principles discussed here into the QISMC guidelines as we revise the QISMC cultural competence standards.

We believe that the delivery of culturally competent health care and services requires health care providers and administrative staff to possess a set of attitudes, skills, behaviors, and policies that enables the organization to function effectively in cross-cultural situations. Appropriate care delivery should reflect an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices and communication patterns of beneficiaries and their families to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups.

Activities to promote achievement of this objective fall under a variety of categories, including but not limited what we refer to as ''Organizational Readiness,'' ''Community Assessment,'' ''Program Development,'' and ''Performance Improvement,'' for example. Under Organizational Readiness, M+C organizations would conduct educational programs to increase the knowledge of their staff about the unique health care beliefs, attitudes, practices, and communication patterns of the populations served by their plan. Title VI of the Civil Rights Act (see 28 CFR § 42.405(d)(1)) specifically requires that M+C organizations provide assistance to persons with limited English proficiency, where a significant number or percentage of the eligible population is likely to be affected. These requirements may require the organization to take some of the following steps: assess the language needs of beneficiaries in their service area, provide sufficient access to proficient interpreters, and disseminate written policies on the use of interpreters. In addition, the M+C organization provider network should be capable of meeting the cultural, linguistic, and informational needs of the beneficiaries residing in the service area. Ideally, the racial and ethnic diversity of the service area would be reflected in the provider network and staff of the M+C organization. The literature has demonstrated that enrollees are more likely to seek and accept health care services when delivered by one of their own racial or ethnic group. The M+C organization must ensure that all employees have received education regarding the importance of providing clinically competent and culturally appropriate services.

Community Assessment entails conduct of a market assessment to identify the specific health care needs of the beneficiary population as they relate to enrollee groups' health problems (for example, some diseases are ethnically and genetically linked). Using existing and secondary data resources, organizations would collect data to the extent necessary to identify any special culturally-based health care needs among their beneficiaries. Program Development would entail implementation of formal programs and culturally sensitive patient education projects that reduce and eventually eliminate cultural, linguistic, and informational barriers known to deter or discourage health-seeking behavior.

Finally, Performance Improvement would entail addressing an identified need or opportunity for improvement, either through a quality improvement project or other formal program that seeks to resolve undesirable differences in utilization of services and outcomes of care across all relevant racial, ethnic and cultural groups served by the managed care organization.

The goal is to promote quality health care services, ensure effective dissemination of information, and enhance consumer rights and protections by fostering a demonstrated commitment to and establishing a coordinated and integrated system for, cultural competence. This approach is consistent with other Federal initiatives and recommendations from the President's Race Initiative and from the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

As achieving this objective is a M+C program requirement, M+C organizations will be monitored for compliance in this regard. We have developed additional implementation tools to assist M+C organizations in meeting the cultural competency requirement, such as operational specifications for five initial test measures and further steps which could be taken to improve, test, and expand on enrollee, disparity and standard-based inventories. The specifications for the five initial measures were developed based upon the recommendations of an expert panel and would require no new data collection on the part of the M+C

organization. We will soon be offering these measures to M+C organizations for use in their QAPI projects.

Finally, ensuring culturally competent care is congruent with our commitment to being a prudent purchaser of health care services. A growing body of knowledge demonstrates that when care is provided in a clinically competent and culturally appropriate fashion, it is more readily understood and accepted by the patient. As a result, patient compliance with treatment is enhanced, outcomes are improved, and health care costs and expenses are reduced as a result of diminished morbidity and mortality.

Comment: One commenter pointed out that physical and mental disabilities are unrelated to cultural competence issues. The commenter stated that including a reference in § 422.112(a)(9) to individuals with physical and mental disabilities was insensitive and inappropriate, noting that such disabilities are not a ''culture''.

Response: We believe that the principle objective underlying the requirement to provide services in a culturally competent manner is to address unique racial and ethnically-related health care concerns. Thus, we agree with this commenter, and are deleting the relevant language. We note that the special concerns and rights of individuals with physical or mental disabilities are addressed elsewhere in the M+C regulations (for example, under §§ 422.110(c) and 422.502(h)(1)(iii)).

Comment: One commenter believes that Federal law prohibits providing material below high school reading level.

Response: We were unable to locate any statutory citation in support of the commenter's view, and none was provided by the commenter. We believe that the commenter is mistaken that materials at a reading level below high school cannot be provided. Market research has shown that the majority of Medicare enrollees are able to most effectively comprehend the complex issues addressed in our literature when the information is targeted for those at a 4th–6th grade reading level. The Medicare Handbook accordingly is geared for individuals at precisely that level. Therefore, we believe that our current approach is both appropriate and well-justified.

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

Consistent with section 1852(h) of the Act, § 422.118 requires M+C organizations to establish procedures that safeguard the confidentiality and accuracy of enrollee records that identify a particular enrollee, including medical documents, administrative documents, and enrollment information. The regulations specify that information from these records may be released only to authorized individuals. Each M+C organization must establish procedures for complying with the confidentiality standards, including policies governing access to information within the organization as well as when and how information may be disclosed outside the organization without enrollee authorization. Additionally, the M+C organization must maintain accurate records and ensure timely access for enrollees who wish to examine their own records.

The M+C organization must abide by all applicable State and Federal laws regarding confidentiality and disclosure of health information and any other information about enrollees. In the existing regulations, ''mental health records'' are mentioned separately as subject to this requirement. However, because mental health records clearly constitute a subset of the other health records specified at § 422.118 (that is, ''medical records, health information, and any other enrollee information''), we are revising the regulations via this final rule to eliminate the redundant separate reference. This has no effect on the substance of the requirement.

Comment: Several commenters have suggested that the industry needs one Federal standard for confidentiality, especially in light of the fact that State confidentiality laws would not be preempted unless they conflict with Federal requirements. One commenter stated that there thus could be 50 different sets of patient confidentiality standards.

Response: The M+C regulations are not the appropriate vehicle for establishing the balance between State and Federal confidentiality laws. This issue is under discussion in Congress, which is a more appropriate venue for making this determination. Further, because Federal standards for confidentiality and privacy of individually identifiable health information have recently been proposed by the Secretary (as discussed in some detail below), and because M+C organizations will be required to comply with those regulations once they are finalized, we have chosen not to make substantive changes in the existing M+C confidentiality regulations at this time. In the interests of clarification, however, we have made some technical changes in the existing requirements, including reorganizing them to (1) promote consistency with the confidentiality requirements under other Federal health care programs (such as Medicaid) and (2) emphasize the importance of applicable Federal and State laws, while still ensuring that the privacy of M+C enrollees' health information is safeguarded in the absence of other applicable laws.

Pursuant to Section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191), the Secretary of Health and Human Services was directed to promulgate regulations on the confidentiality and privacy of individually identifiable health information if confidentiality legislation governing electronic health information was not enacted by August 20, 1999. Such legislation was not enacted, and the Secretary published a notice of proposed rulemaking, Standards for Privacy of Individually Identifiable Health Information, in the **Federal Register** at 45 FR 160, *et seq.*, on November 3, 1999. (This proposed rule is available at the Administrative Simplification web site, http://aspe.hhs.gov/admnsimp/). As proposed, these regulations would apply to health information that has been maintained or transmitted electronically, or held by health plans, health care providers who engage in certain electronic transactions, and health care clearinghouses. M+C organizations would be considered health plans for the purposes of the proposed privacy regulation. The proposed rule would establish detailed standards for the use and disclosure of electronic health information.

Comment: Several commenters suggested that we develop procedures regarding the maintenance of confidentiality of patient records, and have said that these procedures should be provided to the beneficiary.

Response: As noted above, in light of the pending privacy regulations, we are not imposing any additional requirements here. The Secretary's proposal would require health plans (including M+C organizations) and other covered entities to develop procedures for maintaining the privacy of health information and to inform patients and enrollees of their confi dentiality practices.

Comment: Several commenters asked for clarification of preamble language at 63 FR 34991, which they read to preclude M+C organizations from sharing patient information with outside contractor claims administrators without individual patient consent.

Response: The M+C regulations are not intended to prohibit the sharing of patient identifiable information within an M+C organization or between the

organization and its contractors for the purposes of payment, treatment or coverage decisions. Thus, an M+C organization may circulate such information within the organization, and externally, to the extent that such information is needed to coordinate or bill for the care of an M+C enrollee. However, M+C organizations generally are prohibited from selling or circulating patient identifiable data to outside organizations or entities that are not involved in payment, treatment, or coverage decisions, without specific authorization from the enrollee or an enrollee's authorized representative.

Comment: Several commenters asked us to specify that patient data may be shared for bona fide medical research, and to limit the extent to which patient identifiable information could be released for research purposes. One commenter asked for clarification as to whether information can be shared in the event of a court order or subpoena.

Response: As discussed above, we are not expanding on the existing M+C confidentiality requirements to address specific issues here, such as to whom and under what conditions release of patient identifiable information is authorized. To the extent that M+C organizations have proper safeguards in place and to the extent that State law authorizes the release of such information, this section of this regulation does not bar the use and disclosure of records for medical research. Section 422.118(a) expressly states that medical records may be released in accordance with ''court orders or subpoenas.'' The Department's proposed privacy regulation would set forth specific standards for disclosing information in both of these situations, and when that regulation is finalized, M+C organizations will be permitted to disclose information only in accord with those standards. In the interim, M+C organizations could voluntarily use those proposed privacy standards as a guide in formulating their policies and making disclosure decisions.

13. Information on Advance Directives (§ 422.128)

Advance directives are documents recognized under State law, signed by a patient or his/her authorized representative that explain the patient's wishes concerning a given course of medical care should a situation arise when he or she is unable to make these wishes known. The M+C organization is legally responsible for providing enrollees with information on their rights under State law to establish advance directives, and ensuring that advance directives are documented in a prominent part of the beneficiary's medical record. The M+C organization is permitted to contract with other entities to furnish information concerning advance directives requirements. The M+C regulations retain for M+C organizations the requirements that applied to HMOs and CMPs under part 417, which state an HMO must maintain written policies and procedures concerning advance directives as defined in § 489.100 with respect to all adult individuals receiving medical services by or through HMOs.

Comment: Commenters asserted that M+C organizations should not be responsible for obtaining or documenting the existence of an advance directive, and that organizations should ensure that ''responsible health care entities educate patients and document the existence of advanced directives.'' The commenters stated that an M+C organization cannot reasonably be held responsible for documenting whether an individual has elected an advance directive because the chart is in the control of the primary care physician.

Response: Our position that an M+C organization should be responsible for obtaining and documenting the existence of advance directives is consistent with the requirements of both State law and the Patient Determination Act of 1991, which we expanded upon in our final rule on June 27, 1995 (42 CFR § 489.100). Both the Act and the regulations include managed care organizations among the entities responsible for obtaining and documenting advance directives information. The BBA made these same standards applicable to M+C organizations.

Comment: A commenter asked for clarification as to what we will accept as evidence of best efforts and reasonable plan oversight. Another commenter suggested we should require M+C organizations to submit and receive approval on all advance directive documents. This commenter feared (and alleged that there is proof) that an M+C organization might lead beneficiaries down a path of less care in times of greatest need, and that advance directives could be used by an organization to coerce a beneficiary to forego care.

Response: The M+C advance directive requirements, which fee-for-service providers have been following for some years, are guidelines which refer to State law. Therefore, M+C organizations must comply with the advance directive requirements of the States which they serve, and we cannot give detailed guidelines as to what constitutes best efforts in each State. We believe the Medicare regulations give provider entities and States a great deal of flexibility, and we are prepared to work with them on specific entities.

Regarding the commenter's concerns about possible encouragement of inappropriate underutilization as the result of advance directives, we believe that the monitoring process will prevent and/or identify abuses of advance directives. For example, the M+C contractor interim monitoring guide states that an organization's policies must promote enrollee understanding of their conditions and facilitate the development of mutually agreed upon treatment goals. We have stated in QISMC and OPL 98–72, that with respect to advance directives, the M+C organization must meet several criteria, including that it may not make treatment conditional or otherwise discriminate on the basis of whether an individual has executed an advance directive. Underutilization patterns should be revealed by other aspects of the monitoring process, and, with regard to advance directives specifically, we are exploring the possibility of developing further monitoring criteria.

D. Quality Assurance

1. Overview

The quality assurance requirements for M+C organizations were addressed in subpart D of the June 26, 1998 interim final rule. These requirements implement and are based on the provisions of section 1852(e) of the Act. Further, they incorporate the requirements of section 1851(d)(4)(D) of the Act, which provides that the information made available to Medicare beneficiaries for plan comparison purposes must include plan quality and performance indicators, to the extent available. Section 1852(e)(1) of the Act sets forth the general rule that each M+C organization must establish an ongoing quality assurance program, consistent with implementing regulations, for the health care services it provides to enrollees in the organization's M+C plan or plans. The remaining portions of section 1852(e) of the Act contain the required elements of the quality assurance program, requirements for external review, and provisions concerning the use of accreditation organizations to determine compliance with the quality assurance requirements.

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

Section 422.152 incorporates each of the explicit statutory requirements of

sections 1852(e)(1) and (2) and section 1851(d)(4)(D) of the Act. Section 422.152 also includes additional detail to clarify what an M+C organization must do to meet the statutory requirements. Sections 422.152(b) through (d) of the interim final rule set forth requirements that M+C organizations must meet with respect to M+C coordinated care plans and network MSA plans.

Section 422.152(c) requires that the organization: (1) measure and report its performance to HCFA using measures required by HCFA; and (2) for M+C coordinated care plans, achieve any minimum performance levels that may be established locally, regionally, or nationally by HCFA.

Section 422.152(d) establishes the requirements for performance improvement projects, beginning with the requirement that performance improvement projects focus on specified areas of clinical and nonclinical services. It also explains that we will set M+C organizational and plan-specific requirements for the number and distribution of these projects among the required areas. In addition, it authorizes us to direct an M+C organization to undertake specific performance improvement projects and participate in national and state-wide performance improvement projects. Section 422.152(d) reflects many of the provisions of section 1852(e)(2) of the Act.

In enacting the quality assurance provisions of the BBA, Congress recognized that not all of the quality assessment and performance improvement activities that are appropriate for a plan with a defined provider network would be appropriate for an M+C non-network MSA plan or an M+C PFFS plan. The requirements specific to these types of plans are addressed in § 422.152(e). (Note that, as discussed below and in section I.C of the preamble, section 520 of the BBRA amended section 1852(e) of the Act to apply the non-network plan requirements to PPO plans as well.)

In order to support the measurement of performance levels and the conduct of performance improvement projects, if applicable, M+C organizations offering all types of M+C plans must maintain a health information system that collects, analyzes, integrates, and reports data. This requirement is covered at § 422.152(f)(1). Section 422.152(f)(2) requires that for each M+C plan an M+C organization offers, it has a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the quality assessment and performance improvement program strategy with respect to services under that plan.

Comment: A number of commenters asserted that the quality assessment and performance improvement (QAPI) requirements will be difficult for M+C organizations offering M+C plans with loosely organized provider networks to meet, and will discourage such organizations from participating in the M+C program. In particular, commenters were concerned that the QAPI requirements will deter organizations from offering MSA plans, PFFS plans, and PPO-type coordinated care plans. One commenter explained that organizations offering non-HMO plans cannot require physicians to track outcomes for these plans because the organizations do not have contracts with the physicians, making data collection and reporting infeasible. Four commenters specifically addressed the challenges facing PPOs in producing performance data and influencing provider practice patterns as required to demonstrate performance improvement. Two commenters complained that it is not appropriate to require reporting of all clinical performance indicators from the ''Healthplan and Employer Data and Information Set'' (HEDIS) in the case of a broad access PPO-type coordinated care plan. These and other commenters suggested that we instead establish quality standards that account for variation in organization capabilities.

Response: The BBA recognized that the structure of health plans has a direct impact on the degree to which the organizations that offer them can reasonably be expected to directly affect the health care services provided to their enrollees. As a result, the M+C statute and interim final regulations, as well as guidance implementing these provisions, have been tailored to the varying structural differences and associated capabilities of M+C organizations. As discussed in section I.C of this preamble, section 520 of the BBRA amended section 1852(e) of the Act to revise the quality assurance requirements for PPO plans. Consistent with the commenters' concerns, the quality assurance requirements for PPO plans are now the same requirements that apply to non-network M+C MSA plans and M+C PFFS plans. Thus, while PPO plans are still considered coordinated care plans, they are treated differently than other coordinated care plans for the purposes of the M+C quality assurance requirements of § 422.152, in recognition of the fact that their provider networks are subject to a lesser degree of control and accountability. The result is that M+C organizations are no longer required to conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the QAPI requirements that apply to all plans, such as those relating to health information and program review. We are revising § 422.152 to implement these changes.

Section 520(a)(3) of the BBRA defined a PPO plan as an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization. This definition is being added to the regulation at § 422.4.

Comment: A few commenters addressed the costs associated with collecting and reporting QAPI data. They argued that the data required will add significant administrative costs to M+C organization operations, with two commenters contending that most of the patient encounter data required for quality improvement projects go beyond the claims data currently collected and processed by organizations and Medicare fiscal intermediaries. Another commenter suggested that because the data collection and reporting costs will be so significant, we should make decisions as to what information to require only after much deliberation. One commenter expressed concern that M+C organizations will pass along the costs of data collection and reporting to hospitals.

Response: While not all M+C organizations are accredited, the majority are either seeking or have already been granted accreditation by national bodies such as the National Committee for Quality Assurance (NCQA). For those organizations in particular, the collection and reporting of standard measures does not constitute a new activity as it is a condition of the accreditation process. In addition, many managed care organizations have been voluntarily conducting a variety of quality improvement projects over the years, although they may not have routinely reported on standard measures. Again, for these organizations, the process of identifying quality of care concerns, selecting a patient population for study, implementing an intervention and

collecting data on the outcomes of that intervention are not at all new. The quality improvement process under the M+C program is essentially comparable to current industry practice, with the slight addition of the requirement to report on specific types of indicators relevant to the condition in question. For these reasons, we do not believe that the data collection and reporting requirements established under the M+C regulations will impose unreasonable costs, and we believe that a great deal of deliberation has already gone into the establishment of these requirements (for example, the collection and reporting of HEDIS measures) at this time.

With respect to the issue of whether hospitals will be asked to bear costs associated with data collection, we do not expect these costs to be unreasonable, and we note that they are voluntarily assumed when the hospital decides to participate in the M+C organization's network.

Comment: A few commenters contended that the costs of implementing their QAPI programs would be excessive.

Response: We have given M+C organizations significant latitude in terms of designing their performance improvement projects, so that they can choose efforts that are relevant to their enrollees and that involve cost effective interventions To further reduce administrative and financial burden, M+C organizations may collaborate with entities such as the Peer Review Organizations (PROs) on their performance improvement projects.

Comment: Two commenters addressed the collection and reporting of HEDIS measures. These commenters were concerned that the HEDIS measures do not, in their view, adequately address the health issues of older adults in Medicare, and they do not track the experiences of people with chronic and disabling conditions.

Response: M+C organizations are required to report HEDIS measures for the purposes of §§ 422.152(c)(1) and (e)(1). Currently, the HEDIS measures offer the most comprehensive view of managed care performance available. We have been working with the Geriatric Measurement Advisory Panel to develop additional measures for people with chronic and disabling conditions. It is important to recognize that HEDIS is an evolving instrument, and as valid measures of other aspects of care are developed, they will be incorporated. For example, HEDIS 1999 added measures for cholesterol management after acute cardiovascular events, and HEDIS 2000 has added a measure to assess whether blood pressure was controlled among people with diagnosed hypertension. Additionally, Medicare will be requiring six measures for people with diabetes. Additions such as these, plus others that will be added as valid measures are developed, should address the commenters' concerns.

Comment: Two commenters suggested that we add other areas for standard measures in § 422.152(e)(1) for M+C PFFS and non-network MSA plans. These commenters believe that the information collected for these types of plans should be as consistent as possible with that collected for other types of M+C plans to allow for comparison among them. The commenters recommended that if certain types of data are unavailable for non-network M+C MSAs and M+C PFFS plans, a statement should be made available to beneficiaries explaining the lack of information.

Response: We agree with commenters that for purposes of plan comparison, reporting on standard measures should be as consistent across plan types as possible. Therefore, we are revising § 422.152(e) to specify that the standard measures on which reporting will be required for M+C PFFS plans, non-network MSA plans and now PPO plans will relate to the same areas to which the measures required for M+C coordinated care plans (other than the PPO plans) and network M+C MSA plans relate. As stated in the preamble to the interim final rule, no M+C organization will be required to report information to which it does not reasonably have access under a plan. Where data on particular measures are not reasonably available with respect to a given plan, organizations will be allowed to report ''not available.''

Comment: A number of commenters addressed the form and content of the required standard measures. One commenter asked that we develop core measures not just at the M+C plan level, but also at the provider and facility level. Another commenter asked that we develop core measures for high-risk, low-incidence conditions. Another commenter asked that we develop measures for all persons with disabilities under age 65 that are comparable to the senior health status data that are being collected for a sample of Medicare beneficiaries over 65 in Medicare managed care plans as part of HEDIS 3.0.

Response: Each of these suggestions has merit; however, we are taking an incremental approach to implementation with respect to the QAPI activities under the M+C program that includes working with private purchasers to expand the set of measures. We believe it is important to give M+C organizations time to adjust to the current standard measures before imposing further requirements. Our experience with the standard measures in place now will also be helpful in deciding whether additional measures are appropriate, and if so, which measures would be most effective.

Comment: Certain commenters asked that the standard measures we require be predictive of outcomes, and be established utilizing evidence-based medical research. One commenter asked that we establish a ''data dictionary'' that will give M+C organizations detailed and clear definitions of the required measures. Another commenter cautioned that the development of another set of core measures for M+C organizations will result in unnecessary duplication and lead to confusion if the measures are defined differently by accreditation organizations and by HCFA.

Response: As mentioned earlier, M+C organizations are required to report HEDIS data. The HEDIS measures are predictive of outcomes, are well defined, and are well established in the private sector. Our requirements may change in future years as the HEDIS instrument evolves and as other measurement instruments are developed.

Comment: One commenter asked what role, if any, JCAHO's ORYX performance indicators will have in meeting our data reporting requirements, and whether there would be duplication. One commenter asked that we consider the OASIS data set and OBQI system for home care (and eventually PACE) to be reasonable alternatives to HEDIS for managed long-term care plans.

Response: Again, our goals with respect to data management are to minimize burden and maximize effectiveness. We are working collaboratively with accrediting organizations like the JCAHO, with these goals in mind. The ORYX indicators are still in the developmental stage and, furthermore, since they focus specifically on hospitals, they cannot be used to measure much of the performance of managed care organizations. All home health agencies serving Medicare beneficiaries, whether in managed care or traditional Medicare, are required to provide information through OASIS. In general, we are not requiring managed long-term care plans to provide HEDIS information, with the exception of several demonstration sites. However, reporting requirements

for long-term care entities may change in the future.

Comment: A few commenters addressed our intention to consider historical plan and original Medicare performance data and trends when establishing minimum performance levels. One asked for clarification as to the standards we will use. Two objected to basing minimum performance levels on historical performance data and trends, explaining that many Medicare program requirements, including those related to access to services, emergency services and due process, are not ideal targets, but rather legal requirements under Federal law. The commenters were concerned that looking to historical performance might result in establishing a minimum performance level that is less than what the law requires.

Response: We agree with commenters that it would not be appropriate to establish minimum performance levels for aspects of care or service for which required levels of performance have already been dictated by regulation or statute. However, there are many measures of care, such as mammography or immunization rates, for which no mandated minimum exists. In these areas, it is useful to know what historical performance has been, because while we are interested in establishing minimum performance levels that motivate improvement, we want those levels to be achievable. At this time, the process for establishing minimum performance levels has not been finalized, but we expect that we will set the minimum at a percentile of previous performance, and revise the minimum year by year as overall performance rises.

Comment: A number of commenters objected to our intention to establish minimum performance levels. One commenter said that it would be inconsistent with our statement in the preamble to the interim final rule that we would not adopt a ''one size fits all'' approach to performance measurement. Another commenter, although not opposed to minimum performance levels, asked that we take into consideration variation in the model of delivery, such as network-model or group-model, when establishing the levels.

Response: We believe that it is feasible and in the best interest of Medicare beneficiaries to require that the quality of care provided by M+C organizations offering network plans meet minimum standards. This is an additional protection above making performance information available to beneficiaries for the purpose of plan selection. We believe that there would be a de facto requirement that organizations achieve minimum performance levels, even if there were no explicit requirement in the regulation. That is, even if the regulation required only that organizations report their performance on standard measures, we would still judge their performance by comparing it with some benchmark for the purpose of determining whether to take remedial action or continue contracting with the organization, which would have the same effect as applying a minimum performance level. We see no reason not to recognize this implicit requirement in the regulation.

As we stated in the preamble to the interim final rule, we are sensitive to the different structures of plans. We will consider the impact plan structure has upon the ability of an M+C organization to affect provider behavior. We will consider these issues when making our decisions regarding the standard measures for which it is appropriate to establish minimum levels of performance.

Comment: Two commenters addressed the possibility that some of the minimum performance levels HCFA establishes will be regional instead of national. One commenter objected to establishing non-national performance levels. The other supported the idea of establishing minimum performance levels with consideration for regional area variation.

Response: Because it is our intention to establish minimum performance levels that are meaningful as well as achievable, we must consider regional variation where it exists. It is our ultimate goal to have national minimum performance levels, but it may be necessary to move towards this goal incrementally by first establishing regional performance levels.

Comment: One commenter asked how we can require that M+C organizations meet minimum performance levels 1 year after the levels are established, if we recognize a 3-year cycle as the standard for performance improvement.

Response: The purpose of performance improvement projects is not to bring plan performance up to minimum performance levels, but rather to move it closer to national benchmarks. In most cases, we believe that plan performance would already surpass the ''minimum performance levels'' that we are now in the process of developing. An immediate intervention and not a lengthy performance improvement project would probably be called for if a plan offered by an M+C organization failed to meet a minimum performance level.

Comment: One commenter asked that we establish some minimum performance levels related to the care of persons with disabilities.

Response: As noted above, we are still in the early stages of identifying the measures for which minimum performance levels will be established. When we do, we will consider the commenter's suggestion.

Comment: A number of commenters objected to the possibility that we will nonrenew an organization's contract on the basis of its failure to meet minimum performance levels. Two of these commenters complained that any organization might fall short of a specific numerical standard because of random events beyond its control. As an alternative to nonrenewal, one commenter asked that we impose intermediate sanctions. Another asked that we not impose sanctions at all if an organization is making a good faith effort to meet the requirements. Some commenters suggested that we work with organizations to improve their performance in lieu of nonrenewal. In particular, one commenter recommended that we require organizations to participate in PRO-sponsored improvement projects when minimum performance levels are not met.

Response: As a value-based purchaser, HCFA has a responsibility to implement requirements that promote accountability on the part of M+C organizations. Although we have the authority to nonrenew an organization's contract for failure to meet quality assurance requirements, we have stated that in most instances we will first offer technical assistance and/or require corrective action plans. Intermediate sanctions are also within HCFA's prerogative.

Comment: One commenter asked that we reward an organization that shows demonstrable improvement in the health status of beneficiaries by giving it a bonus payment such as a percentage of its capitation rate. The commenter contended that a bonus payment is necessary to ensure that organizations are equitably reimbursed, since under a risk-adjusted ACR, organizations will receive lower payments for healthy enrollees.

Response: It is appropriate that an M+C organization receive lower payments for healthy enrollees because the cost of caring for them is proportionately lower. Because an organization that successfully completes a performance improvement project will have reduced the incidence of negative

outcomes and the expenses associated with them, any reduction in Medicare payment as the result of risk adjustment should not adversely affect the organization's profitability. Indeed, the successful completion of performance improvement projects should bolster an organization's business. The information that an organization has successfully completed performance improvement projects will be shared with potential enrollees, and should help its market position.

Comment: One commenter asked that we establish public recognition awards at the state and national level for innovative and successful organization performance improvement projects.

Response: Although there has been much discussion around the issue of establishing performance incentives, we currently have no plans to develop an awards program for M+C organizations. However, they may wish to consider promoting their excellent performance themselves through the media and their marketing materials.

Comment: One commenter requested that we specify the nature and form of the documentation and data that organizations must make available to demonstrate compliance.

Response: With respect to monitoring compliance, we have completed the design of a revised M+C interim monitoring tool that follows the structure of both the M+C regulations and the Quality Improvement System for Managed Care (QISMC) Interim Standards and Guidelines (which provide interpretive guidance for both subpart D standards as well as standards relating to the delivery of health care and enrollee services). The monitoring tool specifies the documentation and data that we will look for in our compliance monitoring.

Comment: Many commenters emphasized the importance of collaboration between the managed care industry and HCFA as implementation of the regulation proceeds. One commenter recommended that we establish a formal advisory counsel composed of representatives of industry associations. Other commenters urged that we consult with physicians and accreditation organizations in selecting standard measures and setting minimum performance levels.

Response: Since we began developing QISMC 4 years ago, we have been engaged in an ongoing dialogue with representatives of the managed care industry, advocacy groups, various health care providers, and state regulatory bodies to ensure broad involvement in the document development process. We recognize the value of this type of collaborative exchange and intend to continue this activity.

Comment: A number of commenters asked that we coordinate our quality improvement efforts with those of the private sector, particularly NCQA. One commenter was concerned that we are establishing an independent system of quality improvement requirements rather than building upon the collaborative public-private efforts that we have participated in, such as HEDIS.

Response: The QAPI requirements established in the regulation build upon a number of the public-private efforts mentioned by commenters. For instance, as noted above, the standard measures on which M+C organizations now are required to report to comply with § 422.152 (c)(1) and (e)(1) are the HEDIS measures; we have been collaborating with private sector group purchasers since 1994 to develop these measures, and we recognized the value of incorporating them into our QAPI strategy.

Comment: One commenter questioned HCFA's authority to require that performance improvement projects achieve ''significant'' improvement, pointing out that the statute requires only that M+C organizations ''take action'' to improve quality. Another commenter questioned our authority to impose as much structure on performance improvement projects as we have, asserting that by requiring that projects focus on specified areas of clinical and nonclinical services, and directing M+C organizations to undertake specific projects among the required areas, we have exceeded our statutory mandate.

Response: We believe that our responsibility as a value-based purchaser and duty as a trustee of Medicare funds includes requiring that M+C organizations provide high quality services, and the statute recognizes this responsibility. For instance, section 1852(e)(2)(A)(vi) of the Act requires that M+C organizations ''provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care provided under this part'' (emphasis added). Requiring that M+C organizations conduct projects that achieve improvement that is significant and sustained over time is one way for us to meet our obligation under the statute. We also believe that the language quoted by the commenter, requiring that M+C organizations ''take action'' to improve quality can be reasonably interpreted to require that improvement actually occur. A requirement to ''take action'' to improve quality clearly suggests that the M+C organization have an objective in mind in doing so. We believe that a significant improvement is a reasonable and logical objective for ''action'' to improve quality. While the structure imposed in the interim final rule is flexible, and grants M+C organizations broad discretion in many areas in designing their QAPI programs, we believe that some structure is necessary in order to ensure that the projects will be meaningful for Medicare enrollees. We believe that the M+C quality assurance requirements represent a reasonable interpretation of requirements in section 1852(e), and a reasonable exercise of our broad authority under section 1856(b)(1) to establish M+C standards by regulation.

Comment: Two commenters addressed the issue of the number of performance improvement projects M+C organizations are required to perform. One commenter explained that it is difficult to conduct valid and reliable performance improvement projects with a small number of participants, and asked that the number of required performance improvement projects be proportionate to the size of the plan. The second commenter asked that we limit the number of required performance improvement projects to one new project per year, and limit the number of projects required to be underway at any one time to four.

Response: QISMC requires that M+C organizations initiate two performance improvement projects a year. Given that projects are allowed 3 years in which to achieve significant improvement, once QISMC is fully implemented an organization will not need to have more than six projects underway at any one time: two in the initiation stage, two in the intervention stage, and two in the completion stage. We believe this is a reasonable burden for both large and small plans. Smaller plans are not at a disadvantage because organizations are not required to show statistically significant improvement on every topic affecting a small population. Statistical significance is only required in instances when an organization chooses to sample its population. For small populations, an organization has a strong incentive to measure the results of its project on the entire affected population, because, when the organization's project targets the entire affected population, only a 10 percent reduction in the ''performance gap'' is required, not statistical significance. For example, if an organization chose to study a condition that affected only 100 enrollees, and its current performance was 50 percent, to achieve a 10 percent

reduction in the performance gap it would have to demonstrate that it improved the care to five enrollees. If the organization measured the results of its project on a sample of the population, it would have to show improvement for many more enrollees to achieve statistical significance.

We are aware that a number of technical issues relating to improvement project design remain to be resolved. For instance, we must decide what to do when a project population is so small that measurement of the results of the project is not meaningful or what to do if the baseline performance is so high that the sample size required for statistical significance is very large. We intend to resolve these issues in an updated version of QISMC.

Comment: One commenter pointed out that a significant period of time will be required following the intervention before improvements are observed at the population level, and the commenter was concerned that there appears to be no allowance for this time period.

Response: QISMC allows for such a time period. As mentioned earlier, QISMC does not require a performance improvement project to achieve significant improvement until the end of its third year. Experience has shown that there are many opportunities for an intervention to yield results within three years. QISMC makes an even more generous allowance for more complicated projects.

Comment: Many commenters addressed the requirement that performance improvement projects achieve significant improvement. The majority of these commenters opposed the 10 percent standard for reduction in the performance gap. As discussed above, this standard (which is specified in QISMC) requires that the organization reduce by at least 10 percent the percentage of cases in which the quality indicator that measures its performance in the project's focus area is failed. Several of these commenters complained that the standard is not realistic. One commenter explained that in many data situations, administrative claims may not be complete or be reliable to allow for a meaningful evaluation. Other commenters offered other examples of impediments to achieving significant improvement, including regional variation of utilization and imperfect provider and enrollee compliance. One commenter asked us to recognize that enrollee lifestyle choices, diet, and compliance with medical treatment will impact upon an organization's ability to achieve significant improvement in health status. Another commenter asked that we recognize that it is the provider who actually has control of the care process. For these reasons, these commenters asked that we not hold organizations responsible for achieving significant improvement, but for initiating activities that, if followed by enrollees and providers, are likely to improve the health status of enrollees.

Two other commenters suggested that we take a different approach. They recommended that in lieu of requiring a 10 percent reduction in the performance gap, we follow NCQA's approach and require that managed care organizations provide meaningful evidence that they are making improvements in clinical care and service. One of these commenters suggested that to define ''meaningful,'' we consider whether the improvement resulted in a better outcome for the enrolled population, whether it is attributable to the organization's actions, and whether it affects high-volume, high-risk, and/or high-cost conditions or services. The commenter added that this would be more effective in encouraging complex or innovative projects that have a high risk of failure but that offer significant potential, a comment that was echoed by other commenters who were concerned that a rigid numerical significant improvement standard would encourage organizations to pursue performance goals that are easily attainable.

A third alternative to the 10 percent standard was submitted by a commenter concerned that certain characteristics of the Medicare population will complicate the achievement of significant improvement. This commenter pointed out that the elderly population is at a higher risk of illness and disease, and that a greater percentage of Medicare beneficiaries have multiple disabilities and comorbidities, which results in greater instability in their health status. This commenter recommended that we require only that organizations establish measurable goals for their interventions, and that we evaluate organizations on their ability to demonstrate the strength of their interventions and performance gains over time. Further support of this approach was offered by an additional commenter who was concerned that the 10 percent standard would encourage risk selection and discourage the enrollment of sicker beneficiaries with more complex health issues.

Response: We chose to make a 10 percent reduction in the performance gap the standard because we believe it is necessary to have an objective standard to assess whether an organization has achieved significant improvement in health care quality, and because we have observed much higher percentage increases in performance than 10 percent. Therefore, 10 percent is a reasonable benchmark to use based on our observation of past organizational performance in improving health care quality. Nationally recognized standards that do not incorporate objective standards for determining if quality improvement has occurred have been criticized as being subjective and lacking in reliability and validity. We have learned from the lessons of such standards, and based on the strong evidence from the Medicare and Medicaid programs, have elected to implement a standard that is consistent with our knowledge of quality improvement in both the Medicare and Medicaid programs.

The 10 percent improvement standard is the best way we have at present to ensure that projects are meaningful, and that they translate into positive changes in enrollees' lives. In the long run, in order to mitigate the incentive to choose trivial projects, we will attempt to devise a way to measure and report the relative contribution of each performance improvement project, taking into account such factors as the number of enrollees affected by the improvement and the impact the improvement actually has upon enrollee health and satisfaction. Such a system is years away, but we have taken a first step towards it by starting to develop a common vocabulary for performance improvement projects.

As for the comment that requiring a 10 percent reduction in the performance gap will encourage risk selection, we believe that there exist numerous opportunities for M+C organizations to improve performance on measures relating to the care of sicker enrollees with complex health care needs. In fact, we believe the improvement potential associated with the care of sicker enrollees exceeds that associated with the care of healthier enrollees. In addition, the introduction of risk-adjusted payments to M+C organizations should further discourage risk selection.

Comment: One commenter was concerned that allowing an organization to set its own performance goals would be a disincentive to undertaking any project that might ''lower its status'' with us or with enrollees.

Response: We believe the commenter is referencing the QISMC standard that addresses projects in which data are collected on the entire population to be studied (that is, in which a census is involved). QISMC specifies that, in the case of a project developed by the

organization itself, significant improvement is demonstrated by achieving a benchmark level of performance that is defined in advance by the organization. However, the standard goes on to say that the organization's benchmark must reduce the opportunity for improvement by at least 10 percent, which is the same standard for HCFA specified projects. So, the commenter's concern is unfounded because the objective nature of the benchmark ensures an acceptable level of effort on the part of the organization.

Comment: One commenter noted that when multiple interventions are employed, they all would have the potential to bring about improvements in outcomes. The commenter asked how we will determine which intervention was responsible for the observed change.

Response: It is only necessary that an M+C organization show that its improvement was the result of its own actions and not chance. It is not necessary to determine to which of its interventions the improvement should be attributed, although we expect that the M+C organization will want to do so for its own management purposes.

Comment: A number of commenters addressed the issue of required participation in national or statewide performance improvement projects. Half of the commenters supported the idea of such projects. One commenter asked that we consider the identification and diagnosis of persons with Alzheimer's as a possible national performance improvement project, and another asked that we require organizations to participate in national improvement projects pertaining to persons with disabilities.

One of the commenters opposed to national or statewide performance improvement projects complained that mandated projects will detract from the flexibility organizations need to best care for their enrollees. This commenter pointed out that many organizations have already conducted projects addressing flu and pneumonia; consequently, it would be a poor use of resources for them to be required to conduct another such project. Another opponent argued that national or statewide performance improvement projects may prove to be inconsistent with local market considerations.

Response: In response to these concerns, we included in OPL 98–72 a statement that an M+C organization is not required to participate in the HCFA-sponsored national diabetes project but may, at its discretion, conduct another diabetes-focused project that utilizes the Diabetes Quality Improvement Program (DQIP) indicators, and meets the project requirements as outlined in QISMC Domain 1. For their second performance improvement project, M+C organizations were free to select a topic and focus area of their choice.

With respect to the concern that organizations may have already conducted projects addressing influenza and pneumonia, which have been selected as the national project topics for 2000, there are many aspects to the care and prevention of these diseases that organizations may not have fully addressed in previous projects that would lend themselves very well to further projects.

At this point, we have not selected national project topics beyond year 2000, but we will consider the care of enrollees with Alzheimer's and with disabilities when making future selections.

Comment: One commenter asked us how we will decide who must participate in national or statewide performance improvement projects.

Response: It is a contracting requirement for all M+C organizations offering coordinated care plans that they conduct a project addressing a topic that we have determined represents a national health care priority. At this time, although we have the authority to specify State-specific topics, we have not done so.

Comment: One commenter advocated that we explicitly include requirements in the regulation for organization participation in PRO-sponsored activities.

Response: There is no requirement that organizations participate in PRO-sponsored activities: there is only the requirement, as stated in QISMC, that one of the two performance improvement projects that an organization initiates per year relate to a topic and involve quality indicators chosen by us. The PRO is required to provide technical assistance on the national project (and on all other projects) if an organization requests it, but organizations are not required to work with the PROs on their projects. However, we expect that many organizations will choose to work with the PROs, because the PROs can provide clinical and biostatistical expertise; assistance in the design and conduct of projects; advice on sampling, data collection and analysis; and, review and analysis of project findings and interventions.

Comment: A few commenters opposed allowing organizations to select the topics of their performance improvement projects from within the specified clinical and nonclinical areas. One commenter was concerned that organizations will choose the disease with which they are most familiar, thereby neglecting low-incidence diseases. Two other commenters were concerned that organizations will avoid undertaking projects in areas that highlight poor performance or that relate to discrete, but vulnerable, cohorts of patients, such as those with disabilities or rare conditions. These commenters recommended that as alternatives to allowing organizations to select their own performance improvement project topics, we standardize the topics across all organizations; we standardize the topics across all organizations within a given service area, selecting the topics on the basis of the morbidity and mortality measures for seniors in the service area; or, we select the topics for each individual organization on the basis of needs identified through an annual onsite audit.

Response: We believe it is essential that M+C organizations be allowed to target at least some of their performance improvement activities to those areas they determine would be of most benefit to their enrollees. Balanced against this opportunity is the obligation to address areas that we consider to be of universal importance to the Medicare population. Between organization-specific projects and national projects, we expect that all significant improvement opportunities can be addressed. If upon review we find that an organization's performance in a particular aspect of care or service is poor and the organization has repeatedly failed to initiate action to improve it, we have the authority to direct that the organization do so.

Comment: Two commenters asked that we expand the required clinical focus areas. One asked that we include high-risk, low-incidence conditions and populations, and the other asked that we include laboratory and other diagnostic services.

Response: High-risk, low-incidence conditions are subsumed within the high-risk focus area. Although issues selected for study generally should affect a significant portion of the organization's Medicare enrollees (or a specified subpopulation of enrollees), organizations should target infrequent conditions or services if data indicate they warrant study. As for laboratory and other diagnostic services, they could fall under a number of the current focus areas. Therefore, we do not find it necessary to add to the current list of focus areas.

Comment: One commenter asked how ''high-volume services'' and ''high-risk services'' are defined.

Response: We did not provide a definition of ''high-volume'' or ''high-risk'' services for several reasons. First, it was our intention to allow organizations discretion in developing their own definitions and criteria, consistent with the needs of their organizations. For the most part, both terms have commonly understood meanings, and therefore, we did not think they required explanations.

Since M+C organizations will be monitored on whether they conduct QAPI projects addressing these focus areas, and to respond to the request for further information, we suggest that organizations consult the QISMC Interim Standards and Guidelines (specifically, Standards 1.3.4.5 and 1.3.4.6) for further guidance as to our expectations. In selecting a quality improvement project focusing on high-risk or high-volume services, we note that the focus does not necessarily have to be on a clinical condition per se, but on a service and how it may be improved. In HEDIS 99, Volume 2, Technical Specifications, there are several clinical conditions for which suggested indicators are provided in assessing ''High-Occurrence/High-Cost'' DRGs. Congestive heart failure, angina pectoris, chronic obstructive pulmonary disease and other conditions which place the enrollee at risk of increased morbidity or mortality would certainly constitute appropriate conditions under the ''high-risk'' category. An organization may assess experiences of care received from specialized centers inside or outside of its network, such as burn centers, transplant centers, or cardiac surgery centers. With respect to ''high-volume'' services, an M+C organization may target quality improvement in a frequently performed surgical procedure, or across different surgical or invasive procedures.

Comment: One commenter asked how ''clinical area'' is defined. The commenter asked whether it is a clinical condition, such as diabetes, or, an opportunity within a clinical condition, such as the number of glycohemoglobin blood tests performed for diabetic enrollees.

Response: The answer is that it can be either. Standard 1.3.4 of the QISMC Interim Standards and Guidelines provides additional detail regarding the specific focus areas. It should be noted that in choosing the areas, we avoided a disease-specific focus, opting instead to define them in a broad sense and therefore allow M+C organizations maximum discretion in determining where their specific project might best fit. For example, performance of dilated eye exams in the diagnosis and treatment of diabetic retinopathy might best be placed under the clinical focus area of Secondary Prevention of a chronic condition (Standard 1.3.4.2), as it serves to identify and potentially control a diabetes-related condition.

Comment: One commenter recommended that the clinical area of ''continuity and coordination of care'' include an evaluation of whether the appropriate mix of services is being furnished, and of whether there is adequate access to specialty care.

Response: These are aspects of continuity and coordination of care that organizations may choose to select as project topics. However, we will not require these as topics because such specificity might serve to unduly restrict an organization in its efforts to identify those aspects of care and service most in need of a formal performance improvement project. General requirements and concepts relating to continuity of care and access to services are found at § 422.112.

Comment: Two commenters addressed the need to coordinate performance improvement projects. The first commenter asked that in areas where there are multiple M+C organizations, we require that organizations coordinate their selection of project topics so as to minimize the data gathering and reporting burden that will be imposed on hospitals. The second commenter asked that we allow M+C organizations serving in more than one region to partner in collaborative projects, perhaps under the aegis of a national organization such as the Blue Cross Blue Shield Association. This commenter also asked that we permit collaborative projects through the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality) or professional organizations/societies.

Response: We agree with these commenters. We have consistently stated that we encourage M+C organizations to collaborate across plans, with other organizations, and within their States and regions to promote reduction of administrative burden and to enhance the general applicability of study findings. Certainly, the PROs may serve in a convener/collaborator role with respect to promoting such activity. To further this effort, we co-sponsored a National Diabetes Conference in conjunction with the American Association of Health Plans and the American Diabetes Association to provide additional guidance and materials which may be used uniformly by M+C organizations in the conduct of their diabetes performance improvement projects. We expect other ad hoc collaborations to occur in the future.

Comment: One commenter asked that we encourage M+C organizations to work with their contracted providers, as well as other health care professionals and associations, in developing their performance improvement projects.

Response: As indicated in the previous response, we recognize the importance of collaboration. To that end, QISMC requires that an organization allow its providers (and enrollees) an adequate opportunity to provide input regarding the selection and prioritization of performance improvement projects.

Comment: Two commenters addressed the requirements relating to health information. One commenter claimed that without uniform collection methods, it is unreasonable to require organizations to ensure that the information they receive from providers of services is reliable and complete. This commenter believes that some organizations, especially those offering non-network M+C MSA plans and M+C PFFS plans, will be unable to meet this requirement. The other commenter asked that we clarify what level of organization oversight will be necessary for an organization to meet the requirement that it ensure the reliability and completeness of the information it receives from providers of services.

Response: To promote continuous quality improvement, it is essential that collection and management of meaningful statistical information be seen as means to that end. Statistically valid data that assist in explaining patterns of care and in justifying variations in care are as valuable as data that identify problems in the provision of care. Without good data, we cannot make scientifically defensible or financially meaningful health care decisions. Therefore, collection of appropriate and accurate data is both good science and good business. To the extent that a particular M+C organization currently is unable to meet these requirements, we believe that the answer is not to change the requirements, but for the organization to make the changes necessary to be able to meet these requirements.

As for oversight of the health information system, the organization is ultimately responsible for determining at what level within its structure there will be oversight which ensures the reliability and completeness of information received from providers.

Comment: One commenter suggested that we require that organizations, in processing requests for initial or continued authorization of services, follow written policies and procedures that reflect scientifically sound and evidence-based medical guidelines, rather than reflect current standards of medical practice. The commenter contended that not all current standards reflect the best medical practices.

Response: Historically, current standards of medical practice have been the benchmark for care provided by managed care organizations. The purpose of using these standards has been to ensure that the quality of care delivered through managed care organizations was comparable to, or better than, that provided by fee-for-service entities. During the last decade, advances in quality measurement and the development of practice guidelines and improved mechanisms for assessing utilization management have been adopted as standard practice in many organizations.

We agree with the commenter that in processing requests for authorization of services, the organization should follow policies and procedures that are based on scientifically sound and evidence-based guidelines. Nevertheless, we recognize that in instances where such guidelines do not exist, individuals making authorization determinations may need to refer to current standards of medical practice. In those cases, an M+C organization must have in place written policies and procedures to ensure that all coverage decisions are designed to provide care in the safest, most beneficial and cost-effective fashion.

Comment: One commenter asked that we require organizations offering M+C PFFS and non-network MSA plans to use written protocols for utilization review, and to provide their utilization review findings to enrollees and providers at least annually.

Response: Section 1852(e)(2) of the Act does not require that M+C PFFS and non-network MSA plans (and under the BBRA, PPO plans) establish written protocols for utilization review. To the contrary, section 1852(e)(2)(B)(ii) imposes requirements ''insofar as'' an organization provides for such protocols, clearly contemplating that some M+C organizations may choose to do so, and some may not. Thus, we do not believe that such a requirement would be consistent with statutory intent.

Comment: Four commenters were concerned about the lack of an explicit requirement that organizations take immediate remedial action when individual quality problems are found. Two commenters explained that performance measurement and performance improvement projects result in the collection of data that can be used to establish baselines and track performance over time, but neither serves as a mechanism for ensuring that real problems experienced by current enrollees are systematically identified and corrected. These commenters recommended that we require that organizations ''take appropriate remedial action whenever inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.''

Response: Clearly, an essential component of any effective ''ongoing quality assurance program'' as required under section 1852(e) of the Act is the correction of identified problems. QISMC already requires that an organization correct significant systemic problems that come to its attention through internal surveillance, complaints or other mechanisms. As the commenters suggested, we are adding a modified version of this requirement under new § 422.152(f)(3) to require correction of all identified problems, because it is our intention that an organization take appropriate remedial action whenever a problem comes to its attention. Although § 422.152 generally focuses on systemic improvement, we believe it is appropriate to make our intention explicit. In monitoring this requirement, HCFA reviewers will operate by a ''rule of reasonableness,'' taking into consideration factors including but not limited to the severity and prevalence of the complaints and the level of effort demonstrated by the organization in seeking to resolve the matter.

Comment: Many commenters addressed the relationship between QISMC and the M+C regulations. Two commenters asserted that it was premature to model the regulation on the QISMC requirements, arguing that the QISMC requirements should be tested and evaluated before being applied to M+C organizations. These commenters asked that we scale back the quality assurance requirements until after they have been tested and evaluated, and if appropriate, restore them to the regulation using the normal notice and comment process. Two other commenters also recommended deleting the QAPI requirements of QISMC from the final rule, explaining that there are areas within QISMC that should be refined before they are implemented, such as the number and kinds of performance improvement projects that will be required.

Response: As we mentioned earlier, we have developed a cross-walk between the QISMC requirements and the NCQA accreditation requirements, which are currently considered the industry standard. For the most part, QISMC requirements are either identical to or consistent with NCQA requirements. Therefore, we are confident that our expectations have not outpaced the state of the art. Also, the HEDIS measures on which M+C organizations must report have already been fully tested and adopted by the managed care industry.

Finally, in response to concerns raised by managed care organizations regarding the potential burden imposed by the QISMC performance improvement project requirements, we significantly scaled back the number of required projects per year from nine required projects to only two per year. To assist M+C organizations further in this effort, we are currently developing model performance improvement projects and other implementation tools.

Comment: Two commenters addressed the time frame for QAPI program implementation. The first commenter recommended that the regulation reflect the transition policy found in the QISMC document, which allows organizations a period of time in which to build and refine their quality assessment infrastructure before their quality improvement projects will be expected to achieve significant improvement. The second commenter echoed the need for a long implementation time frame.

Response: Implementation policy is more appropriately handled through the issuance of operational policy letters and program manuals than through regulation. In addition, we have stated publicly that we will ''phase-in'' both implementation and enforcement of these requirements, in recognition of the fact that many organizations are still navigating the performance improvement learning curve.

Comment: A few commenters objected to the statement in the preamble to the interim final rule that we would not make public the results of an organization's performance improvement projects. One commenter complained that such a policy would be contradictory to our commitment to informed consumer choice. Another commenter challenged our rationale for withholding results, which was that releasing them might compromise enrollee confidentiality as they might involve enrollee-specific information. This commenter suggested that we

redact enrollee-specific information, or direct organizations to report information in ways that protect enrollee identities. Another commenter also supported the notion of releasing pertinent, non-confidential information about organization quality gleaned from performance improvement projects.

One commenter praised the policy we put forth in the preamble, explaining that providing the results of performance improvement projects to Medicare beneficiaries could undermine the legal confidentiality of peer review activities and could make such information reported outside the organization discoverable in legal proceedings. Another commenter also expressed support for our disclosure policy, noting that performance improvement requirements are new and that a non-punitive atmosphere is most conducive to improvement. However, this commenter recommended that we reexamine our disclosure policy in the future, and make it our goal to provide public access to performance information that will not violate patient confidentiality.

Response: To promote collaboration, we believe that it is important where possible to share development of best practices and interventions that work. In addition, to provide the necessary information to assist enrollee decision-making as they choose among various health plans, it is essential that we inform the public generally as to whether an M+C organization has met its responsibility to achieve demonstrable improvement. M+C organizations are free to release the specific results of their performance improvement projects, and we encourage this, but we do not believe such release should be mandatory. We are concerned that M+C organizations might be reluctant to undertake projects addressing their areas of poorest performance, if that means that their poor performance will be highlighted. The natural progression of performance improvement projects will be to generate additional measures for inclusion in the HEDIS data set. At that point all organizations will be required to submit this information for public disclosure.

We note that we do make a substantial amount of information available to the public for research purposes, such as the HEDIS public use file on our website; moreover, there is nothing to preclude researchers from attempting to obtain information directly from the M+C organizations themselves as long as enrollee confidentiality is protected.

Comment: Certain commenters asked that we require M+C organizations to report their performance on standard measures and the results of their performance improvement projects to entities other than HCFA. One commenter asked that we require that organizations report their performance on standard measures to their designated external review entity. The commenter explained that this information would help optimize the effectiveness and timeliness of interventions by the PROs, which as the external review entities will be assisting organizations in meeting their QAPI requirements. Another commenter recommended that organizations be required to make information available to their State, in that the organization is licensed under State law. A third commenter asked that organizations be required to share the results of their performance improvement projects with the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality).

Response: We agree that it is essential that the PRO, in its role as independent quality review and improvement organization, have access to performance data, but it is preferable that the data not go directly from the M+C organization to the review organization (or State) for two reasons. First, the M+C organization's reporting burden would be doubled. Also, raw performance data are not useful to the review organization, State, or HCFA, which is why we have contracted with NCQA to analyze the data for us. M+C organizations will report the HEDIS measures to NCQA, and after its analysis, NCQA will report the measures to us. At this point, we will share summary data with the review organizations and States.

The same is true for the results of performance improvement projects. We again believe it preferable that performance improvement project data not go directly to the PRO. The data will be reported either to HCFA or to the specialized quality review organizations with which we have contracted to evaluate the success of performance improvement projects (the M+C/QROs). HCFA or the M+C/QROs will then present and interpret the results for the PROs.

3. External Review (§ 422.154)

Section 422.154 implements section 1852(e)(3) of the Act. Section 1852(e)(3) requires, subject to certain exceptions, that each M+C organization, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization approved by us to perform functions of the type described in part 466 of chapter 42, which establishes review responsibilities for utilization and quality control Peer Review Organizations (PROs). This general requirement appears in § 422.154(a) of the interim final rule. The terms of the agreement are described in § 422.154(b), and the exceptions to the general requirement are stated in § 422.154(c).

Comment: One commenter expressed concern that organizations contracting with both Medicare and Medicaid would be burdened by dual external reviews.

Response: Sections 1932(c)(2)(B) and (C) of the Act specifically address this scenario. The first provision authorizes a State to exempt a Medicaid-contracting managed care organization (MCO) that is accredited by a private independent entity, or that has a Medicare review conducted under section 1852(e)(3) of the Act, from Medicaid review activities conducted under section 1932(c)(2)(A) of the Act that would be duplicative of the accreditation process or the Medicare review activities. The second provision provides a State with the option to exempt entirely from the external review requirements under section 1932(c)(2)(A) a Medicaid MCO that is also an M+C organization, as long as that organization has had a Medicaid contract under section 1903(m) for at least 2 years during which the new BBA external quality review procedures are in effect. On December 1, 1999, we published a separate notice of proposed rulemaking setting forth our proposed interpretation of these provisions of section 1932(c)(2) of the Act (64 FR 31101).

Comment: A number of commenters asked that the regulation identify distinct review organization functions. One commenter recommended the following functions: population-based surveillance monitoring of access, quality and outcomes of care in M+C plans; auditing and validating the results of performance improvement projects; sponsoring national and statewide performance improvement projects; investigating quality complaints; conducting reconsiderations of hospital notices of non-coverage and conducting expedited appeals; and collaborating with consumer assistance organizations to better understand and use national and statewide performance improvement information when counseling beneficiaries on plan selection. Another commenter asked that we define external review requirements in the regulation that align with the PRO contractual requirements delineated in the Sixth Scope of Work.

Response: As we explained in the preamble to the interim final rule, we have approved the PROs to serve as independent quality review and improvement organizations (review organizations) for the purpose of this section of the regulation. We believe that the functional specifics of review organization responsibility are more appropriately detailed in the PRO scope of work than in the regulation. As M+C organizations implement their QAPI programs, needs may become apparent that will suggest that the review approach of the PRO be refined. The scope of work process permits a more rapid response to changing circumstances than does the regulatory process, which we believe should be used only for purposes of making changes in substantive standards for review.

Comment: One commenter asked that we require review organizations to involve broad community interests, particularly representatives of the Medicare beneficiary and consumer communities, in policy making and review activities.

Response: Such a requirement already exists. As stated in the PRO manual, each PRO is obligated to have at least one consumer representative on its governing board, and that representative must be a Medicare beneficiary. In addition, the Sixth Scope of Work requires each PRO to conduct beneficiary outreach and to maintain a Medicare hotline to facilitate communication with beneficiaries within its State.

Comment: One commenter addressed the external review waiver, supporting our decision to delay rulemaking on the waiver until we have experience with the implementation of the QAPI program.

Response: We appreciate the commenter's support of our decision.

Comment: A few commenters addressed our intention to exempt M+C organizations from external review activities that duplicate our monitoring activities. Two commenters argued that such a policy has no statutory basis and advocated its elimination. These commenters believe that this policy is inconsistent with the fact that HCFA, as Medicare purchaser and regulator, is ultimately responsible for monitoring and overseeing all quality assurance functions including the work of both review organizations and accreditation organizations. The commenters stated that our work, by definition, necessarily duplicates the work of review organizations, and therefore they were concerned that we would use the duplication as a pretense to design a PRO scope of work that is meaningless and insignificant. One commenter, although not opposed to exemption in principle, asked that any exemption of external review activities be subject to the notice and comment process.

Response: Section 1852(e)(3)(B) of the Act mandates that the Secretary ensure that the external review activities under section 1852(e)(3)(A) of the Act ''are not duplicative of review activities conducted as part of the accreditation process.'' The commenter is correct that HCFA has overall responsibility for monitoring and overseeing quality assurance functions. We believe that this extends to our review of areas addressed in the accreditation process. In this sense, we believe that our quality monitoring activities constitute a part of an overall ''accreditation process'' in that they are relevant to the continuing accreditation of M+C organizations. We also believe that Congress intended in section 1852(e)(3)(B) of the Act to require that we ensure that external review activities are not duplicative generally. Because there is little value and much additional burden in having the review organization repeat monitoring activity already conducted by HCFA, we are interpreting section 1852(e)(3)(B) of the Act broadly to extend to review activities that would be duplicative of our own monitoring activities. We believe that this interpretation of the intent of section 1852(e)(3)(B) of the Act, combined with our broad authority under section 1856(b)(1) of the Act to establish M+C standards by regulation, supports our decision to ensure that external review activities are not duplicative of our own review.

With respect to the comment that our application of the ''anti-duplication'' policy in section 1852(e)(3)(B) of the Act be subjected to notice and comment, we believe that the process of determining whether review activities are duplicative in a given case represents ''operational'' implementation of the substantive standard set forth in the regulations. We believe it would be neither workable nor appropriate to subject such operational judgments to notice and comment rulemaking.

Comment: Two commenters complained that the regulation does not indicate how we will determine what constitute duplicative review activities. One commenter recommended that we place the burden on the M+C organization to demonstrate how the accrediting process duplicates a specific external review activity. The commenter advocated that such demonstration include full disclosure of the standards and protocols used by the accrediting organization to reach accreditation decisions, a comparison of the actual survey data and reports, and information about the composition of the review teams. The commenter recommended that the M+C organization's enrollees be informed when the organization seeks exemption from external review activities, and that they be given an opportunity to comment upon the application for exemption. Finally, the commenter asked that the exemption not be granted for more than one year at a time, and not be granted if the accreditation results in nonpublic reports.

Response: We intend to make the decision as to which external review activities an M+C organization accredited by an approved accreditation organization is exempt from as part of the process of approving the accreditation organization. The accreditation organization will supply us with all the information necessary to determine where its activities overlap with those of the review organization. The exemption will be reviewed as the accreditation process or scope of work changes. We are revising § 422.154(b)(2) to make it clear that an exemption based on duplicative review under the accreditation process will be made only with respect to approved accreditation activities because these are the only activities we will be in a position to evaluate when determining whether there is duplication.

With respect to the commenter's advocating that we require ''disclosure'' by accreditation bodies of their protocols, and disclosure to beneficiaries of decisions on duplication (with an opportunity to comment), we do not believe these steps are warranted. The quality standards that apply to M+C organizations apply without regard to whether duplication has been found. A beneficiary has access to detailed information on these standards, which are all public. We believe that it should not make a difference to the beneficiary whether our judgment that these standards are being satisfied is based on the findings of an accreditation body, HCFA, or an external review entity, as long as HCFA is responsible for ensuring that they are met.

We do not see the point in limiting exemptions to a year, if there is no reason to believe that the factors we will consider in making a decision on duplication will be changing.

On the issue of ''nonpublic reports,'' we expect that the public will have access to the same quality information for all M+C organizations, without regard to whether specific review activities were found to be duplicative.

Comment: One commenter asked that we designate the PROs as review organizations in the regulation text, and not simply in the preamble.

Response: We currently have the authority to contract with non-PRO entities to perform functions of the type described in part 466, and although we have not chosen to exercise this authority at this time, we believe that it is important to maintain it. There may come a time when we decide that it is desirable to allow other entities to serve as review organizations; thus, we are not designating the PRO as the review organization in the regulation text.

Comment: One commenter expressed concern that the regulation does not explicitly obligate M+C organizations to cooperate with review organizations' investigation of quality of care complaints. This commenter suggested that § 422.154(b)(1)(ii) be revised to require that the M+C organization provide to the review organization all pertinent data it needs to carry out its reviews and make its determinations, including assessments of beneficiary quality of care complaints.

Response: Because assessments of beneficiary quality of care complaints are among the determinations that the review organization makes, we believe the existing requirement as written is sufficient to compel M+C organizations to cooperate with any complaint investigations conducted by the review organization.

Comment: One commenter asked that M+C organizations not be responsible for the cost of the external review.

Response: HCFA pays the cost of the external review, not the M+C organization. The M+C organization might initially bear the cost of duplicating medical records requested by the review organization, but the organization will be reimbursed for that cost.

Comment: Two commenters stressed the importance of public access to external review results. One of the commenters specifically asked that we require review organizations to release an annual report to the public summarizing their activities and the results of M+C organization performance improvement projects.

Response: In the PRO manual, there are detailed requirements relating to an annual report, which the PRO is required to send to the State and local offices of aging, and to senior citizen groups. In addition, the PRO is obligated to make the report available to beneficiaries upon request. Because specialized quality review organizations (the M+C/QROs), rather than PROs, will be evaluating the results of M+C organization performance improvement projects, the PRO annual report will not include this information. However, we will ensure that there is a vehicle to inform the public of whether M+C organizations have met the requirement for achieving significant improvement.

Comment: One commenter asked that the regulation require that the external review address each component of the health delivery system, including laboratory services.

Response: Our own monitoring will assess the adequacy of an organization's health delivery system, of which we acknowledge laboratory services are a part.

Comment: One commenter asked that we define the adequate space and data requirements in paragraph (b)(1).

Response: We are not defining ''adequate space'' because the PRO's need for room in which to work could vary with each review. As for data requirements, they are generally stated in § 476.102(c). This paragraph requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services provided to Medicare patients as required by the PROs.

4. Deemed Compliance Based on Accreditation (§ 422.156)

Section 1852(e)(4) of the Act gives the Secretary the authority to deem that an M+C organization meets certain requirements if the M+C organization is accredited and periodically reaccredited by a private organization under a process that we have determined ensures that the M+C organization, as a condition of accreditation, meets standards that are no less stringent than the applicable HCFA requirements.

Section 422.156(a) of the M+C regulations specifies the conditions under which an M+C organization may be deemed to meet the HCFA requirements permitted to be deemed under section 1852(e)(4) of the Act.

The current version of § 422.156(b) specifies the requirements that could be deemed under the original BBA deeming provisions. In accordance with those BBA provisions, these included only the quality assessment and performance improvement requirements of § 422.152, and the requirements of § 422.118 related to confidentiality and accuracy of enrollee records. As discussed in section I.C. of this preamble, the BBRA amended section 1852(e)(4) of the Act to provide for deeming of additional requirements. An M+C organization accredited by an approved accreditation organization could be deemed to meet any or all of the requirements specified in section 1852(e)(4) of the Act, depending on the specific requirements for which its accreditation organization's request for approval was granted.

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

Section 422.156(d) establishes the obligations of deemed M+C organizations. An M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of unmet HCFA requirements.)

Section 422.156(e) addresses removal of deemed status. We will remove part or all of an M+C organization's deemed status if: (1) We determine, on the basis of our own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted; (2) we withdraw our approval of the accreditation organization that accredited the M+C organization; or (3) the M+C fails to meet the requirements of paragraph (d) of this section.

Finally, § 422.156(f) explains that we retain the authority to initiate enforcement action against any M+C organization that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

In addition to expanding the types of requirements that are deemable, section 518 of the BBRA also specified procedural changes to the accreditation process which are also discussed in section I.C above and in several responses below. As noted above, these changes have been reflected in a revised version of § 422.156.

The comments and responses regarding § 422.156 are discussed below.

Comment: Several commenters expressed general support for the deeming provisions as stated in the regulation.

Response: The M+C deeming provisions are modeled on those that have been used successfully in original Medicare, and commenters have validated our belief that these

provisions will work equally well in Medicare managed care.

Comment: One commenter was concerned that if we allow deeming, we will not be able to ensure access for disabled enrollees. This commenter recommended that we ensure that accreditation organizations include in their review an assessment of an organization's ability to treat members with disabilities and complex care needs.

Response: We appreciate this comment, and agree that it is important that the needs of disabled enrollees not be overlooked. In evaluating whether standards imposed by an accreditation organization are at least as stringent as HCFA's, specifically QISMC Standard 3.1, we will take into account whether these standards account for the needs of disabled enrollees.

Comment: Two commenters recommended that we expedite the implementation of the deeming program.

Response: We recognize the value of deeming to M+C organizations and intend to proceed with deeming at the earliest opportunity. As a first step in this process, we will require that accreditation organizations develop crosswalks between their standards and the QISMC standards relating to the M+C requirements for which the organizations are seeking deeming approval. Only after we have revised the interim QISMC standards to reflect the changes made in this final rule and the final rule published February 17, 1999, will we have an accurate set of standards for use by the accreditation organizations in completing their crosswalks. We expect to release a revised set of QISMC standards shortly after publication of this final rule. Thirty days after publication we will begin accepting applications from accreditation organizations. A **Federal Register** notice formally announcing this timetable is being published concurrently with this final rule.

Comment: Three commenters addressed the requirement that, as a condition of deemed compliance, an M+C organization be ''fully accredited.'' The commenters believe this condition would be problematic, given that many accreditation organizations have multiple accreditation categories. One of the commenters, an accreditation organization, stated that this policy is '' * * * a significant and substantive change from the current process under Medicare. At this time there exists a variety of accreditation levels * * *,'' not only within accreditation organizations but among them. A second accreditation organization complained that restricting deeming to only M+C organizations that have been ''fully accredited'' contradicts the stated policy of deeming on a standard-by-standard basis. It explained that requiring an M+C organization to meet all of an accreditation organization's standards decreases the potential savings and efficiencies associated with deeming.

Response: Because accreditation categories differ among accreditation organizations, we expect that ''fully accredited'' will have to be defined on an organization by organization basis. Fully accredited will generally mean that all elements within all the accreditation standards for which the accreditation organization has been approved by HCFA have been surveyed and fully met or otherwise determined as acceptable without significant findings, recommendations, required actions or corrective actions. The commenter who complained that the requirement that an M+C organization be fully accredited is inconsistent with our intent to approve accreditation organizations on a standard-by-standard basis has misunderstood the requirement. The M+C organization must be fully accredited for only those standards for which the accreditation organization has been approved, not all of the accreditation organization's standards. We understand how the commenter misinterpreted the existing regulations, and we are revising § 422.156(a)(1) to clarify this requirement.

Comment: One commenter pointed out that if an M+C organization chooses not to be accredited, we will perform a complete audit of its functions. Because there is no cost to the M+C organization for our audit, the commenter believes it would be to an M+C organization's advantage not to be accredited, because it would avoid the cost of accreditation as well as duplicate reviews (for example, an accredited M+C organization's grievance and appeal program would be reviewed both by the accreditation organization and by HCFA because the grievance and appeal requirements are not deemable). The commenter asked whether this interpretation is correct.

Response: The commenter's interpretation is correct, although there are benefits associated with accreditation, such as improved marketability, that we believe make accreditation attractive.

Comment: Many commenters addressed the scope of deeming. The majority of commenters supported the limited deeming reflected in the interim final regulation. One of these commenters cited as support for limited deeming a recent report regarding the problems associated with deeming based on private accreditation of hospitals. One commenter advocated the continued development and implementation of the ''enhanced review'' process begun several years ago. One commenter opposed limited deeming. This commenter, an accreditation organization, asserted that the regulation does a disservice to its clients as they are still subject to a our survey. Further, this accreditation organization complained that the regulation fosters ''the very duplication of effort and stifling of innovation that the BBA sought to avoid by requiring deemed status.''

Response: In recognition of the efficiencies associated with deeming, section 518 of the BBRA amended section 1852(e)(4) of the Act to provide for the deeming of additional requirements. Specifically, the additional deemable requirements are those related to the following sections of the Act: section 1852(b) (which relates to antidiscrimination); section 1852(d) (which relates to access to services), section 1852(i) (which relates to information on advance directives), and section 1852(j) (which relates to provider participation rules). We are revising § 422.156(b) to add these requirements.

We note that HCFA's oversight of managed care accreditors will be different from that of hospital accreditors, *i.e.*, the JCAHO. Deeming based on JCAHO accreditation is explicitly required by statute, whereas potential M+C accreditors must demonstrate their ability to apply and enforce standards at least as stringent as our own as a condition of approval. In the event that a managed care accreditor fails to perform as promised, we retain the authority to withdraw its approval. Therefore, there are safeguards in place to prevent the situation that has arisen in hospital deeming from repeating itself in managed care.

Comment: Four commenters addressed the topic of approving accreditation organizations on a standard by standard basis as outlined in the regulation. Three commenters were in favor. One commenter asked if approving on a standard by standard basis means that we will '' * * * approve an accreditation organization for some standards but not for others.'' One commenter contended that our decision to approve accreditation organizations on a standard by standard basis is ''inconsistent with the need to reduce the duplication of effort.'' This commenter, an accreditation

organization, recommended that accreditation organization standards be assessed to determine if overall they equal or exceed HCFA's requirements. This commenter continued to state that ''* * * approving individual standards will lead to a stifling of innovations and improvements over time.''

Response: Section 518 of the BBRA has caused us to revise our approach to approving accreditation organizations. Originally, section 1852(e)(4) of the Act stipulated that ''the Secretary shall provide that a Medicare+Choice organization is deemed to meet requirements'' of certain subsections of the Act if the organization were accredited by an approved organization. The BBRA changed the provision to read that ''the Secretary shall provide that a Medicare+Choice organization is deemed to meet *all the* requirements'' (emphasis added) of certain cites within the Act. The result of the change is this: it is still possible for us to approve an accreditation organization for a subset of the deemable requirements alone; for instance, we may approve an accreditation organization for the quality assurance subset (which includes the quality assessment and performance improvement program requirements of § 422.152) without approving it for any others. However, the accreditation organization must now have a comparable standard to every one of the M+C requirements within the quality assurance subset. Prior to enactment of the BBRA, an accreditation organization with only some quality assurance standards equivalent to the M+C requirements would have been permitted to participate in deeming; HCFA would have monitored for compliance with the M+C requirements for which no equivalent accreditation organization standards existed. Now, because the BBRA requires, in essence, that HCFA deem an accredited M+C organization by subset, rather than by requirement, we can approve an accreditation organization only if it has a standard that meets or exceeds each of the M+C requirements of the subset. While this policy could limit the extent to which an accreditation organization may be involved in deeming, it could be viewed as simplifying the oversight process, since there is no longer the potential for HCFA and an accreditation organization to divide responsibility for monitoring an M+C organization's compliance with the requirements of the same subset. We have revised the introductory clause in § 422.157(a) (discussed below) to reflect this BBRA change.

Comment: One commenter requested that public notice be given if an M+C organization's deemed status is removed or an accreditation organization's approval is withdrawn.

Response: We agree that when we withdraw an accreditation organization's approval, HCFA should give public notice because the information may influence the choice of accreditation organization made by M+C organizations seeking accreditation. We expect to give this notice by posting it on our website.

When we withdraw an accreditation organization's approval, we also remove the deemed status of all M+C organizations accredited by the organization. Upon removal of an M+C organization's deemed status, HCFA immediately assumes responsibility for ensuring that the organization meets our standards. Because beneficiaries are not at risk, and because notifying them of the loss of their M+C organization's deemed status could cause them to be concerned that they are at risk, we do not believe it is necessary or appropriate to so notify beneficiaries.

Comment: A few commenters addressed our authority under § 422.156(e)(1) to remove deemed status on the basis of a review of accreditation survey results. One of the commenters, an accreditation organization, strongly disagreed with the provision, complaining that it ''* * * would allow us to take the results of an accreditation survey and essentially ignore the decision of the accreditation organization without any independent data gathering.'' The commenter contended that the provision presumes that HCFA staff understand the accreditation requirements, and are better able to judge the performance of the M+C organization against those requirements than the accreditation organization's own surveyors. This commenter encouraged HCFA to conduct its own survey if we believe an M+C organization is not in compliance. If we reach a different conclusion than the accreditation organization after its own survey, then the commenter believes that we would be justified in removing deemed status. Another accreditation organization expressed similar concern with § 422.156(e)(1), stating that the regulation language could be used by us to ''second guess the compliance determination using only the results of the accreditation survey.'' This commenter recommended limiting the removal authority to reflect this concern.

Response: We do not intend to overrule an accreditation organization's survey decision without doing our own investigation. If our own investigation reveals, however, that a condition is not met, we reserve the right to remove deemed status even when the accreditation organization has not removed accreditation with respect to that condition. In order to clarify the distinction between—(1) a removal of deemed status by HCFA, based on HCFA's own survey, and (2) a removal based on a determination of noncompliance by an accreditation organization as a result of its accreditation survey, we have revised § 422.156(a) to separate these two situations. This should make it clear that we will not ''second guess'' the accreditation organization's conclusions based on its review without doing our own independent investigation.

5. Accreditation Organizations (§ 422.157)

In § 422.157(a), we discuss three conditions for our approval of an accreditation organization. We may approve an accreditation organization if the organization applies and enforces standards for M+C organizations that are at least as stringent as Medicare requirements (as discussed above); the organization complies with the application and reapplication procedures set forth in § 422.158, ''Procedures for approval of accreditation as a basis for deeming compliance;'' and, the organization is not controlled by the managed care organizations it accredits, as defined at § 413.17.

Section 422.157(b) of the interim final rule describes notice and comment procedures. Because the approval of an accreditation organization could have broad impact upon large numbers of organizations, providers, and consumers, we are providing notice and comment opportunities similar to those provided in the fee-for-service arena.

Section 422.157(c) establishes ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the requirement at § 422.157(c)(4) that an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited M+C organization, a deficiency that poses immediate jeopardy to the M+C organization's enrollees or to the general public.

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

Section 422.157(d) states that an accreditation organization dissatisfied with a determination to withdraw our approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter. The comments and responses regarding § 422.157 are discussed below.

Comment: One commenter recommended that HCFA, when making a determination based on its own survey or the results of an accreditation survey that an M+C organization does not meet Medicare requirements, ''define the requirements, data collection tools, and scoring (including relative weights) guidelines'' used to make the determination. The commenter explained that disclosure of such information is consistent with assuring beneficiaries and providers that HCFA determinations and surveys are objective and based on criteria that are public, relevant and valid.

Response: We agree with the need to make our process for making determinations available to the public. That is why materials such as our monitoring protocol are available to the public on HCFA's website, www.hcfa.gov/medicare/mgdcar1.htm.

Comment: We received six comments requesting public disclosure of accreditation survey results. One commenter requested that we require in the regulation that enrollees be able to obtain from us their organization's accreditation survey results. An accreditation organization itself agreed with the need for public disclosure and stated that ''If the accreditation is to be used for a public purpose, participation in Medicare, then we are accountable for the decision and the information upon which it was based.''

Response: We agree that public disclosure of accreditation survey results is appropriate. If an accreditation organization does not have a policy for publicly disclosing accreditation survey results, it will be required to develop one as a condition of our approval.

Comment: An accreditation organization recommended that we provide accreditation organizations with quality-related information, for example, performance measurement data, quality improvement projects, etc.

Response: We concur with the importance of ''two way communication,'' which is why we routinely publish or otherwise make available to interested parties the types of information referred to by the commenter, such as HEDIS results.

Comment: One accreditation organization contended that the monthly reporting requirements exceed our needs, and it recommended that the regulation reflect our right to receive the information but not specify a reporting frequency until after information use and need is determined.

Response: We believe the reporting requirements of § 422.157(c)(1) accurately reflect our need for information. The information that accreditation organizations are required to report and the time frames in which they are required to report it are based on requirements that have proven their usefulness and necessity in deeming under original Medicare. We have no reason to believe that the organizations that accredit M+C organizations should be held to a different standard.

Comment: Two commenters addressed the conflict-of-interest provision at § 422.157(a)(3). One commenter stated that the provision is ''so broadly drawn as to preclude managed care organizations from serving on the boards of accreditation organizations, or otherwise participating in the accreditation development process.'' This commenter requested that we clarify that such activities are permissible. The second commenter also objected to the conflict-of-interest provision as written, recommending that we focus instead on whether the accreditation organization has policies in place that separate individuals affiliated with an M+C organization from an accreditation decision impacting that organization. This commenter asked for a definition of ''controlled'' that allows M+C organizations to participate in appropriate accreditation organization governance and policy making activities, but prohibits M+C organizations from having inappropriate influence on accreditation decisions affecting themselves.

Response: We believe it is important that no single or group of managed care organizations be allowed to exert undue influence over a private accreditation organization in any decision making process that would allow that single or group of organizations to benefit at the expense of others. However, we recognize the valuable role that representatives of managed care organizations may play in private accreditation organizations, and we agree that the regulation as written appears to prohibit a number of acceptable activities. Therefore, we are revising § 422.157(a)(3) to require that an accreditation organization ensures that: (1) Any individual associated with it who is also associated with an entity it accredits does not influence the accreditation decision concerning that entity; (2) the majority of the membership of its governing body is not comprised of managed care organizations or their representatives; and (3) its governing body has a broad and balanced representation of interests and acts without bias.

Comment: One commenter asked whether we must act on an accreditation organization's application for approval within 210 days, as is the case with respect to fee-for-service accreditation.

Response: The 210-day time frame that applies to accreditation under original Medicare is set forth in section 1865(b)(3) of the Act, and was not originally included by the Congress in section 1852(e)(4) of the Act. However, section 518 of the BBRA amended section 1852(e)(4) of the Act to add this requirement, and we are incorporating it into § 422.158(e).

In addition, because we are now required to make our decision on an accreditation organization's application within 210 days, we are revising § 422.157(b)(1) to restructure the provisions concerning timing and content of the **Federal Register** notice that solicits public comments on accreditation organization applications to allow for a comment period that is concurrent with HCFA's review. This process, also used by original Medicare, will give the public a meaningful opportunity to comment on the applications.

In the interim final rule, we modeled § 422.157(b)(1) on the original Medicare deeming regulation at § 488.8(b)(1). However, § 488.8(b)(1) was written before section 1865(b)(3)(A) of the Act was amended to require 210-day turnaround on accreditation organization applications, and we are now in the process of revising § 488.8 to conform with the Act. If we do not revise § 422.157(b)(1) to follow original Medicare's model, we are concerned that our review of the accreditation organization's standards will be so time consuming, there will be little time left within the 210 days for the public comment period. Therefore, revised § 422.157(b)(1) specifies that the **Federal Register** notice will announce our receipt of the accreditation organization's application for approval, describe the criteria we will use in evaluating the application, and provide at least a 30-day public comment period. Again, the timing and content of this notice are consistent with the way in which we solicit comments on accreditation organization applications in original Medicare deeming, pursuant to section 1865(b)(3)(A) of the Act.

Comment: One commenter argued that it is not appropriate for us to take action against an accreditation

organization ''irrespective of the rate of disparity'' between certification by the accreditation organization and certification by us or our agent. The commenter agreed that accreditation organizations are ''accountable to us and the public for the decisions they make and failure to properly assess the performance of the organizations they accredit should be grounds for action.'' However, the commenter complained that open-ended authority to withdraw an accreditation organization's approval regardless of the rate of disparity is inappropriate.

Response: It is an approved accreditation organization's responsibility to ensure that accredited M+C organizations meet or exceed our standards. As per the regulation, if widespread or systematic problems are identified that indicate that an accreditation organization can no longer make that assurance, we reserve the right to take appropriate action, regardless of the disparity rate. However, we can assure the commenter that in Federal oversight of accreditation organizations, a variety of factors and measures are considered and utilized, only one of which is the disparity rate.

In response to the commenter's concern, we are requiring that accreditation organizations provide us annually with summary data relating to their accreditation activities and observed trends. These data will assist us in making a comprehensive assessment of accreditation organization performance, and will help ensure that our oversight decisions are well-informed and appropriate. This change appears at § 422.157(c)(6).

Comment: One commenter requested that we clarify the term ''enforces'' as it is used in §§ 422.157(a)(1) and 422.158(a)(3)(iii)(C).

Response: An approved accreditation organization must apply and enforce standards that are at least as stringent as HCFA's requirements. By that, we mean that we expect the accreditation organization to assess compliance with the approved standards, and where it finds that an M+C organization is not in compliance, to ensure that corrective action is taken.

6. Procedures for Approval of Accreditation as a Basis for Deeming Compliance (§ 422.158)

The requirements of § 422.158, which pertain to required application materials, the mechanics of the approval process, and the reconsideration of an adverse determination, are essentially restatements of the original Medicare requirements under § 488.4.

Comment: One commenter disagreed with the provision that prohibits an accreditation organization that has requested reconsideration of a denial from filing a new application while the reconsideration is pending. The commenter believes that this provision will discourage accreditation organizations from challenging a denial and result in a denial of due process.

Response: An accreditation organization may request a reconsideration if it receives a denial of its application. This may be done by submitting a request for reconsideration, the requisite supplemental information, and any necessary supporting documentation. In lieu of the reconsideration, an accreditation organization may select the option of submitting a new application that has been revised to address the deficient areas that led to the initial denial. Therefore, the prohibition against simultaneously submitting a request for reconsideration and a new application does not deprive an M+C organization of the right to submit a new application.

E. Relationships With Providers

Part 422, subpart E of the M+C regulations focuses on requirements for relationships between M+C organizations and health care professionals with whom they contract to provide services to beneficiaries enrolled in an M+C plan. Many of these requirements stem from the rules regarding provider participation that are set forth in section 1852(j) of the Act. In our February 17, 1999 final rule, we addressed comments and made changes concerning several aspects of the provider participation requirements contained in subpart E, including the scope and applicability of the provider participation procedures. This final rule addresses comments on all other requirements in subpart E.

1. Provider Participation Procedures (§§ 422.202(a) and 422.204(c))

For the most part, we responded to comments on issues related to §§ 422.202(a) and 422.204(c) of the regulations in our February 17, 1999 final rule (64 FR 7975). In reviewing the comments on the interim final rule, however, we believe that additional clarification may be necessary on the applicability of the provider appeals procedures now set forth under § 422.204(c).

Comment: Several commenters objected to language in the preamble to the June 26, 1998 interim final rule that implied that health care professionals should have access to a formal appeals process when they viewed changes in an M+C organization's provider participation policies as having an adverse effect. The commenters pointed out that these policies should be subject to the consultation rules set forth under § 422.204(b), but did not believe that changes in these policies warranted a formal appeals process.

Response: As discussed in the February 1999 rule, the appeals procedures set forth under existing § 422.204(c) apply only in cases of adverse participation decisions, that is, when an M+C organization suspends or terminates a physician's contract with the organization. We believe this policy is consistent with the intent of section 1852(j)(1) of the Act, which provides for a process for appealing ''adverse decisions'' relating to the ''participation of physicians'' under a plan. We did not intend to imply that a physician has a right to a formal hearing to appeal a participation policy adopted by the M+C organization, although we would expect physicians to have input on those polices through the consultation process required under § 422.202(b). Clearly, however, an M+C organization ultimately is legally entitled to adopt the policies necessary to govern its operations, as approved by its board of directors, provided they are consistent with applicable Federal requirements. Please note that as part of a minor restructuring of the M+C provider participation provisions, and to help clarify that the appeals procedures apply only for adverse participation decisions, we are redesignating the provider appeals procedures from § 422.204(c) to new § 422.202(d).

Comment: Two commenters objected to the requirement in existing § 422.204(c)(3) that an M+C organization must notify the appropriate licensure or disciplinary bodies when it suspends or terminates a contract because of deficiencies in the quality of care. These commenters suggested that we leave State reporting requirements to the States. Another commenter recommended that the appeals hearing panels (under § 422.202(c)(2)) be required to include physicians that did not contract with the M+C organization as a means of ensuring the ''independence'' of the panel's review.

Response: Existing statutes and regulations consistently establish the need for cooperation between Federal and State authorities in their administration of the Medicare program. A primary example is the requirement under section 1855(a)(1) of the Act that an M+C organization generally must be licensed under State law in order to qualify for participation in the M+C program. Thus, we believe it is wholly

appropriate to require in Federal regulations that the suspension or termination of a physician's contract with an M+C organization be reported to State licensing and disciplinary bodies.

With regard to the membership of appeals panels, an M+C organization is free to enlist non-contracting physicians on these panels if it chooses to do so. However, section 1852(j)(1)(C) of the Act refers to an appeals process ''within the organization,'' and we do not believe it would be reasonable to require the participation of non-contracting physicians.

Comment: A commenter pointed out that at least one State has laws exempting an organization from the State's requirements for provider notification and review procedures in cases of imminent harm to a patient, determination of fraud, or final disciplinary action by a State licensing board. The commenter asked whether the notification and appeals provisions of subpart E would preclude exemption in these situations.

Response: As discussed in further detail below, section 1856(b)(3)(B) of the Act specifies that State ''requirements relating to inclusion or treatment of providers'' are superseded by the analogous Federal standards. Thus, State reporting exceptions to the M+C notification and appeals procedures are precluded under the existing M+C regulations. However, we do not believe that the general notice requirement under existing § 422.204(c)(1) and (3), which do not include specific time frames for notification, should present a conflict with the State law mentioned by the commenter. We note that 60-day time frame for termination notifications under § 422.204(c)(4) applies only for terminations ''without cause,'' rather than in situations addressed by the law in question.

2. Consultation Requirements (§ 422.202(b))

In accordance with section 1852(j)(2) of the Act, § 422.202(b) specifies that an M+C organization must consult with physicians participating in its M+C plans regarding the organization's medical policies, quality assurance programs, and medical management procedures. Under the regulations set forth in our June 26, 1998 interim final rule, these provisions were applied to other health care professionals as well as physicians. However, in response to comments on the interim rule, we revised this section in our February 1999 final rule to limit the applicability of these requirements to physicians. We also received a number of comments on other aspects of the consultation provisions, which are discussed below.

Comment: Commenters generally supported the objectives of the consultation requirements contained in § 422.202(b). However, several commenters representing physician groups suggested that the regulations should be expanded to establish a specific methodology for obtaining consultative input. For example, one commenter advocated requiring the establishment of a medical committee structure broken down into separate subcommittees focusing on various aspects of medical management policy (for example, professional relations, credentialing, quality improvement, *etc.*).

Other commenters representing M+C organizations asked for confirmation that the use of physician committees to obtain consultation was an acceptable means of satisfying the consultation requirements. Two M+C organizations suggested that we define ''consultation'' as ''soliciting and considering advice from participating professionals through committees established by the M+C organization.'' Another commenter noted that local medical review procedures (LMRP) should be part of the consultation process, and could in some instances substitute for the consultative process. One commenter indicated that the consultative requirements could be read to require consultation with hundreds of individual physicians and expressed concern that the consultative requirements would interfere with an individual physician's judgement in treating patients.

Response: We agree that the most appropriate method for an M+C organization to consult with its contracting physicians is likely to be through the establishment of a committee structure. Rather than limit organizational flexibility by establishing a single model for consultation, however, we are revising § 422.202(b) to state that an M+C organization must ''establish a formal mechanism'' for consulting with the physicians who provide services under plans offered by the organization. As we monitor the types of consultative arrangements implemented by M+C organizations, we will consider whether more specific regulatory guidance is necessary.

Similarly, although we agree with the definition of consultation offered by the commenters, we believe that the term is sufficiently self-explanatory and that inserting a formal definition of the term into the regulations is unnecessary. We also agree that M+C organizations should take local medical review policies into consideration in establishing and updating their medical review policies. However, we believe that the regulations need not include that degree of specificity concerning the evidence-based guidelines an M+C organization must consider in adopting practice guidelines. We will consider adding such policies to the list of guidelines now described in the QISMC standards on this subject (QISMC Guideline 3.4.1.1).

Finally, we do not agree that the consultation requirement infringes on the ability of an individual physician's judgement in the practice of medicine. As their name implies, practice ''guidelines'' are intended for general application rather than as procedures to be followed in every case independent of physician judgment.

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

Under § 422.202(c), an M+C organization that uses subcontracted physician groups or other networks of health care professionals must provide M+C participation procedures that apply equally to these subcontracting groups.

Comment: Many commenters raised questions concerning the meaning and implications of the requirement under § 422.202(c), which states that when an M+C organization operates an M+C plan through subcontracted physician groups or other subcontracted networks, it must ensure that ''the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups.'' (Note that this provision was amended in our February 1999 final rule to limit its applicability to physicians.) Although some commenters supported this requirement as written, others were concerned that the requirement was too broad in scope. Several commenters suggested that we clarify that an M+C organization can comply with this provision by requiring subcontracting networks to have their own procedures for consultation and for participation appeals. They believe that it would be imposing ''unreasonable downstream responsibilities'' to require that the subcontractor's consultation and appeals procedures establish participation rights equivalent to those required under § 422.202. Other commenters recommended that we require the subcontracts to include the same specific appeals procedures as required at the M+C organization level. Finally, several commenters asked whether appeal rights extend to all physicians in a terminated group practice or to individual physicians. They recommended that the

subcontracting group practice exercise appeal rights on behalf of its employees.

Response: M+C organizations are contractually obligated to meet all requirements contained in the M+C regulations. They may meet these requirements either by directly providing the requisite health or administrative services or by entering into contracts for the provision of these services. Although we recognize the need for further clarification of how the provider participation rules and other provisions of the M+C requirements apply to subcontracting entities, the presence of a subcontract does not alter the underlying substance of those requirements. Note that § 422.502(i) of the M+C regulations contains a great deal of general information regarding the delegation of responsibility under subcontracts as well as some specific requirements (for example, with respect to provider credentialing). Please see section II.K of this preamble for a further discussion of many related issues. In addition, readers may wish to consult OPL #77, released on December 8, 1998, which offers extensive guidance in this regard (available through the HCFA website at www.hcfa.gov).

As spelled out under § 422.502(i), under any type of subcontracting arrangement, the M+C organization retains ultimate responsibility for ensuring that its subcontractors achieve full compliance with all terms and conditions of the organization's contract with us. This includes ensuring that activities performed by its subcontractors are consistent and comply with the M+C organization's contractual obligations. For activities that are delegated to contractors (such as provider appeals), the contract must specify that the subcontractor must comply with all Medicare laws, regulations, and instructions. Thus, a physician who is employed by a group practice that contracts with an M+C organization would have the same fundamental consultation and appeal rights as a physician who contracts directly with the M+C organization. Whether that physician exercises those rights at the subcontractor level, or directly through the M+C organization, would be left to the discretion of the M+C organization and its subcontractors. For example, an M+C organization could enter into a contract with a physician group under which all individual appeals of adverse participation decisions were adjudicated at the subcontractor level. However, the subcontractor's appeals process would need to meet the requirements established under redesignated § 422.202(d), as discussed above: all procedural rights established there would apply equally for the subcontracting physicians. For situations in which a subcontract with an entire group practice was terminated by an M+C organization, we would expect that the appeal rights would fall to the subcontracting group practice to exercise on its physicians' behalf.

Similarly, with respect to the consultation requirements, we can envision various ways in which the requirements could be met under subcontracting arrangements, such as through direct representation for the subcontractor's providers on M+C organization committees, or through committees convened by the subcontractor, with its consultative input channeled to the M+C organization. In either case, though, the underlying requirement must be met that practice and utilization management guidelines be developed in consultation with contracting physicians.

In general, our policy to date has been to afford extensive flexibility to M+C organizations in meeting subcontracting requirements. In 1999, for example, we required risk contractors that became M+C organizations to submit a plan demonstrating how they would work toward executing new or revised provider or administrative service contracts, with full compliance required by January 1, 2000. Again, for further information on the ways in which an organization can demonstrate compliance with provider contracting requirements, please see OPL 77.

4. Provider Antidiscrimination (§§ 422.100(j), 422.204(b), new 422.205)

Sections 422.100(j) and 422.204(b) both relate to the provision set forth in section 1852(b)(2) of the Act that precludes M+C organizations from discriminating against providers based on their licensure or certification. Section 422.204(b), for the most part, simply incorporates the statutory prohibitions on discrimination based on provider licensure or certification, but also provides that these prohibitions do not preclude the ''use of different reimbursement amounts for different specialties.'' Section 422.100(j) states that if more than one type of practitioner is qualified to furnish a particular service, the M+C organization may select the type of practitioner to be used.

Comment: Numerous commenters addressed the provider antidiscrimination provisions set forth at §§ 422.100(j) and 422.204(b). Commenters generally believed that additional guidance beyond that offered in the June 1998 interim final rule was necessary to clarify our interpretation of the antidiscrimination provisions of the statute (section 1852(b)(2) of the Act). Commenters differed in their views on how these provisions should be interpreted and implemented, however.

In general, commenters representing M+C organizations supported the inclusion of the choice-of-practitioners provision (§ 422.100(j)); they believe that this provision establishes that M+C organizations are not required to adopt an ''any willing provider'' policy, but rather have the flexibility to choose the practitioners that participate in an organization's provider network. In contrast, commenters representing physicians and other health care professionals believe that the choice-of-practitioners provision is unnecessary and confusing; they see the provision as undermining the antidiscrimination provisions of the statute and the M+C regulations. These commenters particularly objected to the wording in § 422.100(j) that allows an M+C organization to select the ''type of practitioner'' to be used. These commenters offered various recommendations, including: (1) delete the provision in its entirety; (2) add a requirement that an M+C organization employ a ''representative range of providers'' (comparable with the available range of providers under original Medicare); (3) amend the provision so that it would focus on the availability of all Medicare-covered ''benefits'' (many of which can be furnished only by qualified practitioners), rather than ''services''.

Commenters displayed similar perspectives with regard to the antidiscrimination prohibitions set forth under § 422.204(b). As noted above, the only portion of this section that is not taken directly from the statute is the provision under existing § 422.204(b)(2)(ii) that indicates that an M+C organization is not precluded from use of different reimbursement amounts for different specialties. Commenters representing M+C organizations generally supported the addition of this language, although one commenter believed that it unnecessarily restricted an M+C organization's ability to negotiate with physicians or other practitioners. This commenter stated that the regulations do not give an organization sufficient leeway to take into consideration the reputation, volume, or experience of a practitioner, or alternative payment methods, in establishing compensation.

Other commenters representing various types of physicians and other health care professionals objected to this

provision because they believe that it confers too much authority on M+C organizations. They argued that permitting an M+C organization to pay different amounts for different specialties was inconsistent with legislative intent. They also contended that this language was inconsistent with the Supreme Court's decision in *Bowen* v. *Michigan Academy of Family Physicians,* 476 U.S. 667 (1986), which they characterized as requiring that Medicare ''reimburse similar services in an equal manner regardless of who performs the service.'' These commenters believed that we should require that payment rates be tied to the services provided, as under the fee schedules used in original Medicare. One commenter suggested that we revise § 422.204(b)(2)(ii) to clarify that payment differences are permissible only if they ''result from competition or other legitimate factors,'' rather than differences based solely on licensure or certification.

Response: The statutory antidiscrimination provision is intended to ensure that health care providers are not arbitrarily excluded from participation under a managed care plan's provider network solely on the basis of their license or certification. We recognize that the existing regulations, which refer to this prohibition on discrimination in both §§ 422.100(j) and 422.204(b), have created the potential for confusion.

To assist in clarifying the relevant requirements, we believe it is appropriate to consolidate the regulations concerning antidiscrimination and choice of providers into a new, separate § 422.205, Provider antidiscrimination. This section will begin with the general rule prohibiting discrimination based solely on licensure or certification, consistent with the law. We then will specify that in choosing its practitioners, an M+C organization must ensure that all Medicare-covered services must be available to a plan's enrollees. We are also incorporating under § 422.205(a) a revised version of the existing provision regarding choice of practitioners that eliminates any reference to ''type of practitioners.'' Thus, the general rule will continue to permit M+C organizations the flexibility to choose their practitioners, consistent with the statute's antidiscrimination constraints, which are set forth under § 422.205(b). At the same time, this provision will emphasize the mandatory availability of all Medicare-covered services (such as physical therapy or manual manipulation of the spine to correct a subluxation).

Finally, we are adding at, § 422.205, a requirement that when an M+C organization declines to include a given provider or group of providers in its network, it must notify the provider(s) of the reason for its decision. Although this provision does not impart any appeal rights, we believe it is both a reasonable business practice and a means of ensuring that such decisions are subject to our monitoring efforts.

Our goal in implementing these changes is to strike a balance between our responsibility to ensure that M+C organizations are employing all the types of health care professionals needed to ensure that required Medicare-covered services are available to their enrollees, and our aversion to limiting organizations' flexibility in providing these services. Over the next few years, we intend to closely monitor organization compliance with the antidiscrimination provisions, including examining encounter data as it becomes available and tracking organizational participation decisions, to determine the degree to which all Medicare-covered services are made available under different plans.

We believe that the statute is not intended to preclude an M+C organization from negotiating appropriate, market-based, payment rates with its providers. It is quite possible, for example, that the ''market rate'' that must be paid to get a particular type of specialist to participate in an M+C organization's network may be higher or lower than that dictated by the market with respect to another type of practitioner. Section 1852(b)(2) of the Act expressly provides that its antidiscrimination rule ''shall not be construed to prohibit a plan from * * * measure[s] designed to * * * control costs. * * *'' Paying no more than the market rate for a given provider is clearly a component of cost control. We believe that establishing requirements concerning the comparative rates M+C organizations pay for contracting provider services would be inconsistent with the overall design of the M+C program, under which we pay a fixed amount to ensure that Medicare beneficiaries receive the services to which they are entitled, but M+C organizations have wide discretion in managing enrollee care and establishing provider networks. Inherent to this design is the premise that payment rates should be established through negotiated contracts rather than micro-managed by the Federal government. Thus, new § 422.205(b) specifies that an organization may use different reimbursement amounts for different specialties, or different practitioners within the same specialty.

Further, we do not agree with the commenter that the payment rules established under original Medicare's fee schedules necessarily represent the appropriate model for payment under the M+C program, or that it would be appropriate or feasible to establish a requirement that an M+C organization's provider network reflect the identical mix of providers participating in Medicare generally. Beneficiaries have the option of returning to original Medicare if they place a premium on being able to receive services from any provider they wish, or are not satisfied with being limited to a defined network established by an M+C organization.

In addition to addressing measures designed to control costs, section 1852(b)(2) of the Act also makes clear that the antidiscrimination rule therein shall not be construed to prevent an M+C organization from taking measures to ''maintain quality'' of services. For example, we would not want to preclude higher payments to providers for demonstrating quality improvement, or preclude an M+C organization from imposing quality-related requirements, such as using only board-certified physicians.

Finally, section 1852(b)(2) of the Act makes clear that its antidiscrimination provision ''shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees.'' If an M+C organization can provide all physicians' services through a doctor of medicine, it may not ''need'' to contract with another practitioner who can provide only a discrete subset of physicians' services (such as a podiatrist or a chiropractor who under section 1861(r) of the Act are considered physicians under Medicare only for specified purposes). As long as all Medicare-covered services are available in the plan, there may be no ''need'' to assume the additional administrative costs of contracting with another practitioner when an existing contractor is able to perform the services the additional practitioner would be providing. This would not constitute discrimination based ''solely'' on the basis of license or certification, but rather, not contracting with practitioners not ''needed'' to provide the full Medicare range of benefits.

With respect to the choice-of-practitioners provision, this right has always been inherent in the managed care model of health care delivery. While a practitioner is not to be discriminated against *solely* due to his or her license, we believe that M+C

organizations must have the flexibility to deliver services through the most cost-effective practitioner who is qualified to perform the service in question. Again, this is a ''cost control'' measure authorized under the last sentence in section 1852(b)(2) of the Act.

We do not understand the commenter's reference to the Supreme Court's *Michigan Academy* decision, since this decision did not involve a ruling on the merits of any reimbursement issue. Rather, the issue in *Michigan Academy* was whether certain types of claims were subject to judicial review. Even if the decision did hold what the commenter suggested, rules that apply to payments under original fee-for-service Medicare do not apply to payments by M+C organizations to contracting providers.

Comment: Commenters asked how we intended to enforce the antidiscrimination requirements, noting that strong enforcement was particularly necessary in view of the specific preemption of State laws dealing with the inclusion of providers. Several commenters asked how a provider would pursue an antidiscrimination claim, and they urged us to establish an administrative review process for investigating allegations of discrimination based on licensure or certification. To facilitate the reviews, these commenters suggested that the regulations require that notices of adverse participation decisions include a statement of the reasons for the determination.

Response: Although we do not intend to establish a separate administrative review process for investigating allegations of discrimination against providers, we intend to place a strong emphasis on verifying that M+C organizations are in compliance with the antidiscrimination provisions. This will occur both through our scheduled monitoring activities and under our authority to conduct complaint investigations when we believe there is credible evidence of violations.

In addition, as noted above, § 422.205 will now incorporate the requirement that an M+C organization must state in writing its reasons for declining to include any given provider or group of providers in its provider network. This should enhance our ability to identify violations of the antidiscrimination requirements, for example, by detecting situations in which organizations exhibit a pattern of repeated refusal to contract with certain types of practitioners. If a prospective provider has evidence of discrimination on the basis of licensure, the appropriate avenue to raise this concern is the HCFA regional office in the relevant area.

Comment: One commenter expressed concern that without further clarification, the choice-of-practitioners provision at existing § 422.100 could be construed as giving an M+C organization complete and final authority over an enrollee's choice of health care provider. The commenter recommended that we clarify that an enrollee may appeal a plan's decision not to allow access to a specialist, or a specific provider, that the enrollee believes is necessary to furnish adequate services.

Response: The regulations concerning choice of practitioners are not intended to limit in any way the appeal and grievance rights of enrollees under subpart M of the M+C regulations. If an enrollee is denied access to a specialist, the enrollee clearly has the right to a timely organization determination and, if necessary, a reconsideration of this determination. Situations involving whether a specific provider is necessary are more likely to be subject to either the organization's grievance procedures or possibly to external review by a PRO if quality issues are involved.

5. Provider Credentialing (§ 422.204(a))

Ensuring that providers have the proper credentials for the services they are providing is a key component of an overall ''ongoing quality assurance program for health care services,'' as required under section 1852(e)(1) of the Act. Section 422.204(a) accordingly sets forth basic requirements that an M+C organization must follow with respect to the credentialing and recredentialing of the providers and suppliers with whom it enters into participation agreements. The M+C organization must ensure that providers and suppliers meet applicable State and Federal requirements. Basic benefits must be provided through, or payments must be made to, providers that meet applicable requirements of title XVIII and part A of title XI of the Act. Also, in the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, § 422.204(a)(3)(i) specifies that basic benefits may only be provided through such providers if they have a provider agreement with us permitting them to provide services under original Medicare. An M+C organization may not employ or contract with providers excluded from participation in Medicare.

Comment: Although commenters generally supported the flexibility built into the M+C credentialing provisions, several commenters suggested that the credentialing standards used by the NCQA be incorporated into the M+C regulations because these commenters believe that they are clear and adequate to protect M+C beneficiaries. Several commenters contended that many of the M+C credentialing standards were somewhat vague; one commenter identified as particularly unclear the requirement under § 422.204(a)(2)(iii) to establish a process to ''receive advice'' from contracting health care professionals with respect to credentialing criteria. Another commenter asked if, in general, an M+C organization that complies with NCQA credentialing standards would also be in compliance with the M+C requirements. The commenter asked for confirmation that, like under the NCQA standards, the following categories of practitioners are not subject to the credentialing requirements: (1) hospital-based practitioners that provide care for an M+C organization's enrollees only as a result of members being directed to the hospital, and (2) practitioners who provide care only under the direct supervision of a contracting physician. Another commenter asked for additional clarity as to what types of practitioners must be credentialed and suggested following NCQA standards. One commenter argued that the credentialing provisions should include substantive criteria governing which physicians will be credentialed in the network, which excluded, and on what grounds.

Response: In view of these comments, we have reexamined the existing credentialing provisions and are making several changes. First, as discussed above, we have removed both the antidiscrimination and the provider appeals provisions from § 422.204. Section 422.204 will now be entitled ''Provider selection and credentialing'' and will include a new § 422.204(a) to establish the general rule that an organization must have written policies and procedures for the selection and evaluation of providers. These policies and procedures must conform with the existing credentialing requirements, which will be redesignated as § 422.204(b), as well as the antidiscrimination procedures now contained under new § 422.205. These changes do not impose new substantive requirements on M+C organizations, but we believe they constitute both a necessary reorganization of the existing requirements, and a means of clarifying in the regulations the inherent purpose of the credentialing rules—the need for a systematic approach to provider selection. We note that both the NCQA standards and our QISMC standards

already incorporate the underlying concept that an organization's credentialing requirements are an integral component of its provider selection policies.

This change in no way obviates our awareness that an organization's selection criteria, and thus its credentialing policies and procedures, should be tailored to take into account the individual characteristics of each M+C organization. The process of provider selection also should be integrated with the process of establishing and maintaining an adequate provider network to assure enrollee access to plan services. Thus, we do not intend to add to the regulations greater specificity concerning the procedures an M+C organization must follow for credentialing and recredentialing purposes, or establish detailed criteria as to what constitute adequate credentials. Instead, the regulations will continue to require that M+C organizations follow a ''documented process'' for these activities that meets the relatively flexible existing standards.

With respect to the question about whether meeting NCQA standards would constitute compliance with M+C requirements, we are currently evaluating this question in the context of the ''deeming'' provisions discussed in section II.D above. If we find that NCQA, or any other private accreditation organization, applies and enforces standards that are at least as stringent as those set forth in § 422.204, then satisfying NCQA standards would constitute compliance with M+C requirements. Until we make such a determination, however, meeting NCQA credentialing standards does not necessarily achieve compliance with the M+C requirements. We note that we agree with NCQA that credentialing is not required for health care professionals who are permitted to furnish services only under the direct supervision of a physician or other provider, or for hospital-based health care professionals (such as an emergency room physician, anesthesiologist, or certified registered nurse anesthetist (CRNA)) who provide services to enrollees only incident to hospital services. (This exception does not apply if the practitioner contracts independently with the M+C organization or is promoted by the organization as being part of its provider network.)

Finally, we agree that the requirement that an M+C organization's process include ''receiving advice'' from contracting health care professionals could be misconstrued. We are changing this requirement to indicate that the organization must have a process for consulting with its contracting health care professionals on its credentialing and recredentialing criteria.

Comment: Several commenters suggested technical changes to the regulations in subpart E. For example, one commenter recommended that the credentialing provisions consistently refer to suppliers as well as providers, noting that the subpart E basis and scope section (§ 422.200) explicitly mentions both providers and suppliers, while § 422.204(a)(3)(i) only refers to the furnishing of basic benefits through ''providers.'' The commenter also recommended that pharmacies be considered as providers. Another commenter suggested that we add ''or certification'' to the licensure verification requirement under § 422.204(a)(2)(i), and asked whether Joint Commission on Accreditation of Health Care Organizations/Community Health Accreditation Program or Medicaid certification of an HHA was sufficient to meet the provider credentialing requirements, as has been the case in the past for Medicare managed care.

Response: The definition of providers that applies for purposes of the M+C program is found at § 422.2 and includes both entities that would be considered providers and suppliers for other Medicare purposes. However, to avoid any possible confusion, we are adopting the commenter's recommendation that suppliers be explicitly mentioned under existing § 422.204(a)(3)(i) (now redesignated as § 422.204(b)(3)(i), as discussed above). Pharmacies, thus, are considered ''providers'' for purposes of the M+C program. We are also amending the regulations to indicate that initial credentialing should include verification of licensure or certification.

Existing § 422.204(a)(3)(i) requires that in the case of providers of services that meet the original Medicare definition of ''providers'' under section 1861(u) of the Act (such as HHAs or SNFs), that provider must have a provider agreement with us in order to be permitted to furnish basic benefits under an M+C plan. Under this requirement, neither accreditation nor approval under the Medicaid program is necessarily sufficient to enable an HHA to furnish services under an M+C plan, unless the HHA is Medicare-certified. The objective of this policy is to ensure that M+C enrollees are guaranteed services of a quality level at least equal to that available to other Medicare beneficiaries. We continue to believe that the existence of a provider agreement with us is the best way to ensure that HHAs providing services to M+C enrollees meet uniform standards in all States and are subject to Federal enforcement authority. Thus, we believe it would be inappropriate to create an exception for HHAs to the general rule that ''providers of services'' as defined under section 1861(u) of the Act must have a provider agreement that permits them to furnish services under original Medicare.

Comment: One commenter stated that the credentialing requirements appeared to require individual credentialing for physicians in group practices. The commenter believed that this requirement is too inflexible and could delay a physician's inclusion in a network. Instead, the commenter recommended that an M+C organization have the option of credentialing a group practice as network participants, and then transferring the obligation to credential new members of the practice to the practice itself.

Response: When an M+C organization contracts with a group practice, it has an obligation to ensure that all members of that practice meet its credentialing standards. Consistent with the discussion of subcontracting rules above (and with the subcontracting requirements of § 422.502(i)(4)), subsequent credentialing may be carried out either by the M+C organization itself or be delegated to the subcontracting organization (that is, the group practice). If delegated, however, the M+C organization must review and approve the credentialing process, and audit the process on an ongoing basis.

Comment: One commenter objected to several aspects of the credentialing requirements, and urged that they be modified to take into account the varying characteristics of M+C networks such as PPOs. The commenter recommended that the requirement for site visits be eliminated for PPOs, and that the requirement for recredentialing every 2 years be modified in favor of permitting M+C organizations to determine when recredentialing was appropriate depending upon the size and stability of the provider network.

Response: Under the existing regulations, site visits are required ''as appropriate'' for initial credentialing; thus, sufficient flexibility already exists in this regard. We believe that recredentialing every 2 years is a reasonable time frame and note that it coincides with NCQA standards. We believe it would be inappropriate for each M+C organization to substitute its judgment for a national standard as to when it should recredential its practitioners. If the provider network is

small and stable, the administrative burden associated with the recredentialing process should be relatively small.

Comment: One commenter noted that the prohibition on entering into contracts with providers that are excluded from participation in the Medicare program (under existing § 422.204(a)(3)(ii)) is impossible to implement unless the HCFA website includes a Social Security number (SSN).

Response: As noted in the interim final rule, M+C organizations are expected to consult the Office of Inspector General's (OIG) website (www.dhhs.gov/progorg/oig) to access the list of providers that are excluded from participation in the Medicare program. For privacy reasons, this listing does not include SSNs. However, we also maintain an internal excluded provider list (HCFA Publication 69) that includes unique identifying information for the providers in question. This publication generally is available to all of our contractors, including M+C organizations. We suggest that any M+C organization that needs this information contact either its regional or central office plan manager, or HCFA's Office of Issuances to obtain the latest version of Publication 69.

6. Prohibition on Interference With Health Care Professionals' Communication With Enrollees (§ 422.206)

Consistent with section 1852(j)(3)(A) of the Act, § 422.206(a) prohibits an M+C organization from interfering with the advice of a health care professional to an enrollee who is his or her patient. Thus the health professional may act within his or her scope of practice in advising the enrollee about his or her health status, all relevant medical or treatment options available regardless of whether care or treatment is provided under the plan. Section 422.206(b) incorporates the requirements of section 1852(j)(3)(B) of the Act. The regulations state that the prohibition against interference with the content of advice a health care provider has given to enrollees regarding medical treatment should not be construed as requiring counseling by a professional, if the M+C organization objects, based on moral or religious grounds, and fulfills certain notification requirements to prospective and current enrollees. The regulations incorporate the notification process and time frames included in the law and clarify that the plan must also notify us at the time of application and within 10 days of submitting its ACR proposal. We received 12 comments addressing the provisions set forth under § 422.206.

Comment: The majority of the commenters simply expressed their support for this provision, which has been referred to as the ''anti-gag rule.'' One commenter asserted that an M+C organization should not be forced to provide care that is not medically effective, approved by the Food and Drug Administration (FDA), or covered under the enrollee's plan. A commenter also suggested that M+C organizations be prohibited from requiring health care professionals to sign ''gag rule'' clauses that interfere with full disclosure of all treatment options, regardless of whether theses options are covered under a plan. Another commenter noted that § 422.206(d) states that an M+C organization is subject to intermediate sanctions for violations of these provisions, and recommended that the regulations also specify that we will not renew the contract of an M+C organization that substantially violates the provisions in § 422.206.

Response: As indicated in the June 1998 interim final rule, a health care professional's freedom to inform an enrollee about available treatment options in no way implies that all of the possible treatment options (for example, experimental or noncovered alternatives) are covered under the enrollee's M+C plan. In other words, the prohibition on interference with provider-enrollee communications does not affect the M+C benefit and coverage requirements. Clearly, these rules prohibit an M+C organization from requiring health care professionals to sign a ''gag rule'' clause, such as that mentioned by the commenter. Finally, we note that under § 422.506(b)(1)(iv) of the M+C contracting regulations, an M+C organization that commits any acts that can support the imposition of intermediate sanctions is also subject to nonrenewal of its contract.

Comment: One commenter representing health insurance agents recommended that the regulations include a prohibition on physicians ''advising seniors on M+C plans.'' The commenter asserted that only individuals with health insurance licenses should be permitted to proffer such advice.

Response: Although we recognize that there are situations where it would be inappropriate for physicians or other health care professionals to ''steer'' beneficiaries to particular health care plans, we do not believe that prohibiting patients from seeking advice from physicians regarding insurance coverage choices is either necessary or practical. For example, a physician should be able to disclose to a patient the M+C plans in which he or she is a network provider. (For additional discussion of this issue, please see the portion of section II.B of this preamble that discusses M+C marketing requirements at § 422.80.)

Comment: Two commenters recommended that we either delete or clarify the requirement in § 422.206(a)(2) that health care professionals provide information regarding treatment options in a ''culturally competent manner.''

Response: We recognize that the term ''culturally competent'' can be subject to various interpretations, as discussed in detail above in section II.C of this preamble concerning M+C access requirements. For the purposes of this provision, our intent is that M+C organizations establish and maintain effective communication with enrollees, including informing them of treatment options in a language they can understand.

Comment: Two commenters raised concerns related to the conscience protection exceptions set forth in § 422.206(b). One commenter strongly supported the provisions, but recommended that the final rule clarify that: (1) nothing in the conscience protection provisions be construed as limiting the range of services to which Medicare beneficiaries are entitled; (2) an enrollee may terminate enrollment and choose another M+C plan if he or she receives notification under this section that an M+C organization will not cover or pay for a particular counseling or referral service; and (3) like other disclosure requirements, notifications required under § 422.206(b)(2) must be provided in a clear, accurate, and standardized form, consistent with the special needs of individual enrollees.

Another commenter asserted that there was a potential conflict between the conscience protection provisions and the information disclosure rules in § 422.111 and recommended that we establish an exception to the advance disclosure rules for ''duly adopted religious policies.'' The commenter noted that the conference agreement to the BBA indicates the Congress' intent that the Secretary not ''impose burdensome regulatory, legal, or stylistic requirements with respect to this notice requirement.'' (House Report, 105–217, pg. 607.)

Response: As the commenter points out, the conscience protection provisions in no way diminish or otherwise affect the range of benefits or services to which Medicare beneficiaries are entitled. As discussed in section II.C

above, the conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A), not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) to provide all Medicare-covered services available in the area served by the M+C plan. To the extent that the operation of the right to advice and counseling under section 1852(j)(3)(A) would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) allows the organization to decline to provide such service on conscience grounds if notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A), it could not be affected by a provision that by its own terms affects only the way that ''[s]ubparagraph (A) [of section 1852(j)(3)] shall * * * be construed.'' It in no way affects obligations that arise elsewhere in the statute. Therefore, an M+C organization could not rely upon section 1852(j)(3)(B) or § 422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover. We note, however, that in the case of abortion-related services, the Congress has provided M+C organizations with certain conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 216 of the fiscal year 1999 appropriations legislation (Pub. L. 105–277), we are prohibited from denying an M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. Beneficiaries, nevertheless, retain the right to such services, and Medicare must cover them. We are required, however, to make appropriate adjustments to such an entity's M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

We agree that the disclosure provisions under § 422.206(b) should be read consistently with other disclosure provisions in the regulations, and thus M+C organizations must take into account the special needs of individuals who are blind, disabled, or cannot read or understand English. The notification requirements set forth in § 422.206(b)(2) are not intended to result in an M+C organization being put in the position of being required to furnish counseling or referral services that violate a duly adopted religious policy. Experience indicates that neither changes in Medicare coverage policies nor in ''duly adopted'' religious policies take place so quickly as to preclude an M+C organization from providing advance notice to us, and then to enrollees, concerning service restrictions based on such policy changes. Thus, we believe that only very rarely, if ever, would a conflict exist between the advance disclosure requirement of § 422.111(d) and the provision that permits an organization to implement a conscience exception, provided that it notifies its enrollees of such changes within 90 days after adopting the change. Consequently, we do not view the advance disclosure procedure as a burdensome requirement.

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

Sections 422.208 and 422.210 outline the limitations and disclosure rules for physician incentive plans. Specifically, § 422.208 applies to an M+C organization and any of its subcontracting arrangements that use a physician incentive plan in their payment arrangements with individual physicians or physician groups. With the exception of the deletion of a requirement that information on expenditures of capitation payments be reported to us, the provisions in these sections are essentially the same as those that previously applied to Medicare risk plans under § 417.479. We received several comments regarding physician incentive rules.

Comment: A commenter contended that the 25 percent threshold for substantial financial risk is too high, noting that we have acknowledged that this represents an outlier approach, and that risk arrangements in the range of 10 to 15 percent are far more prevalent than those in excess of 25 percent. This commenter argued that the 25 percent threshold may render the rule irrelevant as applied to the majority of M+C organizations. In addition, the commenter is concerned that because the exemption level is set so high, the effect of the exemption may be to discriminate against plans that are in the process of growth, thus giving the larger plans a competitive advantage.

Response: As we indicated in the preamble to the physician incentive plan regulation published on March 27, 1996 (61 FR 13430), we believe that the 25 percent risk threshold is appropriate because of the outlier methodology that we used. The median withholds are in the 10 to 20 percent range. This was the best methodology in formulating the risk threshold. Actuarial analyses also supported the 25 percent risk threshold. Furthermore, many physicians typically give discounts in the 25 percent range.

The majority of arrangements that exceed the threshold are capitation arrangements, where 100 percent of the income is put at risk. For these arrangements, the precise amount at which we set the threshold will not make a difference, they will exceed any reasonable risk threshold.

Comment: One commenter pointed out a conflict in the regulatory language. At § 422.208(c)(2), the regulation specifies that the M+C organization provides stop-loss protection; while at § 422.208(f), it specifies that the M+C organization must assure that all physicians and physician groups have stop-loss protection.

Response: The commenter is correct and we are revising the incorrect language in § 422.208(c)(2) to eliminate this discrepancy. We note that paragraph (f) incorporates the language from § 417.479 (the physician incentive regulation that applied to section 1876 contracts) that we indicated in the preamble to the physician incentive regulation that we intended to adopt.

Comment: One commenter contended that the physician incentive plan requirements are excessively detailed, prescriptive, and confusing. The commenter argued that the detailed stop-loss insurance requirements impose additional costs on the delivery of health care, costs that are increasingly borne by the physician practices, not M+C organizations. The commenter urged us to monitor the stop-loss insurance market carefully, and provide prior review of panel size, and deductible limits set forth in the rule to ensure that they are not necessarily restrictive.

Response: In the preamble to the December 31, 1996 final rule (61 FR 69034) containing the section 1876 physician incentive requirements upon which §§ 422.208 and 422.210 were based, we presented a regulatory impact analysis. In that analysis, we concluded that only a small number of organizations and physician groups would need to increase their stop-loss protections, and that this increase would be small relative to the total amount of income. Furthermore, stop-loss insurance is required by statute where substantial financial risk is imposed, and it provides increased protection to physicians that helps reduce possible incentives to deny necessary care. These requirements have been in place for 3 years, and do not appear to have caused any significant problems for M+C organizations or their predecessors.

Comment: A commenter requested that these rules should apply to Federally Qualified Health Centers

(FQHCs) and all associated health care providers. The commenter pointed out that these rules appear limited to individual physicians, physician groups, and intermediate entities acting as subcontractors.

Response: If the FQHC is an intermediate entity, subcontractor, or a physician group as specified in these regulations, then the provisions apply.

Comment: One commenter wanted to know if we review disclosures for both the Medicare and Medicaid programs.

Response: The regulations require that M+C organizations that participate in the M+C program must disclose incentive plan arrangements to us, while managed care organizations that participate in the Medicaid program disclose incentive plan arrangements to the State Medicaid Agencies. We review the monitoring activities of State Medicaid Agencies.

Comment: One commenter indicated support for the methodology for disclosing incentive plans, but requested that we make clear that we do not require the precise formula and payment amounts be disclosed.

Response: Section 422.210(b) requires that an M+C organization must provide the following information to any Medicare beneficiary who requests it: (1) Whether the M+C organization uses a physician incentive plan that affects the use of referral services; (2) the type of incentive arrangement; (3) whether stop-loss protection is provided; and (4) if the M+C organization was required to conduct a survey, a summary of the survey results.

As we indicated in guidance provided in December 1996 to section 1876 contractors, M+C organizations do not have to disclose to beneficiaries the precise formula and payment amounts involved, nor do they have to provide incentive plan information for individual physicians or physician groups. Only summary information needs to be reported. However, the M+C organizations are required to report more detailed information to us or the State Medicaid Agencies.

8. Special Rules for Services Furnished by Noncontract Providers (§ 422.214)

Consistent with sections 1852(k)(1) and 1866(a)(1)(O) of the Act, § 422.214 requires that any health care provider that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan must accept, as payment in full, the amounts that they could collect if the beneficiary were enrolled in original Medicare (less the amounts specified in §§ 412.105(g) and 413.86(d) of the regulations on hospital graduate medical education payments, when applicable). Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an M+C plan also apply to the payment described in § 422.214(a)(1) of our regulations. We received three comments regarding this section.

Comment: Several commenters suggested that we revise § 422.214 to provide that payment to a noncontracting provider must equal the amount that provider would be allowed to collect under original Medicare. These commenters believe that M+C organizations should only be permitted to pay the billed amount when this is the same amount that Medicare would pay under original Medicare.

Response: Section 422.214 implements section 1866(a)(1)(O) of the Act, with respect to services furnished by a ''provider of services'' as defined in section 1861(u), and section 1852(k)(1), with respect to other services. Neither of these provisions requires an M+C organization to pay a provider more than the amount of the provider's bill, or even impose obligations on M+C organizations at all. Rather, these provisions serve as a limit on the amount the provider can collect from the M+C organization. Specifically, each of these provisions states that a provider ''shall accept as payment in full'' the amount (less the amounts specified in §§ 412.105(g) and 413.86(d) of the regulations) that it would receive under original Medicare, including cost sharing and permitted balance billing (''the Medicare payment amount''). While this means that under these provisions the provider cannot collect *more* than the Medicare payment amount if its billed amount is *higher*, this obligation to ''accept'' the Medicare amount as payment in full does not obligate the M+C organization to pay this amount if the provider's bill is *lower*. Thus, in the case of emergency services and certain other services referred to in section 1852(d)(1)(C) of the Act furnished to an enrollee in a coordinated care plan, the provider or providers must accept the Medicare payment amount for the services if their billed amount is higher, but would have no right under sections 1852(k)(1) or 1866(a)(1)(O) to be paid more than the amount of their bill if the billed amount is lower than the Medicare payment amount.

We note, however, that a provision in the BBA does give providers furnishing services to coordinated care plan enrollees the right to be paid the Medicare payment amount under certain circumstances. Section 1852(a)(2) provides that where an M+C organization chooses to furnish services through providers that do not have contracts with the organization in order to meet its obligation under section 1852(a)(1) to make Medicare services available, it must provide for payment ''equal to at *least*'' the Medicare payment amount. (Emphasis added.) This new provision, unlike section 1866(a)(1)(O) or section 1852(k)(1), establishes a ''floor'' for payment when it applies. This ''floor,'' combined with the ''ceilings'' under sections 1866(a)(1)(O) and 1852(k)(1), essentially requires that the Medicare payment amount be paid where section 1852(a)(2) applies. Because section 1852(a)(2) refers to an M+C organization's furnishing services in fulfillment of its obligations under section 1852(a)(1), we are interpreting section 1852(a)(2), in the coordinated care plan context, as providing M+C organizations with the opportunity to arrange to provide nonemergency services through noncontracting providers. Under this interpretation, the ''minimum payment'' requirement in section 1852(a)(2) would only apply where the M+C organization has arranged for the services in question to be provided by a noncontracting provider. In the coordinated care plan context, therefore, payment for emergency services and those services referred to in section 1852(d)(1)(C) would continue to be subject only to the rules in sections 1852(k)(1) and 1866(a)(1)(O). In the private fee-for-service plan context, however, section 1852(k)(2)(B)(i) of the Act provides that all services furnished by noncontracting providers are subject to the ''minimum payment rate'' in section 1852(a)(2).

To summarize our position, in the case of services arranged by an M+C organization to be furnished by a noncontracting provider to a coordinated care plan enrollee, or any services furnished by a noncontracting provider to a private fee-for-service plan enrollee, section 1852(a)(2) applies, and the M+C organization must pay the Medicare payment amount. In the case of emergency services (referred to in section 1852(d)(1)(E)), urgently needed services (referred to in section 1852(d)(1)(C)(i)), renal dialysis services provided out of the M+C plan's service area (referred to in section 1852(d)(1)(C)(ii)), and maintenance care or poststabilization services (referred to in section 1852(d)(1)(C)(iii)) furnished to a coordinated care enrollee by a noncontracting provider, the provider is required to accept the Medicare

payment amount as payment in full, but the M+C organization is not required to pay more than the billed amount.

Comment: One commenter suggested that we should clearly lay out the process and requirements for compliance with the provisions of § 422.214. In order to implement the payment limits in § 422.214 and not overpay noncontracting providers, M+C organizations will have to develop a process that would apply applicable Medicare payment limits to charges for services furnished to enrollees by noncontracting providers. M+C organizations will need detailed information from us describing each of Medicare's payment limits, how each limit is applied, and which limits apply to which provider.

Response: The comment addresses the need for a process to implement the payment limits contained in § 422.214. We understand that any process used to apply Medicare payment limits will require a significant amount of data and will be relatively complex. However, we do not feel that the requirements for such a process should be set forth in regulation. Each M+C organization should be allowed to develop a process that will satisfy that organization's needs.

As discussed in further detail in section II.Q of this preamble, we anticipate that the organizations offering M+C private fee-for-service (PFFS) plans may have a particular need for such a process, both to pay non-contracting providers who must be paid at least the amount they could collect under original Medicare, and to pay contracting and deemed contracting providers, assuming that the M+C organization offering the PFFS plan has chosen to meet access requirements by paying contracting providers ''no less than'' the amount paid under original Medicare. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish ''proxies'' for use in paying services for which no Medicare prospective payment system or fee schedule exists, provided that the proxy methodology has been approved by us as not being less than the expected Medicare payment amount.

We emphasize that the proxy methodologies will be designed to provide an accurate estimate of the Medicare payment amount, including possible beneficiary cost-sharing under original Medicare. In some cases (for example, for Medicare-certified hospitals, SNFs, or HHAs, or for Medicare-participating physicians), this is the amount that a noncontracting provider is required to accept as payment in full from the M+C organization. In other cases, the amount that a noncontracting provider may collect is not limited to the Medicare payment amount but could include allowable balance billing amounts under original Medicare. In such a case, the provider has a right to collect more from the M+C organization than the Medicare payment amount reflected in the proxy (and in the case of a non-contracting provider furnishing services to a PFFS plan enrollee, the M+C organization may have an obligation to pay more than the proxy amount).

Comment: One commenter asked whether the statement in the preamble that ''the M+C organization must hold beneficiaries harmless against any such balanced billing'' means that an M+C organization must pay billed charges to noncontracting providers regardless of the Medicare fee schedule.

Response: No. Section 422.214 clearly states that a noncontracting provider must accept as payment in full what the provider could collect under original Medicare (less any payments under §§ 412.105(g) and 413.86(d)). Please note that some providers may be entitled to receive an amount that is in excess of the Medicare fee schedules, but that does not exceed the limiting charge.

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

An M+C organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts with the beneficiary under section 1802(b) of the Act. An M+C organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Comment: One commenter contended that it is difficult to exclude private contracting physicians and practitioners from payment because there is no central list of private contractors. This commenter believes that we should list these physicians and practitioners on our website, and include unique identifiers, like the physician or practitioner's SSN.

Response: We recognize that it is difficult for M+C organizations to acquire timely and accurate information on ''opt out'' physicians with whom they do not have a contract, and we are working on a way of making this information available to them as soon as possible. M+C organizations offering coordinated care plans could seek this information from the provider or supplier before they authorize the use of a noncontracting physician or practitioner. Moreover, we do not anticipate that the absence of such knowledge would be a problem in cases of emergency or urgent care since in those cases, the services of the opt-out physician or practitioner are covered (unless the enrollee/beneficiary has previously signed a private contract).

As part of our effort to streamline the flow of information on opt-out physicians and practitioners, we are also considering what information can be placed on a list or made available through a website. Some information such as the SSN cannot be disclosed under the Privacy Act.

Currently, M+C plans should contact the Medicare carrier with jurisdiction over the payment of claims under original Medicare in their service area to work out a mutually agreeable means of receiving this information on a timely basis. Disputes should be referred to the HCFA regional office for resolution.

With respect to contracting physicians, M+C organizations may, through their contracts, require contract providers to notify them immediately when they enter into private contracts under section 1802(b). This will provide the information more timely than any process that might be arranged with Medicare carriers or through a listing prepared by us, and will permit the M+C organization to cease payment immediately to the contracting physician or practitioner who has opted out of Medicare.

Comment: One commenter urged that we monitor the disease type and severity of diseases of beneficiaries who privately contract with physicians to determine what future program changes are appropriate.

Response: We are required by section 4507 of the BBA to provide a report to the Congress by October 1, 2001 on the effect of private contracting and to provide recommendations for legislation in this regard. We are conducting a broad study of claims data that will be used to prepare that report.

Comment: A commenter suggested that the private fee-for-service plan discussion of deemed and non-contracting providers be revised to indicate that these payment restrictions do not apply if the provider has opted out under § 422.220.

Response: We have included a clarification by cross reference.

Comment: A commenter believes that beneficiaries need to be advised in both HCFA and M+C plan information that no payment can be made by the M+C organization for services provided under private contract with a physician who has entered into a contract under section 1802(b).

Response: We agree that it is important that M+C plan enrollees know that no payment can be made under the M+C plan for services of physicians and practitioners who have entered into contracts under section 1802(b). Section 1802(b) and private contracting regulations at § 405.400 both require that a private contracting physician or practitioner have the beneficiary (enrollee in the case of M+C plans) sign a private contract that notifies him or her that no Medicare payment will be made for the services of the opt-out physician or practitioner, and that he or she accepts full responsibility for payment of the opt-out physician or practitioner's services (except in cases of emergency medical condition or urgent care in which the physician or practitioner cannot ask the beneficiary to sign a private contract and Medicare will pay for the care). Hence, the plan enrollee should be specifically aware of the effect of receiving services from an opt-out physician or practitioner before he or she receives these services. We will, however, also consider adding a discussion of private contracting to the model evidence of plan coverage.

10. M+C Plans and the Physician Referral Prohibition

The physician referral prohibition in section 1877 of the Act concerns M+C organizations, although the implementing regulations are located in subpart J of part 411 rather than in part 422. Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (through an ownership interest or a compensation relationship), the physician may not refer Medicare patients to that entity for any of 11 designated health services, unless an exception applies. Under section 1877(b)(3) of the Act and § 411.355(c) of the regulations, services furnished by section 1876 contractors to their enrollees were exempted from the physician referral prohibition. In the June 1998 interim final rule, we revised § 411.355(c) to similarly exclude from the physician referral prohibition services furnished under an M+C coordinated care plan to an enrollee. We did not exclude services furnished by private fee-for-service plans or MSA plans from the physician referral prohibition. Subsequently, section 524 of the BBRA amended section 1877(b)(3) of the Act by adding a new subparagraph (E) to exempt an M+C organization offering an M+C coordinated care plan from the physician referral prohibition. The comments and responses regarding this subject are discussed below.

Comment: One commenter argued that services furnished under an MSA plan or private fee-for-service plan should also be excluded from the physician referral provisions. The commenter believed that while there are differences between these types of plans and coordinated care plans, patients who elect coverage under an MSA plan or a fee-for-service plan do so knowing that their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan. In the commenter's view, concerns about beneficiaries should be addressed in the context of disclosures by the M+C organization offering the MSA plan or private fee-for-service plan, prior to enrollment, rather than by the section 1877 provisions. At most, this commenter would require only that M+C organizations offering plans of these types disclose financial interests in entities that furnish designated health services in return for an exception from the prohibition in section 1877.

Response: As we understand the argument, the commenter has suggested that we should exclude M+C private fee-for-service plans and M+C MSA plans from the prohibition on referrals under section 1877 because the concerns addressed by section 1877, that, in general, a physician should not profit from his or her referrals for certain services, has already been accommodated. The commenter believes that beneficiaries already understand that in these plans their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan, and that any problems that still might exist can be addressed by more disclosure.

We do not understand why a beneficiary's knowledge of the differences between coordinated care plans and private fee-for-service/MSA plans addresses the concerns behind our decision not to exempt services furnished under the latter plans from the prohibition in section 1877. Under section 1877, we can create a new exception only if the Secretary determines, and specifies in regulations, that a financial relationship between a physician and an entity to which the physician refers does not pose a risk of program or patient abuse. Pursuant to this authority, we exempted services furnished under coordinated care plans because the Congress had already exempted the identical type of arrangement when it exempted services furnished under section 1876 contracts, (and likely inadvertently failed to make a conforming change to this exception when M+C contracts replaced section 1876 contracts), and because we did not see a potential for program or patient abuse in the case of coordinated care plans. This latter conclusion was based on the facts that, as in the case of a section 1876 risk contractor: (1) A physician working with an M+C organization offering a coordinated care plan has no incentive to order unnecessary care, since physicians are not paid for ordering additional services; (2) the organization has control over its network of providers, and provides incentives for its network providers to avoid unnecessary care; and (3) incentives to deny necessary care are addressed by physician incentive plan requirements limiting the risk that can be imposed on physicians. These are the same physician incentive plan requirements that are incorporated in a section 1877 provision permitting certain risk arrangements that would otherwise be subject to the referral prohibition. (See section 1877(e)(3)(B) of the Act.)

In contrast, under M+C MSA plans or private fee-for-service plans, individual providers, including physicians, are paid on a fee-for-service basis for services provided, and thus have the same kind of incentives to provide unnecessary services that gave rise to the enactment of section 1877. Although this would not result in more Medicare funds being expended during the year in question, it could harm beneficiaries in two ways. First, it could result in higher cost-sharing paid by beneficiaries in the current year. Second, it could result in the M+C organization offering less in benefits the following year than it would otherwise be able to offer if its expenses were not as high. For these reasons, we do not believe that the exception from the physician referral prohibition that we have created for services furnished under coordinated care plans should apply to services under M+C private fee-for-service plans or MSA plans. We note that the Congress implicitly endorsed our position through the amendments to section 1877 included in section 524 of the BBRA. This section explicitly exempted M+C coordinated care plans from the physician referral prohibitions, but did not include any changes related to other types of plans.

F. Payments to M+C Organizations

1. General Provisions

Part 422 Subpart F sets forth rules that govern payment to M+C organizations, including the methodology used to calculate M+C capitation rates. These rules are based primarily on section 1853 of the Act. (For a complete discussion of these requirements, see the June 26, 1998 interim final rule at 62 FR 35004.)

One of the more significant payment changes in section 1853 of the Act is a gradual transition from rates based on local Medicare costs to ''blended'' rates based on a 50/50 mix of local and national costs. Under the Adjusted Average Per Capita Cost (AAPCC) payment methodology that applied to section 1876 risk contracts, payment was based on Medicare fee-for-service expenditures in the county in which the enrollee resided. These fee-for-service expenditures were adjusted for demographic factors (that is, age; sex; institutional, welfare, and employment status).

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

''Greatest of'' Payment Rate: Since January 1, 1998 (when the M+C payment methodology under section 1853 was made applicable to section 1876 risk contractors pursuant to section 1876(k)(3) of the Act), the Medicare capitation rate for a given county has been the greatest of: (1) The above-referenced blended capitation rate; (2) a ''minimum amount'' rate established by statute; or (3) a minimum percentage increase. These county rates are then adjusted by demographic factors (and after 2000, by risk adjustment factors) to determine the actual payment amount.

- The blended capitation rate is a blend of the area-specific (local) rate and the national rate, with the latter adjusted for input prices. The blended capitation rate is then adjusted by a budget neutrality factor designed to ensure that payment is not higher than it would be under purely local rates.
- The minimum amount rate was $367 per month per enrollee in 1998 for all areas in the 50 States and the District of Columbia. Outside the 50 States and the District of Columbia, the rate was limited to 150 percent of the 1997 AAPCC for the area in question, if this amount was lower than $367. The minimum amount rate is adjusted each year using the update factors described in § 422.254(b).
- The minimum percentage increase is 2 percent. The minimum percentage increase rate for 1998 was 102 percent of the 1997 AAPCC. Thereafter, it is 102 percent of the prior year's capitation rate.

With the exception of payments under M+C MSA plans, we pay M+C organizations monthly payments for each enrollee in an M+C plan they offer 1/12th of the annual M+C capitation rate for the payment area described in § 422.250(c). Except for ESRD enrollees, these payments are adjusted for such demographic risk factors as an individual's age, disability status, sex, institutional status, and other factors determined to be appropriate to ensure actuarial equivalence. Since January 1, 2000, these rates also have been adjusted for health status as provided in § 422.256(c). For 2000, only 10 percent of the capitation payment will be risk adjusted, with the other 90 percent determined based on the 1999 methodology.

Comment: Several commenters contended that section 1853(c) of the Act set forth artificial and arbitrary limits on capitation rate increases. Because the budget neutrality adjustment applies only to the ''blended rate,'' and the final rate is based on the greatest of the three rates specified, it was not possible to achieve budget neutrality in 1998 or 1999. Once the blended rate was lowered below at least one of the other two rates in each county, no further savings could be achieved through a budget neutrality adjustment. As a result of the adjustments made in an attempt to achieve budget neutrality, however, capitation rates in 1998 and 1999 were all based either on the minimum percentage increase of 2 percent from the prior year, or the new minimum payment rate. The commenters argued that the effect of this would be that M+C organizations would withdraw from Medicare, either entirely or in low payment areas. These commenters suggested that we propose legislative changes to section 1853 of the Act in order to change the formula used to calculate the county payment rates.

Response: The commenter's suggestions concerning changes in legislation are outside the scope of this rulemaking. In this rulemaking, we are charged with implementing the BBA as enacted (and in this final rule, as revised by the BBRA).

However, passage of the BBRA may alleviate some concerns of the commenters. The BBRA requires several modifications to the payment calculations set forth in the BBA, including: lowering the reduction of the national per capita growth percentage defined in § 422.254(b), offering bonus payments to eligible M+C organizations as described in § 422.250(g), and revising our original schedule for transitioning to risk-adjusted payments to providing for an even more gradual introduction of risk adjustment. (See Section I.C for a full discussion of the BBRA provisions.)

Comment: One commenter wanted to know if adjusted excess amounts (determined through the Adjusted Community Rate process identified in § 422.312) affect the computation of the county payment rates if these amounts are placed in a stabilization fund, described in § 422.252.

Response: Amounts deposited in a stabilization fund reduce the payment to the M+C organization for the year in which the funds are deposited (the organization gives up that amount to use it for benefits in a future year), but do not affect the county payment rates.

Comment: Some commenters argued that funding for the ESRD network (§ 422.250(a)(2)(B)) should not be taken from capitation payments to M+C organizations.

Response: Section 422.250(a)(2)(B) implements section 1853(a)(1)(B) of the Act, which specifically requires this reduction in payment rates for enrollees with ESRD. We have, however, changed the wording of our regulations to ensure that the amount taken from the capitation payments remains consistent with the amount required under section 1881(b)(7) of the Act. This does not change our current policy in any way; it merely allows that, if the amount mandated by changes in section 1881 of the Act changes for any reason, our regulations at § 422.250(a)(2)(B) will remain consistent with such a change.

Comment: One commenter requested clarification on the application of the budget neutrality adjustment contained in § 422.250(e)(3).

Response: Section 422.250(e)(1) allows a State's chief executive to request a geographic adjustment of the State's payment areas for the following calendar year. The chief executive may elect to change the area in which a uniform rate is paid from a county to one of the three alternative payment

areas identified in § 422.250(e)(1). Specifically, the governor may choose to have—(1) a single Statewide M+C payment area, (2) a single non-metropolitan payment area, with a separate payment area including metropolitan areas defined in one of two ways, or (3) consolidation of non-contiguous counties. Section 422.250(e)(3) requires us to make a budget neutrality adjustment to all payment areas within that state regardless of which payment area designation is selected by the chief executive. The budget neutrality adjustment is designed to limit the aggregate Medicare payment for Medicare enrollees residing in that state to what would have been paid absent any geographic adjustment.

Comment: One commenter proposed a statutory change that would permit a budget neutrality adjustment to be made to the final capitation rate, not just the ''blended rate,'' as currently provided. Such a change could result in lower payment rates.

Response: The full impact of the BBA and the subsequent revisions included in the BBRA are not yet known; thus, it may be too soon to give Congress recommendations that would have a major effect on our payment to managed care organizations. Therefore, we are not pursuing such a statutory change at this time.

Comment: One commenter suggested that we provide for increased payments to an M+C organization for Part B services provided by contract with federally qualified health centers, and require the increased payment be passed on these centers.

Response: The statute does not authorize us to pay certain M+C organizations differently than others, other than the special rules that apply to determining payments made to an M+C organization offering an M+C MSA plan. Payment for services furnished by a contracting federally qualified health center is limited to the amount negotiated by the two entities.

Comment: One commenter suggested that payment rates should be structured on a regional basis instead of a county by county basis.

Response: Section 1853(d) of the Act defines what is considered an M+C payment area. For Medicare enrollees without ESRD, the payment area is a county. For Medicare enrollees with ESRD, the payment area is a State. The only exception to these rules would be a State that has exercised its right under section 1853(d)(3) of the Act to request an alternative payment area in accordance with § 422.252(e).

Comment: A commenter believes that it is important that M+C organizations have the opportunity to validate our calculations and methodology in calculating payment rates. The commenter accordingly suggested that we cooperate with interested parties by releasing sufficient data to allow those parties to validate our calculations.

Response: We agree. We have complied, and will continue to comply, with all reasonable requests for all relevant and releasable data. M+C organizations must keep in mind that we use a significant amount of confidential data that cannot be released to the public.

2. Risk adjustment and encounter data (§§ 422.256 through 422.258)

Section 1853(a)(3) of the Act required implementation of risk adjustment for payment periods beginning on or after January 1, 2000. In the June 26, 1998 rule, we provided for such risk adjustment in § 422.256(d). We also provided that, in the period prior to the implementation of risk adjustment, we would continue to apply the demographic adjustments used under the old AAPCC methodology.

On September 8, 1998, we published a **Federal Register** notice describing our preliminary risk adjustment methodology and requesting public comments (53 FR 173, pp. 47506 *et seq.*). On January 15, 1999, we published an advance notice, as provided under § 422.258(b) of the regulations, describing the risk adjustment methodology that we implemented for 2000. This advance notice included a detailed description of the new risk adjustment methodology that is in effect in 2000, and information on how risk adjustment will be implemented, including an explanation of the transition method that would be employed. It also responded to comments received in response to the September 8, 1998 **Federal Register** notice. Briefly, the approach we used to meet the year 2000 mandate for risk adjusted payments was:

(1) Based on inpatient data;

(2) Applied individual enrollee risk scores in determining fully capitated payments;

(3) Utilized a prospective PIP–DCG risk adjuster to estimate relative beneficiary risk scores;

(4) Applied separate demographic-only factors to new Medicare enrollees for whom no diagnostic history is available;

(5) Applied a rescaling factor to address inconsistencies between demographic factors in the rate book and the new risk adjusters;

(6) Used 6-month-old diagnostic data to assign PIP–DCG categories (the ''time shift'' model, as opposed to using the most recent data and making retroactive adjustments of payment rates part way through the year);

(7) Allowed for a reconciliation after the payment year to account for late submissions of encounter data;

(8) Phased-in the effects of risk adjustment, beginning with a blend of 90 percent of the demographically-adjusted payment rate, and 10 percent of the risk-adjusted payment rate in the first year (CY 2000); and

(9) Implemented processes to collect encounter data on additional services, and move to a full risk adjustment model as soon as is feasible.

On March 1, 1999, we published the annual Announcement of Calendar Year (CY) 2000 Medicare+Choice Payment Rates, as provided under § 422.266(a) of the regulations. In this announcement, we informed Medicare+Choice organizations of the county rates and factors that were employed for payment in calendar year 2000, including the rescaling factors for use with the risk adjusted portion of payment, and tables of risk and demographic adjustment factors. We also responded to questions and comments on the January 15 notice. (These notices are available on the HCFA Web site, at http://www.hcfa.gov/stats/hmorates/aapccpg.htm.)

Section 1853(a)(3)(B) of the Act provided for the collection from M+C organizations, of encounter data needed to implement the risk adjustment methodology. The BBA required the collection of inpatient hospital data for discharges beginning on or after July 1, 1997, and allowed the collection of other data for periods beginning on or after July 1, 1998. We were prohibited from requiring the actual submission of data before January 1, 1998. This data submission requirement appeared in section 1853(a)(3) of the Act, which was titled ''Establishment of Risk Adjustment Factors.'' (See § 422.256(d).)

Requirements concerning collection of encounter data apply to M+C organizations with respect to all M+C plans, including private fee-for-service plans. Instructions for the collection of hospital encounter data were sent to M+C organizations in December 1997 (OPL 97.064) and May 1998 (OPL 98.71). Hospital discharges for the period July 1, 1997 through June 30, 1998 have been collected and used for estimating the impact of risk adjustment at the contract level and in the aggregate. We announced in the January 15, 1999 notice of methodological changes that comprehensive risk adjustment would be implemented for

payments beginning on January 1, 2004. We will soon be providing M+C organizations with guidance concerning requirements for submission of outpatient, physician, and other non-inpatient encounter data.

There are two different ways encounter data are used for risk-adjustment purposes. To calculate payment rates, encounter data are necessary to tie payment to expected patient resource use using diagnosis codes. (The initial risk-adjusted payment will be based on inpatient hospital encounter data. However, we are developing a more comprehensive risk-adjustment methodology that uses diagnosis data from physician services and hospital outpatient department encounters.) Encounter data are also necessary to ''recalibrate'' any risk-adjusted payment model. Recalibration adjusts payment models for changes in resource requirements that derive from such factors as technological change and improved coding.

While these are the primary purposes collecting the encounter data, we discussed other possible uses of these data in the June 1998 interim final rule. These other uses include identification of quality improvement targets and monitoring the care received by M+C enrollees through targeted special studies (such as an examination of post-acute care utilization patterns). Encounter data will also be useful for program integrity functions, both by providing additional utilization norms for original Medicare billing and by providing additional information regarding M+C organizations' behavior.

As noted above, the notices of January 15, 1999, and March 1, 1999, contained detailed discussions of the risk adjustment methodology and responses to comments. Similar notices, reflecting BBRA changes, and our methodology and rates for 2001, were published in January and March of 2000. Here we respond formally to comments submitted on the June 26, 1998 rule.

Comment: A number of commenters recommended that we not adopt a risk adjustment system based solely on hospital encounter data. As a matter of public policy, the commenters objected that basing the initial risk adjustment methodology solely on inpatient data would create inappropriate incentives to hospitalize patients, skew payments toward plans with higher hospitalizations, and penalize plans that have appropriately reduced inpatient services by focusing on outpatient care. Other commenters requested a phase-in of the methodology to minimize the disruption on M+C organizations, and allow time to assess the impact of the new methodology.

Response: We do not believe it would be desirable to delay implementation of risk adjustment until data other than inpatient data are available. We have analyzed the PIP–DCG system sufficiently to be confident that it represents an improvement over the current system of demographic-only adjustment, that it provides an appropriate interim step toward a comprehensive risk adjustment model, and that it provides appropriate levels of payment for different classes of beneficiaries. We believe that the blend transition methodology should relieve concerns about disruption of payments, especially since the initial blend percentage for the risk-adjusted portion is 10 percent.

Even if we believed that delaying risk adjustment were desirable, we do not have the authority to do so. The Balanced Budget Act specifically required ''implementation of a risk adjustment methodology * * * no later than January 1, 2000.'' In order to meet that deadline, we were constrained to employ a model based on hospital encounter data alone in the interim until the data to implement a comprehensive risk adjustment methodology can be provided by all plans and processed by us. The Medicare+Choice legislation (section 1853(a)(3)(B) of the Act) provided for the collection of non-inpatient data for periods beginning on or after July 1, 1998, a full year later than the date for which inpatient data would be collected. This provision envisioned that a hospital-only system would be implemented initially, both because it seemed more feasible for M+C organizations to produce inpatient data only in the short term, and because the effect of a hospital-only system on payments would be smaller than a system based on comprehensive encounter data. (The Medicare+Choice regulations further provided that we would collect physician, outpatient hospital, SNF, or HHA data no earlier than October 1, 1999. See § 422.257(b)(2)(i).) However, the statute grants us broad authority to develop a risk adjustment methodology, and does not prohibit us from including a transition or ''phase-in'' period as a component of the methodology we develop.

We therefore included a transition period as a component of our risk adjustment methodology, initially using a blend of payment amounts under the current demographic system and the PIP–DCG risk adjustment methodology. Under a blend, payment amounts for each enrollee would be separately determined using the demographic and risk methodologies (that is, taking the separate demographic and risk rate books and applying the demographic and risk adjustments, respectively). Those payment amounts would then be blended according to the percentages for the transition year.

In order to provide adequate safeguards against abrupt changes in payment, our transition mechanism initially provided for a low blend percentage of the risk-adjusted payment rate. Specifically, first year blend percentages will be 90 percent of the demographically adjusted rates, and 10 percent of the risk-adjusted payment rate. We are also contemplating a five-year transition, which would culminate in full implementation of comprehensive risk adjustment, using all encounter data, in the fifth year. Our initial transition schedule, announced in the January 5, 1999, Advance Notice of Methodological Changes for the CY 2000 Medicare+Choice Payment Rates was:

	Demographic method	Risk method
CY 2000	90 percent	10 percent.
CY 2001	70 percent	30 percent.
CY 2002	45 percent	55 percent.
CY 2003	20 percent	80 percent.
CY 2004	100 percent comprehensive risk adjustment (using encounter data from multiple sites of care).	

Subsequently, passage of Section 511(a) of the BBRA has revised the original transition schedule, providing for an even more gradual introduction of risk adjustment. Specifically, the legislation provides that the blend percentages will be:

	Demographic method	Risk method
CY 2000	90 percent	10 percent.
CY 2001	90 percent	10 percent.
CY 2002	at least 80 percent	no more than 20 percent.

In order to implement comprehensive risk adjustment in CY 2004, we will soon be providing M+C organizations with guidance concerning requirements for submission of outpatient, physician, and other non-inpatient encounter data.

Comment: Some commenters emphasized that implementation of risk adjustment could inject uncertainty and reduce the predictability of payments to M+C plans.

Response: Our most recent estimate, based on the 285 organizations that were active in September, 1998, and that did not terminate their contracts with Medicare in 1999, (including 10 organizations that merged into other active M+C organizations as of January 1, 1999), was that aggregate payments would decrease 0.6 percent, taking into account the blend percentages in effect for 2000, (90 percent demographic adjusted amount, 10 percent risk adjusted amount). While the impact on specific organizations will vary, our analysis suggests that, except for highly unusual circumstances (for example, a high proportion of working aged enrollees), the maximum decrease in payment to any organization from risk adjustment alone will be less than 2 percent. The analysis did not suggest that smaller organizations, or any other specific category, would experience a disproportionate impact. We will, however, continue to monitor the impacts on organizations throughout the transition period. We believe that our transition mechanism should alleviate concerns about large and abrupt changes in payment.

Comment: One commenter expressed concern about the effect on people with Alzheimer's disease of a risk adjustment methodology based solely on hospital encounter data. Because Alzheimer's and dementia are often not included in the recorded diagnoses of hospitalized beneficiaries, hospital data alone cannot support accurate conclusions about the cost of hospital care for these beneficiaries. Several other commenters expressed similar concerns about the implications of the initial risk adjustment methodology for beneficiaries with other chronic conditions.

Response: Our validation tests on the PIP–DCG model actually show that this model offers a substantial improvement over the system of demographic-only adjustments that has been previously in use. One measure of a model's accuracy is its ability to predict mean expenditures for groups correctly. Health Economics Research (HER), which served as a contractor to HCFA in developing the PIP–DCG model, measured the predictive ratios, (that is, the ratio of mean predicted expenditures to mean actual expenditures), for groups of Medicare beneficiaries that are of policy or technical interest. Among the groups used in this validation analysis were chronic condition groups, defined by ambulatory as well as inpatient diagnoses. HER found that, while the PIP–DCG model underpredicted for many chronic disease groups, this model performed better than the demographic model. For example, the predictive performance for persons with dementia (which includes individuals diagnosed with Alzheimer's) increased from 0.91 under the demographic system to 1.07 under the PIP–DCG model. Further detail on the validation analyses can be found in our ''Report to Congress: Proposed Method of Incorporating Health Status Risk Adjusters into Medicare+Choice Payments,'' and in the HER report ''Principal Inpatient Diagnostic Cost Models for Medicare Risk Adjustment,'' which is appended to it. The reports can be found on our Web site (http://www.hcfa.gov/ord/rpt2cong.pdf).

Comment: One commenter objected that the risk adjustment system does not account for secondary diagnoses. A patient with two acute diagnoses could be more ill and more costly than a patient with the same primary diagnosis, but a less severe secondary diagnosis. Another commenter supported the development of an initial risk adjustment methodology based on inpatient data alone, since inpatient costs represent the largest expense item of health plans. But this commenter recommended that such a methodology should account for both primary and secondary diagnoses, since secondary diagnoses are necessary to account for the higher costs of beneficiaries with multiple health problems and chronic conditions that are more expensive to treat.

Response: The analysis conducted in the early stages of developing an inpatient-based risk adjustment model included consideration of incorporating secondary diagnoses. The analysis concluded that secondary diagnoses did not contribute significantly to predictive accuracy in the context of an inpatient model. As noted above, the inpatient hospital model represents a significant improvement in predictive accuracy over the demographic adjustments that have been in use. However, it is only an interim step toward a comprehensive risk adjustment system. We anticipate that the comprehensive risk adjustment model under development will base risk scores on multiple diagnoses from disparate sites of care.

Comment: One commenter recommended that we develop the capability to use diagnosis data from all sites of care as quickly as possible in the risk adjustment system. Other commenters expressed concern about the costs and burdens of collecting the physician, outpatient hospital, skilled nursing facility, and home health agency encounter data that will be necessary for the implementation of comprehensive encounter data in 2004. Several commenters objected that the time frame contemplated for the submission of these data is too short to allow M+C organizations to procure and install the required systems. One commenter urged that, in preparing for submission of encounter data from physician offices, mechanisms should be established for the transition from paper claims to electronic bills for those practices that ''have not entered the electronic age.''

Response: The PIP–DCG model represents a substantial improvement over the current system. Because it identifies a subset of seriously ill beneficiaries for increased payment and because the effect of a hospital-only system on payments is smaller than a system based on comprehensive encounter data, the PIP–DCG model is an appropriate interim step toward comprehensive risk adjustment. A comprehensive model is nevertheless preferable, and we plan to move toward implementing such a model as expeditiously as possible. However, implementation of the comprehensive risk adjustment model is not operationally feasible for 3 to 4 years, because of data constraints on both plans and on us. The transition plan announced in the January 15, 1999

notice therefore provides for implementation of comprehensive risk adjustment in 2004, without ever reaching full payment under the PIP–DCG system. In the interim, the PIP–DCG model offers a substantial improvement over the current system.

In providing for payment under a comprehensive risk adjustment system in 2004, we have taken into account the costs and burdens necessary for organizations to develop the capacity for collecting and submitting physician, outpatient hospital, skilled nursing facility, and home health agency encounter data. This is the most ambitious schedule that we believe we can adopt consistent with allowing sufficient time for organizations and the agency to prepare.

Comment: A number of commenters objected that the collection of encounter data is burdensome and expensive. Some commenters asserted that this requirement may deter new managed care contractors, especially smaller organizations, from participating in the M+C program. Several commenters observed that not all the data required for submission of encounter data are necessary for computing risk adjustment. Another commenter urged us to monitor the trade-off between risk adjustment accuracy and risk adjustment data-collection requirements, and seek opportunities to streamline the burdens of encounter data collection. One commenter recommended that we explore alternatives to collection of all encounter data, such as survey-based approaches.

Response: We have made every effort to minimize the burden of collecting encounter data, and to assist M+C organizations with problems that have arisen in collecting and processing these data. In the initial stages of collecting encounter data, we are permitting organizations to use an abbreviated version of the standard UB–92 form employed in hospital billing. Data elements in the abbreviated UB–92 form have been restricted to those items necessary to calculating risk scores and pricing the discharge, as well as some document identification items that are normally generated automatically in electronic processing. (As we discuss below, pricing of discharges is necessary to allow recalibration of the model.) Use of the abbreviated UB–92 form will be allowed for discharges at least through June 30, 2001.

The legislation mandating risk adjustment also provides for the collection of inpatient and other encounter data. The legislation therefore contemplates a risk adjustment system based on encounter data rather than surveys. We believe that the greater accuracy of a system based on full submission of encounter data justifies the additional burdens that this requirement entails.

A range of problems in the submission of encounter data have arisen. These problems have included: not following the required UB–92 format, difficulties in accurately tracking counts of discharges, failure to arrange hospital submission of encounter data, difficulties in understanding Fiscal Intermediary reports, and HCFA/FI and FSS processing problems. Plans themselves may have problematic data processing systems in-house. We have worked with Medicare+Choice organizations, managed care associations, and other parties to address many specific issues that have arisen concerning data transmission and processing, and we will continue to do so. We have taken a number of specific steps to facilitate and improve the encounter data submission process. These activities have included the following:

- Encounter Data Reconciliation Analyses—We have shared with M+C organizations analyses of their individual M+C plan level data. The data have been successfully posted at our offices. We have further conducted analyses upon request at the provider level and by the different methods of submission to help explain discrepancies. We are in the process of sharing these analyses with the plans. The detailed provider level analyses are requiring additional time to conduct, and the results of these analyses will be shared with plans over the coming weeks.
- Onsite Consultations—Our contractor conducted a series of onsite consultation visits to 20 M+C organizations in order to learn more about the process of data submission. The majority of the 20 organizations selected for the visits were those that experienced problems with encounter data submission. The information gained during these visits will be used to assist plans to identify and resolve problems.
- HCFA Data System Fixes—Processing problems have been identified that relate to beneficiaries who change from one M+C plan to another. The estimated number of affected encounters from all plans is less than 3,000. These problems will be fixed over the next 2 months, and they are not expected to impact the March 1 rate estimates, which, in any case, will not be used to make direct enrollee payments.
- Communication with the FIs—We have shared data problems raised by M+C organizations with the FIs. Furthermore, discussions between us, FI's, and plans have been encouraged in order to address problems.

Comment: Several commenters objected that we should not place the burden of collecting encounter data and assuring their accuracy solely on M+C organizations, but rather on the providers submitting the data to the organizations. Some of these commenters suggested imposition of a requirement on providers that they cooperate with M+C organizations in collecting encounter data.

Response: We did not include requirements on providers in the interim final rule because we traditionally have tried to minimize the adoption of measures that would insert our requirements into the contractual relationships between managed care organizations and providers. We therefore suggested to M+C organizations that they modify their contracts with hospitals to ensure that managed care discharges are identified, and the appropriate records are provided to the organization by the hospital. We also have taken every opportunity to inform hospitals and hospital associations of the encounter data requirements and the importance of collecting complete and accurate encounter data to assure correct payment. Collection of encounter data for the ''start up'' year of July 1997 through June 1998, which was the basis for estimating the impacts of risk adjustment, was quite successful, and we have every reason to believe that collection of data for the next year, which will be used to determine actual risk adjustments in 2000, will go at least as well.

However, M+C organizations have informed us that some providers are either failing to submit encounter data at all, or submitting data that do not conform to quality standards for submission to our systems (for example, that the coding often fails to meet standards required to pass the coding edits). To the extent usable data are not submitted, M+C organizations are denied the benefit of any risk adjustment that might be justified based on the costs in question. We are therefore proposing to make several changes to the rules that are designed to give M+C organizations greater leverage in obtaining adequate cooperation from providers to submit complete and accurate data.

First, we will make explicit in § 422.257 that M+C organizations are required to obtain from providers,

suppliers, physicians, or other practitioners information sufficient to submit the required encounter data. (Currently the regulation states that M+C organizations must submit encounter data, but leaves the requirement of obtaining the necessary information from providers and others to inference.)

Second, we will specifically state in the rules that M+C organizations may include a requirement for submission of complete and accurate encounter data, conforming to the format used under original Medicare, in their contracts with providers, suppliers, physicians, and other practitioners. Contracts with providers and others may impose financial penalties, including withholding payment, for failure to submit complete and accurate data conforming to all requirements for submission. We have revised § 422.257 of the regulations to reflect these two changes.

Third, as discussed below in section K, we have modified the definition of ''clean claim'' in § 422.500 to specify that a claim must include information necessary for purposes of encounter data requirements, and must conform to the requirements for a clean claim under original Medicare. This will exempt claims that do not, for example, meet accurate coding requirements from the application of the ''prompt payment'' standard that applies to claims submitted by non-contracting providers. This standard requires that ''clean claims'' submitted by non-contracting providers be paid within 30 days, or interest will be owed. M+C organizations will therefore be able to withhold payment in cases in which non-contracting providers submit claims with inadequate coding or other deficiencies that make the claims impossible to use for encounter data purposes.

Fourth, we are providing a reconciliation process which will give M+C organizations additional time to submit encounter data before final payment determinations are made. M+C organizations have approximately 3 months after the end of a data collection year to submit the encounter data that will be used to develop beneficiary risk scores to their fiscal intermediary. For example, M+C organizations must submit encounter data for the period July 1, 1998 through June 30, 1999 to their fiscal intermediary by September 17, 1999. If organizations submit encounters after this date, they will not be incorporated into payments for CY 2000. However, in response to concerns expressed by M+C organizations over this short time frame, we expect to institute a reconciliation process that will take into account late data submissions. M+C organizations should attempt to have all data in by the annual deadline of September 10. However, if organizations receive UB–92s from hospitals after this date, they may submit the encounter to their fiscal intermediary and the data will be processed. M+C organizations should note that the deadline for submission of all data from a payment year will be June 30 of the payment year for the period ending the previous June 30 (for example, the final deadline for the period of July 1, 1998 to June 30, 1999, which is used for payment in 2000, will be June 30, 2000). After that date, the fiscal intermediary will no longer accept these data. After the payment year is completed, we will recalculate risk factors for individuals who have late encounters submitted. Then, we will determine any payment adjustments that are required. This reconciliation will be undertaken after the close of a payment year and will be a one-time only reconciliation for each payment year. We are adding § 422.256(g) to provide for this reconciliation process.

Comment: Some commenters expressed doubts about the completeness and accuracy of the encounter data submitted during the ''start up year,'' which was used to develop estimates of the impact of risk adjustment. Some expressed concern that systems problems have impeded the posting of complete and accurate data. Several commenters expressed doubts that sufficiently complete and accurate encounter data could be available in time to begin risk-adjusted payment on January 1, 2000.

Response: Hospital encounter data were collected from managed care organizations for discharges between July 1, 1997 and June 30, 1998. Approximately 1.5 million encounters were submitted to us for over 5.7 million beneficiaries. The volume of data received is sufficient to generate an estimate of the impact of risk adjustment, and to conduct other analysis in order to prepare for implementation of risk adjustment. Based on this experience, we are confident that sufficient data will be generated to calculate beneficiary risk scores and other information necessary for implementation of the PIP-DCG model.

Comment: One commenter requested clarification of the statement in the preamble that encounter data may be used for purposes other than calculating risk adjustments.

Response: We commonly use data collected in the course of calculating payments for other purposes. These purposes include monitoring program integrity, studying utilization patterns and quality of care, and a variety of research purposes. Our use of data is always governed by consideration of privacy concerns and confidentiality of business operations.

Comment: Several commenters asked for further information concerning how we intend to recalibrate risk-adjusted payments to account for upcoding. Another commenter questioned whether use of the full UB–92 is necessary for this recalibration, and suggested that we consider other approaches.

Response: As we discussed above, recalibration is necessary to adjust the payment models for changes in resource requirements that derive from such factors as technological change and improved coding. Upcoding may occur if plans improve coding of beneficiary diagnoses and, as a result, the average use of resources for enrollees in a particular category may be less than when the relative payment rates were determined. When this happens, the average actual expenditures per enrollee for these diagnoses may be less than the average expenditures used to assign the original payment weights. The result is overpayment for some diagnoses in the risk adjustment model. On the other hand, technological changes, which often result in more intensive use of resources for certain diagnoses, can lead to underpayment for certain diagnoses unless the model is recalibrated. Recalibration is a standard feature of well-established payment systems, such as the hospital prospective payment system. We have not yet developed a specific timetable for recalibrating the PIP–DCG model. We will not recalibrate the model until we have sufficient data from Medicare+Choice organizations to incorporate managed care practice patterns into the recalibration.

Comment: Several commenters expressed concern about the attestations required of M+C organizations, with respect to the accuracy and completeness of encounter data. One of these commenters expressed the view that the requirement for an attestation that submitted encounter data are ''accurate, complete, and truthful'' is designed more as a legal trap for those that might innocently submit incomplete or inaccurate data, than as good public policy. Another commenter recommended that the attestation allow for honest mistakes and unavoidable margins of error.

Response: Attestation of encounter data has been a contentious issue. Attestation of encounter data is essential for guaranteeing the accuracy and

completeness of data submitted for payment purposes, and to allow us to pursue penalties under the False Claim Act, where it can be proven that a plan knowingly submitted false data. However, in response to concerns from M+C organizations, we have restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding. Since this is information that M+C organizations are, or should be, in the position to know, the attestation requirement is thus in no way a legal trap.

Comment: One commenter recommended that we develop mechanisms, with the assistance of consumer representatives, to make encounter data available to Medicare beneficiaries and their representatives.

Response: The commenter did not identify the ''beneficiary representatives'' to whom encounter data would be made available, nor the purposes for which the data would be used. We would consider specific requests for data in the light of privacy and other considerations which normally govern the use of data gathered for official purposes in the program.

Comment: Several commenters expressed concern about the short time frame for submission of Adjusted Community Rate proposals after the release of county rates, rescaling factors, and risk adjustment impact estimates on March 1. The commenter urged disclosure of key information such as the rescaling factors earlier in order to give plans the opportunity to base their rate and benefit submissions on more complete financial information.

Response: Section 516 of the BBRA extended the ACR deadline to July 1, and applied that extension retroactively to 1999. Therefore, we have changed our regulations at § 422.306(a)(1) to reflect this statutory change, which has addressed the commenter's concerns.

3. Special Rules for Hospice Care (§ 422.266)

Comment: One commenter requested clarification on reporting institutionalized members who have elected hospice care, and how the M+C organizations will determine whether a new member is in hospice care.

Response: Medicare enrollees who have elected hospice care should not be reported as institutionalized. Medicare beneficiaries that have elected hospice, and subsequently elect an M+C plan will be identified by our system.

Comment: One commenter requested clarification of the M+C organization's responsibility in arranging for the provision of hospice care for those enrollees who have elected hospice care.

Response: Section 422.266 requires the M+C organization to inform each Medicare enrollee eligible to elect hospice care about the availability of hospice care in the area or outside the area, if it is common practice to refer patients accordingly. An M+C organization is not required to arrange for hospice services when the hospice election has been made.

Comment: One commenter requested further clarification on our payment for a Medicare enrollee when the enrollee elects hospice.

Response: Our monthly capitation is reduced to the adjusted excess amount developed in the ACR. The amount of the reduction is the ACR value (less the actuarial value of Medicare's deductibles and co-insurance) for Medicare-covered items and services. For Medicare-covered items and services, the M+C organization or provider furnishing the service would bill us using Medicare's normal billing rules under original Medicare. Also, hospice services are billed under original Medicare rules.

G. Premiums and Cost-Sharing

1. General Provisions

Part 422, subpart G is based on the provisions found in section 1854 of the Act. These provisions were discussed in detail in the June 26, 1998 interim final rule (63 FR 35007). This subpart addresses how limits on M+C plan enrollee premiums and other cost-sharing are established through the Adjusted Community Rate (ACR) approval process. The ACR process is applicable to all M+C plans except M+C MSA plans. M+C organizations offering an M+C MSA plan are not required to submit an ACR for that plan, but they are required to submit other information for our review using the ACR process.

Section 422.300(b) provides that for contract periods beginning before January 1, 2002, M+C organizations may modify an M+C plan by adding benefits at no additional cost to the M+C plan enrollee; lowering the premiums approved through the ACR process; or lowering other cost-sharing amounts. Also prior to January 1, 2002, under § 422.504(d), contracts may be for a longer period than 12 months, and may begin on a date other than January 1. In the case of such contracts, under § 422.300(b)(2), ACRs must be submitted on the date specified by us. The transition rules for this period are found in § 422.300(b).

Comment: One commenter suggested a revision of the ACR form used to establish the pricing structure for an M+C plan. The commenter suggested that the new form produce more accurate information. The commenter urged that we monitor data submitted in the ACR form to determine whether established policies should be revisited.

Response: We agree. We are developing various systems to capture ACR data for policy analysis. We intend to use the data to determine the effect of established policies so that we can examine policies that need revision.

Comment: One commenter suggested that we consider alternatives to the ACR for private fee-for-service and MSA plans.

Response: Under the June 1998 interim final rule, we do not review or approve premium amounts submitted for private fee-for-service plans or MSA plans. In addition, in the case of an MSA plan, an M+C organization does not complete those parts of the ACR form that request cost information. Thus, in essence, there is an ''alternative'' arrangement in place for these types of plans.

Comment: One commenter suggested that we, in consultation with industry representatives, develop acceptable standards for cost accounting to be used by M+C organizations to complete its ACR form.

Response: We agree that M+C organizations should be using uniform cost accounting standards to complete the ACR form. Therefore, we specified in § 422.310(a)(5) that generally accepted accounting principles (GAAP) should be used instead of other accounting principles (for example, statutory). We have not ruled out the establishment of a standardized accounting system at this time. However, we feel that the existing accounting systems based on GAAP developed by M+C organizations should produce sufficiently accurate information for ACR purposes. We will monitor the accuracy of the ACR data produced by the M+C organizations' accounting systems through audit and other monitoring procedures.

Comment: One commenter suggested that we should either allow M+C organizations to modify their M+C plan after the M+C plan has been approved, or make the transition period rules described in § 422.300(b) permanent. The commenter felt this would benefit the Medicare beneficiary.

Response: After 2002, Medicare beneficiaries will be ''locked in'' to their M+C plan choice for the last 9 months of the year (6 months in the case of 2002 only). The beneficiary will be locked in

for the entire year if he or she wants to remain in the M+C program, and no other M+C plan in the area is open during January, February, and March. The choice of an M+C plan during the annual November open enrollment period thus will be extremely significant, since, in most cases, it will determine enrollment for the entire following calendar year. We believe that under this program design, it is important that beneficiaries have complete information in November about what the benefits will be in each M+C plan in their area for the full following calendar year. If M+C organizations were permitted to change plan benefits mid-year, this could result in a beneficiary deciding that an M+C plan that is changing benefits would have been a better choice had he or she known in November that this change would be made, but it would be too late for the beneficiary to enroll in that plan after April 1.

We accordingly believe that beginning in 2002, (when beneficiaries will be locked in for the last 6 months of the year), benefits for a given calendar year should be established in advance of the November open season. This will allow beneficiaries to make informed decisions about which M+C plan they will choose for the following calendar year. In order for this to happen, the benefits that will apply throughout the following calendar year must be included in the ACR submission filed with us, so that these benefits can be approved by us in time to provide reliable information to beneficiaries.

Our decision to require uniform benefits throughout the calendar year after a transition period is further supported by the nature of the ACR process under M+C. As under the section 1876 risk program, the ACR process under the M+C program serves three important purposes. First, we are required to examine an M+C organization's ACR proposal for each M+C plan to determine if Medicare beneficiaries are entitled to receive additional benefits as a result of Medicare payments that are higher than the organization's charge (adjusted for differences in utilization characteristics of the Medicare population) to a non-Medicare enrollee for a Medicare-covered benefit. Second, we are required to review ACR proposals to determine whether the pricing structure (premiums and cost-sharing charged to beneficiaries) is within the limits established by law as required under section 1854(b)(1) of the Act, and is applied uniformly to all Medicare enrollees as required under section 1854(c) of the Act. Third, we review benefit package information to determine if the benefit package is in compliance with the requirements contained in subpart C. Once this process is complete, M+C organizations are allowed to market the M+C plan as approved.

Under the M+C program, we focus on an entire calendar year in performing the above tasks. Our approval of the pricing structure of an M+C plan is based on the appropriate actuarial value of furnishing the items and services for the entire calendar year. Limits on the amount of premiums (section 1854(b) of the Act), and on the liability of the Medicare beneficiary (section 1854(e) of the Act), are based on a 12 month period. In addition, the capitation payments that will be made to the M+C organization under section 1853(a) of the Act for the M+C plan is an integral part of establishing the value of additional benefits that must be offered under section 1854(f) of the Act. Capitation payments are based on the annual M+C capitation rate for the county (that is, the amount for the full calendar year), adjusted for various demographic and other risk factors. Section 1853(c)(1) of the Act clearly states that capitation rates are based on a contract year consisting of a calendar year. We believe that this entire scheme assumes that benefits will be the same over the 12 month period at issue. This is another reason why we believe our decision to eliminate mid-year changes after a transition period is appropriate.

2. Rules Governing Premiums and Cost-Sharing (§ 422.304)

This section implements provisions of the BBA relating to premiums paid by or on behalf of beneficiaries. The beneficiary in an M+C plan, other than an M+C MSA plan offered by an M+C organization, pays the monthly basic premium plus the monthly supplemental premium, if any. In the case of an M+C MSA plan, the beneficiary must pay the monthly supplemental premium, if any. The M+C monthly basic beneficiary premium, the M+C monthly supplemental premium, and the monthly MSA premium may not vary among individuals in the M+C plan, unless the M+C organization offering the plan has elected to apply this rule to individual segments of a plan service area, as provided in section 515 of the BBRA (See section I.C of this preamble). Also, the M+C organization cannot vary the level of cost-sharing (copayments, coinsurance, or deductibles) charged for the basic benefits or supplemental benefits, if any, among the individuals enrolled in the M+C plan, again unless the M+C organization has elected to apply this rule to segments of the plan service area, as provided in section 515 of the BBRA.

As discussed in section I.C above, under section 515, the premium and cost-sharing uniformity requirements may be applied only within segments of an M+C plan's service area, with premiums or cost-sharing varying between such segments, provided: (1) a separate, and complete ACR is filed for each such segment; and (2) each segment is composed of one or more M+C payment areas. We have revised § 422.304(b) to add a new paragraph (b)(2) that provides for this option.

Comment: A commenter noted that some M+C organizations offer enrollees economic incentives to use mail-order pharmacies by imposing a copayment on all prescriptions dispensed in the community pharmacies, but do not charge a copayment if the same prescription is mailed to the enrollee. The commenter wanted to know whether this practice is prohibited under the uniform cost-sharing rule in § 422.304(b).

Response: The practice the commenter has described is not prohibited, since all enrollees under the plan would pay the same cost-sharing for drugs not ordered by mail, and the same cost-sharing for drugs ordered by mail. However, an M+C organization would not be permitted to impose a structure of cost-sharing that would have the effect of denying access, as described in section 1852(d) of the Act, to an item or service advertised by the organization as being available to the enrollee.

3. Submission Requirements for Proposed Premiums and Related Information (§ 422.306)

This section reflects the original BBA version of section 1854(a)(1) of the Act, which prior to the BBRA provided that each M+C organization, and any organization intending to contract as an M+C organization in the subsequent year, submit specified data for every plan it intends to offer no later than May 1 of each year.

Comment: Many commenters recommended that the May 1 deadline for the submission of the ACR proposal be changed.

Response: As discussed in section I.C above, section 516 of the BBRA extended the ACR deadline permanently to July 1, and applied that extension retroactively to 1999. Therefore, we have changed our regulations at § 422.306(a)(1) to reflect this statutory change.

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

Section 422.308(a) imposes a limit on the amount that an M+C organization can charge as a basic beneficiary premium for a coordinated care plan, or impose as cost-sharing under such a plan. Specifically, the basic premium (multiplied by 12), the actuarial value of any cost-sharing, or a combination of these two forms of beneficiary liability, may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable on average to beneficiaries entitled to Medicare Part A and enrolled in Part B if they were not enrollees of an M+C organization. For those M+C enrollees who are enrolled in Medicare Part B only, the monthly basic premium (multiplied by 12), plus the actuarial value of cost-sharing, may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable to beneficiaries enrolled in Medicare Part B if they were not enrollees of an M+C organization. With respect to supplemental benefits under coordinated care plans, the monthly supplemental beneficiary premium (multiplied by 12) charged, plus the actuarial value of its cost-sharing, cannot exceed the ACR for such services.

In the case of a private fee-for-service plan, there is no limit on premium charges. However, under § 422.308(b), the actuarial value of any cost-sharing imposed under the plan may not exceed the actuarial value that would apply to beneficiaries entitled to Medicare Part A and enrolled in Part B if they were not enrolled in an M+C plan as determined in the ACR. In the case of supplemental benefits, the actuarial value of cost-sharing may not exceed the ACR amounts for the benefits. Additionally, if inadequate data is available to determine actuarial value, we can make the determination with respect to all M+C eligible individuals in the same geographic area or State or in the United States on the basis of other appropriate data.

Comment: One commenter suggested that the limits on premiums in § 422.308 should not apply in the case of dual eligibles, to the extent that the Medicaid program is paying the premiums.

Response: We do not agree. Section 422.308 limits the amount that can be charged to Medicare enrollees, or anyone on their behalf, for the M+C plan. However, we recognize that the Medicaid program may pay additional amounts for Medicaid-covered benefits not included in the M+C plan. Therefore, we have clarified our jurisdiction over Medicaid benefits for dual eligibles in § 422.106. (See the discussion in section II.C of this preamble.)

Comment: One commenter requested clarification of the limit on charges to a Part B-only member for Part A services.

Response: If an M+C organization chooses to include in the B-only M+C plan an equivalent Part A benefit, it may do so as an additional, mandatory supplemental, or as an optional supplemental benefit. There is a limit on what is allowed to be charged for this benefit: the lesser of the ACR for the benefit, our payment amount, (or, in the case of a working individual (or spouse) for whom Medicare is secondary, the amount Medicare would pay if Medicare was not secondary), increased by the actuarial value of Medicare's Part A deductible and coinsurance, or the amount we charge for coverage of Part A services to those individuals that are not otherwise eligible for those services.

Comment: One commenter requested clarification of § 422.308, Limits on premiums and cost-sharing amounts, that the commenter believes to be a new provision. Another commenter asked about a limit on amounts actually collected in cost-sharing.

Response: The limit on premium and cost-sharing charges in section 1854(e) is not new, and in the case of coordinated care plans, is the same as the limit that applied in the case of section 1876 risk contracts. As discussed above, in the case of a coordinated care plan, section 1854 of the Act specifically limits the amount, regardless of source, a Medicare beneficiary may be charged for the M+C plan elected. This would include premiums and cost-sharing collected by the M+C organization or any provider (either contracting or non-contracting with the M+C organization) furnishing services covered by the plan. This limit is applied to the actuarial value of the cost-sharing provided for under the M+C plan. Specifically, in the case of a coordinated care plan, the premium and the actuarial value of cost-sharing cannot exceed the actuarial value of original Medicare cost-sharing. Thus, as noted above, in approving the ACR, we will not approve of beneficiary cost-sharing for Medicare covered services if the actuarial value of the cost-sharing exceeds the actuarial value of the deductible and coinsurance imposed under original Medicare.

Once we have approved cost-sharing amounts specified in an ACR, however, an M+C organization is permitted to collect those amounts, even if the actual amount collected turns out to exceed the amount projected in the original estimate of the cost-sharing's actuarial value. While some of our guidance has indicated that a ''cap'' would be imposed on the aggregate cost-sharing amount actually collected, we have determined, in examining the language in section 1854(e)(1) of the Act in response to this comment, that the limit on cost-sharing was intended to limit the amount of cost-sharing that can be provided for under an M+C plan, not on the amount that is actually collected. The statute provides that the ''actuarial value'' of M+C plan cost-sharing (and any premium charged) cannot exceed the ''actuarial value'' of cost-sharing under original Medicare. Since we do not keep track of cost-sharing actually collected under original Medicare, but instead rely only on the ''actuarial value'' projected up front, we believe that the same approach should apply to the M+C plan side of the equation.

We note that, as discussed above, in the case of private fee-for-service plans, the limit on beneficiary liability applies only to cost-sharing. The actuarial value of cost-sharing for Medicare services may not exceed the actuarial value of the deductible and coinsurance imposed under original Medicare.

Comment: One commenter suggested that we set a limit on the amount that may be charged to low-income beneficiaries and beneficiaries with disabilities.

Response: Section 1854(c) of the Act requires that premium charges be uniform for all enrollees in an M+C plan (or in a segment of a plan service area as provided for in section 515 of the BBRA). As a result, a separate limit for low income beneficiaries would not be permissible. The statute also specifies the overall limits on beneficiary liability, and we do not have the discretion to change them. We note, however, that M+C organizations may not design or market M+C plans in a manner that discriminates against low-income or disabled beneficiaries.

Comment: One commenter suggested that we should prohibit the imposition of a deductible for Federally qualified health center (FQHC) services.

Response: The actuarial value of the cost-sharing imposed by an M+C organization for Medicare-covered items and services cannot exceed the actuarial value of Medicare's deductible and coinsurance under original Medicare. We establish this amount using data on all Medicare beneficiaries that did not elect a managed care organization, regardless of where the beneficiary received the item or service. Therefore, data on items and services that do not have a deductible or coinsurance were taken into account, and M+C enrollees

already have received the benefit of the fact that there is no deductible for FQHC services.

5. Incorrect Collections of Premiums and Cost-Sharing Amounts (§ 422.309)

Section 422.309 requires an M+C organization to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf. We further stated that amounts incorrectly collected include: (1) Exceeding the limits imposed by § 422.308 (that is, exceeding the amounts approved in the ACR as falling within these limits); (2) in the case of an M+C private fee-for-service plan, exceeding the M+C monthly basic premium or monthly supplemental premium; (3) in the case of an M+C MSA plan, exceeding the M+C monthly supplemental premium, or the deductible for basic benefits; and (4) amounts collected from an enrollee who was believed ineligible for Medicare benefits but was later found to be entitled. In addition, ''other amounts due'' include amounts due for services that were considered an emergency, urgently needed, or other services obtained outside the M+C plan; or initially denied, but upon appeal, found to be services that the enrollee was entitled to have furnished by the M+C organization.

Comment: A commenter believes that an M+C organization should be permitted to collect additional amounts if, as a result of utilization patterns, it collects less than the amount actuarially projected in its ACR. The commenter notes that if an M+C organization collects more than the amounts permitted in the M+C plan approved in the ACR process, it has to refund amounts to enrollees, and believed that this same principle should permit the organization to collect additional amounts if it collects less than the amount projected.

Response: We do not agree. There is no indication in section 1854 of the Act that the Congress intended to allow an M+C organization to collect additional amounts from Medicare enrollees when the amount it collects ends up being less than the amount projected in its ACR. An M+C organization, when it submits its ACR, should be providing its best estimate of its charges and collections within the confines of the statute. If we accept this estimate, the M+C organization should be held to the amounts estimated. As noted above, we agree that HCFA also should be held to an estimate we have approved in the ACR process, and will not attempt to limit the aggregate amount an M+C organization can actually collect as long as it collects only approved cost-sharing amounts from any given enrollee. We believe there is a distinction between the process of projecting enrollee liability for the purpose of establishing a premium and cost-sharing structure and the question of whether charges are made in excess of this established structure. Once the premium and cost-sharing structure is established, a charge in excess of the amounts provided for under this structure is impermissible, and grounds for sanction. A refund is appropriate. If the organization inadvertently charged less than the cost-sharing amounts approved in the ACR, it could collect the balance of the approved charge from the beneficiary. To the extent the commenter was referring to our earlier guidance discussing a limit on the aggregate amount that an organization can collect in premiums, as noted above, we have decided not to impose such a limit. This premise of the commenter's point accordingly is no longer valid.

6. ACR Approval Process (§ 422.310)

The June 1998 interim final rule requires that, except M+C MSA plans, each M+C organization must compute a separate ACR for each coordinated care or private fee-for-service plan offered to Medicare beneficiaries. If an M+C organization opts to apply uniformity requirements to segments of an M+C plan service area, a separate ACR must also be submitted for each such segment. We also stated in the June 1998 interim final rule that, in computing the ACR for years beginning in 2000, the M+C organization calculates an initial rate according to the specifications in § 422.310(b), that represents the ''commercial premium'' that the M+C organization would charge its general non-Medicare enrollees for Medicare-covered benefits and any supplemental benefits covered by the M+C plan. The M+C organization would also calculate a separate ACR value for each optional supplemental benefit it offers under the plan. Then, the organization either adjusts the initial rate by the factors specified in § 422.310(c), or requests that we adjust the rate.

Section 422.310(b) dictates that the initial rate for each M+C plan is calculated on a 12-month basis for non-Medicare enrollees, using either a community rating system or a system approved by us, under which the M+C organization develops an aggregate premium for each M+C plan for all non-Medicare enrollees of that M+C plan that is weighted by the size of the various enrolled groups and individuals that compose the M+C's enrollment in that plan. Regardless of the method the M+C organization uses to calculate its initial rate, the rate must equal the premium that the M+C organization would charge its non-Medicare enrollees on a yearly basis for services included in the M+C plan.

The June 1998 interim final rule also established special rules in § 422.310(d) for M+C organizations that do not have non-Medicare enrollees or sufficient Medicare enrollment experience to sufficiently calculate ACR values. We have amended § 422.310(d) because the interim final rule used incorrect citations in describing how such an M+C organization may estimate ACR values.

Comment: One commenter suggested that we test the new ACR methodology before implementation.

Response: We do not agree. The new ACR process requests data from organizations that should be readily available in an organization that has an adequate accounting system used to track the costs and revenues of the products it sells. In addition, we intend to develop a mechanism designed to identify unexpected problems. The form implementing the new ACR methodology allows M+C organizations to identify specific problems. We intend to gather information from our review, approval, and audit processes to develop manual instructions, clarify the ACR instructions, and modify the ACR form, if necessary.

Comment: One commenter suggested that the component of the ACR formula attributable to revenues in excess of expenses (''the additional revenue component,'' or ''profit'' in the case of a for-profit company) should be the same percentage of the Medicare ACR amount as it is in the case of the initial rate (the ''commercial premium'').

Response: We do not agree. Each product an organization offers may have a different additional revenue or profit margin. This would include each of the non-Medicare products included in the base cost figures and the initial rate. To use the same percentage of additional revenue margin included in the initial rate for the ACR for Medicare enrollees would apply an ''average'' additional revenue margin for non-Medicare enrollees to all Medicare enrollees. In addition, using a percentage method, as suggested, would increase the amount of the additional revenue margin for Medicare enrollees if Medicare health care costs were higher. (If costs are higher, the profit margin percentage can be lower while producing the same amount in profit.) We believe actual

additional revenues received in a prior period are the best measure of the amount of additional revenue an organization would expect in a future period, absent some changed circumstances or variables.

While we do not agree with the commenter's specific proposal, in light of this comment, we have reconsidered the relative cost ratio formula contained in the regulations at § 422.310(c)(3). Since additional revenues are produced when revenues exceed expenses, we believe the best way to project additional revenues for a benefit or group of benefits is to first project total revenues of that benefit or group of benefits and, then, subtract projected total expenses of that benefit or group of benefits. Therefore, we have modified the formula in § 422.310(c)(3) to project total revenues using a relative cost ratio of revenues charged in a base period for Medicare enrollees compared to revenues charges to non-Medicare enrollees of the same period and, then, subtracting projected expenses. We have used the calendar year prior to the calendar year the ACR is submitted as the ''base year'' for this purpose. If an M+C organization believes the computation produced under this formula does not adequately reflect the future period for an M+C plan, the organization may, with adequate justifying documentation, make an expected variation adjustment to the amount calculated.

Comment: One commenter interpreted § 422.310(c)(4) to provide that adjustments to additional revenues, after application of the relative ratios, are allowed to reduce the ACR value, but not increase the ACR value.

Response: The language of § 422.310(c)(4) was incorrect as published in our June 1998 interim final rule. On October 1, 1998, we published a technical revision to this section (63 FR 52614) to clarify that adjustments may increase or decrease the amount of additional revenue included in the ACR value of the service or services. These adjustments would be allowed as long as the organization submitted sufficient documentation to justify the need to increase or decrease the ACR values so calculated.

Comment: One commenter suggested that we allow M+C organizations to use representative data to develop ACR values for an M+C plan.

Response: The new ACR process requires M+C organizations to report the costs it incurs for an M+C plan using GAAP. Organizations in business routinely review the costs of each product it sells for various reasons, (for example, budget analysis, profitability). The new ACR method does not create a new process to determine those costs. We have designed the ACR process to require the least amount of information needed to price an M+C plan without creating a new accounting process. We are relying on GAAP since these principles are widely known and are in use by most M+C organizations. We feel M+C organizations should not encounter significant problems in capturing the costs of the Medicare and non-Medicare populations of a prior period using accounting systems already in use to track each of the products it sells. Using representative data would not be as accurate as using costs actually incurred.

Comment: One commenter suggested that some group and staff model M+C organizations may not be able to provide cost data in the form and detail required in the ACR form.

Response: We do not agree. The regulations and the ACR form used to implement those regulations allow for a significant amount of flexibility. The instructions are very clear that there are a limited number of line items that must be reported. Most of the remaining entries will be dependent on the accounting system of the organization. Staff and group models may need to use an apportionment strategy to segregate costs between Medicare and non-Medicare enrollees. These apportionment strategies should be based on the same statistics currently being submitted for the ACR form under section 1876 of the Act.

Some organizations have argued that their accounting systems cannot segregate the revenues and cost of providing services to Medicare enrollees between different service areas and among various products sold. These organizations should discuss these matters with their HCFA-assigned plan manager. Since the M+C ACR process is still relatively new, we expect to grant some flexibility to M+C organizations. M+C organizations unable to comply with ACR requirements would be required to submit a plan of action designed to bring the organization in compliance with the regulations.

7. Requirement for Additional Benefits (§ 422.312)

Section 422.312(b) requires that the M+C organization provide additional benefits if there is an adjusted excess amount for the plan it offers. The actuarial value of these additional benefits, less the actuarial value of any cost-sharing associated with the benefit, must at least equal the adjusted excess amounts. We received no comments on this provision, but are making a technical change to § 422.312(b) to use the term ''cost-sharing'' rather than copayment or coinsurance because the term cost-sharing has been previously defined in § 422.2 to include copayments and coinsurance.

H. Provider-Sponsored Organizations (Subpart H)

Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). A PSO is described in section 1855(d) of the Act as a public or private entity—

- That is established or organized, and operated, by a health care provider or group of affiliated health care providers;
- That provides a substantial portion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of these items and services, and have at least a majority financial interest in the entity.

The PSO regulations at §§ 422.350 through 422.390 include definitions, solvency standards (developed through negotiated rule making), and waiver requirements that have been established through three previous **Federal Register** publications. On April 14, 1999, we published an interim final rule with comment, titled ''Definition of Provider-Sponsored Organization and Related Requirements'' (63 FR 18124), setting forth the PSO definition, clarifying certain terms, and establishing related requirements. On May 7, 1998, we published an interim final rule with comment, titled ''Waiver Requirements and Solvency Standards for Provider Sponsored Organizations'' (63 FR 25360), establishing solvency requirements that apply to PSOs that obtain a waiver of the M+C State licensure requirements, and setting forth procedures and standards that apply to requests for the waivers. The solvency portion of the PSO regulation was based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act. On December 22, 1999, we published a final rule titled ''Solvency Standards for Provider-Sponsored Organizations'' (64 FR 71673), that addressed the comments we received on the PSO solvency standards and waiver requirements. In this final rule, we are responding to comments on the April 14, 1998 PSO definitions interim final rule.

Comment: A commenter believes that the interim final rule did not sufficiently ensure that a PSO is actually

controlled by providers. Another commenter thinks that effective control is defined too loosely in the regulation.

Response: We believe that the existing regulatory requirements are sufficient to ensure that PSOs are organizations that are owned and controlled by health care providers. Among the basic requirements for PSOs at § 422.352(a)(3) is the requirement that to be considered a PSO for purposes of the Medicare+Choice program, an organization must be controlled by a health care provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO. Under the definitions at § 422.350(b), we define control as meaning ''that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.'' This definition is essentially the same as the long-standing definition of control that is used for purposes of providers in the Medicare fee-for-service program (see § 413.17). We believe that the general definition for control we have adopted, which will result in case-by-case determinations by us, will ensure that PSOs are controlled by providers.

Comment: A commenter requested that we exempt PSOs formed by community health centers from the requirement in § 422.352(b)(1) that a non-rural PSO must deliver 70 percent of the health care services and items through the provider or affiliated providers responsible for running the PSO.

Response: We do not believe that a special exemption from § 422.352(b)(1) for community health centers is warranted. As we will note below, we do allow a lower percentage of health care services delivery for rural PSOs as compared to non-rural PSOs. However, because the percentage of health services delivery is in part designed to ensure that the PSO will remain solvent, we believe it would not be prudent to reduce the percentage for different types of organizations such as community health centers. To put our response in perspective, we will briefly discuss the PSO requirement that the PSO providers deliver a substantial proportion of health care services, and the reasons we have selected 70 percent for non-rural PSOs and 60 percent for rural PSOs.

The M+C regulations at § 422.352(b) specify that a PSO must deliver a substantial proportion of the health care items and services through the provider or affiliated group of providers responsible for operating the PSO. We have concluded that setting the substantial proportion requirement at 70 percent for a non-rural PSOs and 60 percent for rural PSOs balances two key interests. These interests are, specifically: (1) That we not set the proportion of services so high as to prevent participation by all but the most sophisticated provider organizations; and (2) that the substantial proportion threshold be sufficient to ensure that a PSO have a well-developed capacity to deliver services, thus meeting the financial stability objective explicit in the statute, and increasing the prospects for successful development and solvent operation of a PSO. There is no indication in the PSO provisions in Part C that the Congress intended that a different standard be applied to community health centers, or any other entity. We see no basis for doing so.

Comment: A commenter recommends that we measure substantial proportion based on encounters rather than expenditures.

Response: As discussed in the previous response, § 422.352(b) requires that a PSO deliver a substantial proportion of the health care items and services through the providers or affiliated providers responsible for operating the PSO. In calculating the substantial proportion percentage, we considered what would be the best method for comparing the proportion of items and services furnished by a PSO-affiliated provider with the overall amount of items and services furnished through the PSO. The two possible approaches we identified involved either the use of Medicare encounter data or Medicare expenditure data. Based on discussions with the health care industry, we learned that using expenditure data generally would not be burdensome for PSOs, because it is already commonly collected for management purposes. Furthermore, expenditure data may also produce a measurement more in line with the intent of the substantial proportion requirement. For example, the expenditures associated with an acute hospital visit would reflect a higher draw upon the PSO's resources than a physician office visit. Likewise, with expenditure data, the dollar amounts associated with each physician office visit, home care visit, etc., will reflect resource use and the ability of PSO providers to manage medical utilization. Therefore, based upon its immediate availability and arguably greater relevance and significance, we have concluded that use of expenditure data is the better approach for determining compliance with the substantial proportion requirement.

Comment: A commenter recommended changing the language in § 422.376 from ''the waiver is effective for 36 months, or through the end of the calendar year in which the 36 months period ends'' to ''the waiver is effective for 36 months.''

Response: We do not believe it is appropriate, as suggested by the commenter, to change § 422.376(b) so that it reads, ''the waiver is effective for 36 months.'' The reason we have chosen to allow a waiver to remain in effect until the end of the calendar year in which the 36 month period ends is that this ensures that the PSO's Medicare contract also remains in effect through the calendar year. To do otherwise could require a mid-year contract termination with significant disruption for beneficiaries enrolled in the PSO.

I. Organization Compliance with State Law and Preemption of Federal Law

1. State Licensure and Scope of Licensure (§ 422.400)

Section 1855 of the Act requires that a potential M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in every State in which it wishes to offer an M+C plan. (An exception to the licensure requirement is made for PSOs, as provided for in part 422, subpart H.) Section 1855(b) of the Act specifies that, with limited exceptions, an M+C organization must assume full financial risk for the cost of the health services it provides under its contract. Thus, the licensure requirement is a two-pronged requirement, and any potential M+C organization must meet both prongs, such that it is licensed, and is assuming the appropriate risk level for its license.

To establish the licensure status of potential M+C organizations, and in particular to determine compliance with the requirement that the organization's M+C contract falls within the scope of its licensure, we require that new M+C applicants supply documentation from the appropriate State regulatory authorities that the organization meets both the licensure and scope of licensure requirements. In the case of noncommercially licensed entities, § 422.400(b) requires that they obtain a certification from the State that they meet appropriate solvency standards.

Comment: With regard to the scope of licensure requirements, one commenter has asked for clarification as to whether managed care organizations with enrollment limited to Medicaid beneficiaries are eligible for M+C contracts. Another is concerned about States licensing organizations to offer

more than one M+C plan, noting that States may not have the resources to monitor multiple plans from multiple organizations. Other commenters have asked for clarification as to what happens if a State does not license insurers to offer high-deductible MSA plans, or does not license preferred provider organizations (PPOs). These commenters wish to know how MSA and PPO plans would be available in States which do not authorize these types of options. A commenter also asked whether States may require, for licensure purposes, that M+C organizations offer only products with ''gatekeepers.'' The commenter believes that these requirements should be preempted in order to permit managed care organizations to offer more choices to Medicare beneficiaries.

Response: Section 1855(a)(1) of the Act requires that an M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in any State in which it offers an M+C plan. As discussed in detail in the interim final rule (63 FR 35011), an entity does not have to have a commercial license to offer the type of M+C plan it seeks to offer under the M+C program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, in the case of an organization that is authorized by the State to assume risk under a Medicaid contract, but is not commercially licensed, the State in which the organization wishes to offer an M+C plan would have to certify that the organization has authority to assume the risk involved in offering the M+C plan in question (*e.g.,* by meeting State solvency requirements). In some States, Medicaid-contracting managed care organizations are operated under the authority of the State Medicaid agency, and the State may take the position that this authority is limited to assuming risk for Medicaid beneficiaries. Since the statute requires that M+C organizations (with the exception of PSOs) be licensed by the State, the State has the discretion to make this decision.

With regard to State monitoring of M+C organizations that they license, we do not have the authority to second guess a State's judgment concerning the sufficiency of its resources to monitor M+C plans for which it has given authorization. The States have the sole authority for licensure of M+C organizations, and can set their own standards for monitoring conditions of licensure.

The question of availability of MSA plans in States that do not approve high-deductible plans again goes back to the question of licensure. An organization wishing to offer an MSA plan must be licensed as a risk-bearing entity eligible to offer health insurance or health benefits in the State in question. If the organization wishes to offer a high-deductible policy as part of an MSA plan, the organization must be authorized by the State to assume risk, and under § 422.400(c)(1), must demonstrate that it is authorized to offer a high-deductible policy to Medicare beneficiaries under an M+C contract. This does not mean that it must be authorized by the State to offer such a policy commercially in the State.

With regard to the availability of PPOs in States that do not have a category of licensure into which PPOs would fit, the organization again would have to demonstrate that it was licensed as a risk-bearing entity or otherwise authorized to assume risk, and that it was authorized by the State to offer a PPO product to Medicare enrollees. (We note that under new section 1852(e)(2)(D), for purposes of the applicability of certain quality assurance requirements, a PPO is defined as an entity that is not licensed as an HMO.) If a State does not have a category for a PPO product, an organization may not offer a PPO product in that State unless it is able to demonstrate that the State has authorized it to do so in the context of an M+C contract. This same analysis applies to the question of whether a State may only allow products with ''gatekeepers.'' If the State only has licensure categories for ''gatekeeper'' products, then only those products may be offered in the State, absent State authorization of an alternative product in the M+C context.

The only exception to the above requirements that the State authorize the M+C organization to offer the type of plan at issue is the exception provided by Congress for PSOs that are unable to obtain a State license.

2. Federal Preemption of State Law (§ 422.402)

a. General Preemption (§ 422.402(a))

Section 1856(b)(3)(A) of the Act reflects the general principle that under the supremacy clause of the constitution, State laws are ''preempted'' when they conflict with applicable Federal laws. Specifically, section 1856(b)(3)(A) of the Act provides that ''any State law or regulation'' with respect to M+C plans is superseded ''to the extent such law or regulation is inconsistent'' with M+C standards. This general preemption authority does not extend to non-M+C enrollees or non-M+C lines of business or activities. We apply this provision in the same manner that Executive Order 12612 on Federalism was applied to managed care organizations with contracts under section 1876 of the Act prior to the BBA. Under that Executive Order (recently superseded by Executive Order 13132; see section VI.1 below), the requirements of section 1876 of the Act did not preempt a State law or standard unless the law or standard was in direct conflict with Federal law. Put another way, if a State law required a managed care organization to do something that it would be permitted to do under section 1876 of the Act, there was no preemption. As discussed below, new Executive Order 13132 (64 FR 43255) contains this same standard for general preemption. The general preemption rule in section 1856(b)(3)(A) of the Act is implemented in § 422.402(a).

Comment: A commenter asked whether State laws that are more restrictive than Federal laws are preempted under our general preemption authority at § 422.402(a).

Response: In its description of the House bill's provision for preemption of State laws ''inconsistent with'' the new BBA standards, the BBA Conference Report (H. Rept. 105–217, page 637) makes clear that this provision (which was retained in the conference agreement) ''should not be construed as superseding a state law or regulation * * * that provides consumer protections in addition to, or more stringent than, those provided under [the BBA].'' We thus believe it is clear that Congress expected the States, in some cases, to have more rigorous or more comprehensive standards for quality and consumer protection that would enhance, rather than be subsumed under, the M+C standards for quality and consumer protection. Except when one of the ''specific preemptions'' discussed below applies, State laws or standards that are more strict than the M+C standards would not be preempted unless they are in conflict with (for example, would preclude compliance with) M+C requirements.

Comment: One commenter representing many plans argues that our interpretation of general preemption is too narrow, and that it should be broadened to encompass State laws that the commenter believes serve as obstacles to the purposes and objectives of the M+C program. This commenter suggests that there are situations in which compliance with both a Federal

law and a State law is theoretically possible, but the administrative burdens associated with dual compliance would be tremendous, making compliance counterproductive in terms of meeting the goals of the M+C program. In these situations, the commenter believes that the State requirements should be preempted, thus relieving the burden of dual compliance.

Response: As just noted above, the legislative history of section 1856(b)(3)(A) of the Act makes clear that Congress contemplated that M+C organizations would be subject to State requirements that were ''more stringent'' than M+C standards. We believe that Congress intended in section 1856(b)(3)(A) of the Act to incorporate the basic principles of Federalism, as applied to section 1876 contractors at the time the BBA was passed. We do not believe that the fact that a burden may be involved in complying with State laws makes those laws ''inconsistent'' with Federal requirements. We therefore believe that under section 1856(b)(3)(A) of the Act, only State standards that prevent compliance with Federal standards are preempted under this general preemption provision. As noted earlier, this position is also consistent with new Executive Order 13132.

Comment: Many commenters sought clarification of the basic principles of general preemption, and asked whether specific issues are covered under the general preemption authority of section 1856 of the Act. Some of these commenters suggested that consumer protection standards should be left to the States. For example, a commenter representing many States believes that the following types of standards are not subject to general preemption: Market conduct evaluation; complaint handling (except to the extent specifically preempted by the BBA as discussed below); enforcement of unfair claim settlement practice standards (except to the extent specifically preempted by BBA); enforcement actions generally; filing and review of policy forms and rate filings; filing and review of advertising and marketing materials; provider access standards; credentialing standards; filing and review of provider contracts; utilization review programs and standards; quality assurance programs; supplemental benefits and cost-sharing arrangements; network adequacy; enforcement of loss ratio standards; standards and enforcement of commission limitations; and provider licensing and regulation. In addition, other commenters have asked for clarification as to whether or to what extent Medicare Secondary Payer mental health parity requirements are preempted. Another commenter suggested that we interpret general preemption as covering all State laws except for financial solvency standards.

Response: We agree that the areas mentioned by the commenter would not be preempted under the general preemption rule in section 1852(b)(3)(A) of the Act, as long as the State law did not conflict with an M+C requirement. In most of the areas mentioned, if an M+C organization could comply with State law without compliance resulting in a violation of an M+C requirement, there would be no preemption. While the commenter has recognized that some of the above-referenced areas of State regulation are subject to the specific preemption provision discussed below (see the second and third items in the above list), there are other areas among those identified by the commenter that are subject to specific preemption as well. For example, State regulation of supplemental benefits would be preempted under the specific preemption of State laws relating to benefits. In addition, some ''provider regulation'' could be preempted under the specific preemption of laws relating to the inclusion or treatment of providers. Thus, while we agree with the commenter that laws in the specified areas would not be preempted under section 1856(b)(3)(A) of the Act absent a conflict with M+C standards, the commenter should consult the discussion below concerning specific preemption of State laws in the areas referenced in section 1856(b)(3)(B) of the Act. With respect to the comment that all areas should be subject to general preemption except solvency, we disagree with this comment. As noted above, we believe that general preemption would only apply in the case of a specific conflict with M+C requirements.

Comment: A commenter asked for clarification as to whether and how State M+C laws apply to employee groups.

Response: As noted in the preamble to the June 26, 1998 M+C interim final rule (63 FR 35013), there is neither general nor specific Federal preemption of State requirements that apply to arrangements between employers and M+C organizations for the provision of negotiated group benefits not covered under an M+C plan. These are purely private benefits that fall outside the scope of the M+C program and the ACR process. Thus, if there are applicable State laws not preempted by the Employee Retirement Income Security Act of 1974, these State laws could apply to employer group benefits, and would not be preempted by M+C standards. M+C standards apply only to M+C plan benefits, including: (1) Medicare-covered benefits; (2) additional benefits paid for with Medicare payments; and (3) both optional and mandatory supplemental benefits for which a premium is charged.

Comment: A commenter asked whether State confidentiality laws are preempted.

Response: General preemption applies to confidentiality requirements. Thus, just as with other consumer protection standards, State requirements that are more stringent than the new M+C standards would not be preempted, unless compliance with the State confidentiality requirements made compliance with the Federal requirements impossible.

b. Specific Preemption (§ 422.402(b))

There are three areas in which section 1856(b)(3) of the Act provides for specific (rather than general) Federal preemption of State law: benefit requirements; requirements relating to treatment and inclusion of providers; and coverage determinations (including related appeals and grievance processes.) In the BBA Conference Report (H. Rept. 105–217, page 638), the conferees noted that benefit requirements, provider participation requirements, and coverage determinations (and related appeals mechanisms) are governed exclusively by Medicare standards under original Medicare, and expressed their view that this should be the case under the M+C program as well. That is, under original Medicare, States cannot specify what must be included as a Medicare benefit; States do not specify the conditions of participation for Medicare providers (though they license providers and practitioners and determine their scope of practice); States may not specify how a coverage determination is made with respect to whether or not the Medicare program covers a benefit; and States do not determine the type of appeal mechanism that is used to appeal a coverage decision made by a Medicare carrier or intermediary with respect to a Medicare benefit. In the specific preemption provisions in section 1856(b)(3)(B) of the Act, Congress provided that States similarly cannot regulate M+C plans in these areas. As in the case of general preemption, these specific preemption provisions do not extend to non-M+C enrollees, activities, or lines of business of the managed care organization.

In the interim final rule (63 FR 35012), we stated our intention to adopt a narrow interpretation of the

applicability of the three areas of specific preemption, thus giving States maximum flexibility within the parameters of the statutory language. (As discussed below, this view is consistent with new Executive Order 13132 on Federalism.) We identified the following examples of areas in which State standards would be preempted:

• Benefit mandates (note that we did not interpret a limit on cost-sharing to be a ''benefit'').

• Appeals and grievances with respect to M+C coverage determinations.

• Requirements relating to the inclusion of providers (such as ''any willing provider'' laws or requirements to included specific types of providers within a plan's provider network). We note that State laws providing enrollees with a right to directly access providers are considered to provide a ''benefit'' to enrollees, and to affect the ''inclusion'' and the ''treatment of'' providers, and thus also are specifically preempted.

Comment: In the interim final rule, we solicited comments on whether the specific preemption of benefits should be extended to cost-sharing requirements, and if there were particular types of cost-sharing that should, or should not, be included under the benefits preemption. We received many comments on this issue. Most industry commenters recommended that we include all State cost-sharing standards within the benefit preemption. They believe that cost-sharing is an integral part of a benefit; that the cost to a beneficiary for a particular service weighs on how much of a benefit he or she is actually receiving; and that the cost-sharing formula is what gives a benefit its market value. Commenters also argued that preempting State cost-sharing requirements would reduce variation in benefit packages, thus making comparison easier for beneficiaries, and easing the administrative burden on organizations that offer plans across State lines. They asserted that not preempting State cost-sharing standards would severely impede M+C organization's efforts to offer national plans. Another commenter wrote that it was unclear whether a State could continue to apply some of its benefit-related provisions, such as limits on copayments, State coordination of benefits and subrogation rules, and required benefit differentials for PPOs.

In contrast, commenters representing the States and beneficiary advocacy groups recommended that we continue to construe the benefit preemption as narrowly as possible, and thus not change our policy to consider cost-sharing a part of a benefit for preemption purposes. They supported our existing policy of generally not preempting State cost-sharing requirements. One commenter believed that even benefit requirements should not be preempted, however, arguing that if States cannot mandate certain benefits, then beneficiaries in M+C plans might have different, lesser benefits than beneficiaries with original Medicare and a Medigap policy.

Response: In the interim final rule, we stated that the specific preemption of benefit requirements does not extend to State cost-sharing standards (63 FR 35013). As discussed in detail in that rule, our position was that a State law establishing limits on cost-sharing generally, or limits on cost-sharing that can be imposed for a particular benefit, would not fall under the benefit preemption as we have defined the term ''benefit.'' We recognize that this is a narrow interpretation of the term ''benefit,'' and that we could have interpreted ''benefit requirements'' to extend to limits on cost-sharing. However, we wanted to minimize the extent to which beneficiary protections enacted by a State were preempted by Federal law. This decision is consistent with our support for beneficiary rights, as well as new Executive Order 13132 on Federalism, which calls for granting States the maximum flexibility permitted under Federal law. If the benefit to which State cost-sharing limits apply is not a Medicare-covered benefit, the State standard would apply only if the M+C organization chooses to offer the benefit, since any State mandate that the benefit be offered would be specifically preempted. Thus, to the extent that limits on cost-sharing are linked to a benefit mandate, the State cost-sharing limits could be seen to be ''indirectly'' preempted, in that the obligation to provide the benefit to which they apply is preempted. To the extent that an M+C organization offers the benefit to which State cost-sharing limits apply (whether as part of the package of Medicare-covered services, or as an additional or supplemental benefit), State cost-sharing standards would remain in effect unless they would be preempted under the general preemption authority discussed above.

Comment: Several commenters representing the State of Massachusetts wrote to request that we reconsider our position that the BBA prohibits State-mandated benefit laws, particularly when such a benefit is neither required by, nor funded by, the Federal government. These commenters believe that where Federal money is not involved, there is no preemption of State law, and that the M+C regulations should be modified accordingly. These commenters were particularly concerned about the effect of Federal preemption on Massachusetts' mandated prescription drug benefit, and pointed out that M+C enrollees in the State will not have access to a comprehensive prescription drug benefit in the absence of the State mandate. The commenters noted both that there is no Federal prescription drug benefit, and that the cost of the Massachusetts benefit is borne in no way by the Federal government.

Response: Throughout the development of the interim final rule and during the summer of 1998, we discussed in depth with Massachusetts officials the effect that Federal preemption would have on the prescription drug benefit in Massachusetts. Although we recognized the State's concerns, we did not believe that the statute permitted any discretion on the issue, absent a legislative amendment. We believe that the reference to ''benefit requirements'' must refer to non-Medicare benefits like those at issue in Massachusetts, since, as noted above, States have never been permitted to mandate what is covered by Medicare. In September of 1998, the Massachusetts Association of Health Plans sued the Commonwealth of Massachusetts, in an attempt to resolve the apparent conflict between the State and Federal regulatory approaches. A Federal court ruled that the specific preemption in section 1856(b)(3)(B) of the Act did apply to the Massachusetts drug benefit. The State appealed, and on October 8, 1999, the ruling was affirmed by the United States Court of Appeals for the First Circuit. *Massachusetts Assn. of HMOs* v. *Ruthardt,* 194 F.3d 176 (1st Cir., Oct. 8, 1999). The Court found that the M+C regulations ''dominate these particular fields, leaving no room therein for State standard-setting'' for benefit requirements (194 F.3d, at 183). We agree with the Court's conclusions.

Comment: Several commenters have asked us to revise § 422.402 to exempt State ''return home'' laws from preemption under sections 1856(b)(3)(B)(i) or (ii) of the Act. These laws generally allow a hospitalized beneficiary, who lived in a retirement home that includes a Medicare-approved nursing facility, to return to this ''home'' facility for post-hospitalization skilled nursing services, even if that facility is not part of his/her managed care plan's network. Commenters argued that these types of provisions are not benefits requirements and are not related to treatment and

inclusion of providers, but rather are consumer protection requirements.

Response: As discussed above, section 1856(b)(3)(B)(ii) of the Act clearly establishes Federal preemption for requirements relating to the inclusion or treatment of providers. We believe that a law granting an enrollee the right to coverage from a particular provider would certainly have to be considered a requirement ''relating to the inclusion or treatment of providers,'' since it requires that the provider in question be ''included'' in the network of providers through which covered services may be obtained.

As a matter of policy, we believe that return home laws have value for beneficiaries, families, and communities, and we encourage M+C organizations to offer a return home option where it would not adversely affect quality or continuity of care, and does not pose an unreasonable administrative burden. However, absent legislative change, we do not believe that the statutory preemption provisions permit any alternative interpretation that would allow enforcement of these State laws for M+C enrollees. We are exploring developing a legislative proposal to establish a limited exception to the M+C preemption provisions to accommodate State return home laws.

Comment: Several commenters offered differing opinions of our interpretation that section 1856(b)(3)(B) of the Act preempts direct access laws. Again, some commenters believe that these requirements are contract or consumer protection laws, and should not be subject to specific preemption; other commenters believe that direct access laws are clearly and specifically preempted. One commenter asked for clarification on the specific preemption of State standards related to the ''treatment and inclusion of providers and suppliers.'' Specifically, this commenter asked for clarification on the following situations: (1) Whether the preemption applies to State standards on how providers are paid; (2) whether State standards that are more stringent than the M+C provider antidiscrimination provisions in existing § 422.204(b) are preempted; (3) whether State requirements that certain categories of health professionals must be treated the same as other providers by an HMO or insurer are preempted.

Another commenter asserted that ''any willing provider laws,'' specific benefit requirements, and requirements for the inclusion of specific types of providers should not be preempted. This commenter believes that if State standards are more stringent than Federal standards and not inconsistent with them, they should not be preempted, regardless of whether these standards relate to the areas specifically preempted by Congress.

Response: In the interim final rule, we indicated that direct access laws and any willing provider laws were illustrative of the types of laws that we believe Congress intended to preempt through the BBA's specific preemption provisions. Although we recognize that these types of State standards may be viewed as consumer protections, we believe that such standards clearly also involve both plan benefits and the treatment and inclusion of providers, and therefore are specifically preempted. With regard to the specific questions raised by the commenter, these standards all appear to involve the inclusion or treatment of providers. In order to make a final determination, however, we would have to review the specific State law in question.

Comment: A commenter asked for clarification regarding whether certain aspects of State law, such as State definitions of medical necessity, and requirements that subscribers be notified of the right to file complaints with State regulators, would be preempted under § 422.402(b)(3), which preempts State requirements for coverage determinations, including appeals and related grievances.

Response: For the purposes of coverage determinations, a State definition of ''medical necessity'' is preempted under § 422.402(b)(3) because any such definition is integral to the determination of coverage. A State's general complaint process, as distinct from a process for appealing coverage decisions, would be subject only to general preemption under § 422.402(a), not specific preemption under § 422.402(b)(3). The State should indicate, however, that its process is separate, and that if the complaint involves a coverage determination, the sole mechanism for resolution is the Federal appeals process outlined in subpart M of part 422. For more information on this issue, please see guidelines issued by the National Association of Insurance Commissioners (NAIC).

Comment: A commenter who was generally supportive of Federal preemption argued that the regulations fail to clarify the ramifications of such preemption at the State level. The commenter requested that we ''formalize the process'' with the relevant State entities, so that managed care organizations are not held liable by a State for noncompliance with a State mandate when the organization is acting in accordance with Federal regulations.

Response: The NAIC and our staff have developed guidelines for use by the States in developing and implementing their managed care regulations and operational policies. We believe that these guidelines should address the commenter's concerns about formalized guidance for States.

Comment: Many commenters support a broader interpretation of Federal preemption such that State law related to grievance procedures would be preempted. Other commenters believe that Congress intended to specifically preempt State grievance procedures.

Response: The statute says only that grievances related to coverage determinations are subject to specific preemption; therefore, we do not believe that Congress intended to preempt all State grievance procedures. We believe that Congress recognizes that many States use the term ''grievance'' to describe a complaint or define a process that constitutes an ''appeal'' under Medicare. Thus, we believe that the intent of the statute was to specifically preempt State requirements for grievances related only to coverage determinations, and to apply general preemption to State requirements for all other types of grievances. Thus, the State requirement would stand so long as it is not inconsistent with a Federal requirement, as discussed in detail above.

Since enrollees may have complaints that involve matters unrelated to coverage determinations, there needs to be a mechanism in place to address other types of complaints involving the manner in which enrollees receive care. Therefore, M+C organizations are required to have a grievance process in place to handle complaints unrelated to coverage determinations.

The preamble to the interim final rule alerted the public that we would establish a grievance procedure through proposed rulemaking, and sought comments on ways to make it meaningful. Until publication of that proposed rule, M+C organizations should look to State requirements for resolving complaints unrelated to coverage determinations.

Comment: A commenter asked for clarification as to whether a State law requiring the external review of all coverage determinations where the independent reviewer's decision would be binding on the M+C organization would be preempted under the specific preemption rules.

Response: Specific preemption would apply in that situation. The M+C appeals process is the only method that can result in a binding decision on the M+C organization. A State may choose

to require external review of coverage determinations for monitoring or licensure purposes, but the requirement would be preempted to the extent that it requires a decision by any entity other than one prescribed under the M+C appeals process.

Comment: A commenter asked that we revisit our position that State tort or contract remedies may be available to beneficiaries whose coverage determination dispute goes through the Medicare appeals process. This commenter believes that coverage determination cases are contract disputes, and therefore should be the sole province of the Medicare appeals process.

Response: In some cases, a case that is cast as a State contract claim may amount to a claim that services are covered under an organization's M+C contract. We agree with the commenter that in that case, the claim would be pre-empted. However, there are other tort or State contract law, or consumer protection-based claims that would be entirely independent of the issue of whether services are required under M+C provisions. For example, a State consumer protection law may provide that certain claims made by an HMO in advertising give rise to particular obligations under State law, that exist independent of the question of what the HMO's M+C contract requires. In other cases, a tort action may exist independent of the question of whether services are covered under an M+C contract. We believe that under principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption narrowly, a beneficiary should still have State remedies available in cases in which the legal issue before the court is something other than the question of whether services are covered under the terms of an M+C contract.

3. Prohibition on State Premium Taxes (§ 422.404)

Section 1854(g) of the Act provides that ''no State may impose a premium tax or similar tax with respect to payments to M+C organizations under section 1853.'' This prohibition does not apply to enrollee premium payments made to M+C plans, which are authorized under section 1854 of the Act. Section 402.404(a) sets forth the statutory provision, and specifies that the term ''State'' includes any political subdivision or other governmental authority within a State.

Section 422.404(b) clarifies the scope of what constitutes a prohibited premium tax, establishing that the prohibition generally does not apply to a generally applicable tax on the net income or profits of any business. As noted in the preamble to the interim final rule, if the tax applies to premium revenue specifically, there is no exception to the prohibition of such a tax, based on the purpose of the tax.

Comment: One commenter agreed with our interpretation that the term ''State'' should include all political subdivisions, and recommended that we retain the regulatory language prohibiting State-levied taxes on payments made by Medicare to M+C organizations.

Response: We agree with the commenter. Since counties and other political subdivisions of a State derive their powers from the State, we believe this broad interpretation of the term ''State'' is the intended and necessary interpretation of the statutory provision. Thus, any prohibitions of State actions contained in Federal statute should be interpreted as prohibitions on actions at any level of State government or any State or local governmental body within the State.

Comment: One commenter noted that section 1854(g) of the Act prohibits only a ''premium tax or other similar tax,'' and argued that this does not support our inclusion of ''fees and other similar assessments'' in the regulatory language at § 422.404(a). The commenter argued that assessments to fund State high risk pools should be permitted.

Response: We believe that any mandatory fee or assessment imposed on premium revenues clearly would fall within the reference to a premium tax or ''other similar tax.'' As noted in the preamble to the interim final rule, we considered whether to exempt an assessment that is used for purposes of an insolvency insurance pool, but determined that if the assessment was mandatory, it amounted to a tax. We noted, however, that an M+C organization that wished to rely on the proceeds from such a pool as part of its plan for insolvency protection could voluntarily contribute to such a pool.

Comment: A commenter objected to statements in the preamble to the interim final rule (63 FR 35014) suggesting that an M+C organization may participate in a ''guaranty fund'' by paying premium taxes voluntarily. The commenter pointed out that the NAIC Life and Health Insurance Guaranty Association Model Act excludes managed care organizations from its definition of a ''membered insurer.'' The commenter recommended that we clarify that State life and health insurance guaranty associations are excepted from the preamble discussion of ''guaranty funds,'' or at least note that under many States' life and health guaranty association laws, M+C organizations would not be considered member insurers.

Response: To the extent the commenter is referring to a guaranty fund operated by a private association, the prohibition on premium taxes would not apply. Our reference in the preamble to voluntary contribution to a guaranty fund involved a State mandated insurance pool established and operated by the government. In this case, the mandate to contribute premium revenue would be preempted, but an M+C organization could voluntarily participate.

4. Medigap

Section 1882 of the Act governs the sale of Medicare supplemental (''Medigap'') policies, private health insurance policies that are designed to cover certain out-of-pocket costs incurred by Medicare beneficiaries. With minor exceptions, a Medigap policy cannot be sold in any State unless it conforms to one of ten standardized benefit packages, labeled plans ''A'' through ''J''.

Before enactment of the BBA, Federal law provided for only one opportunity for a Medicare beneficiary to purchase a Medicare supplemental (''Medigap'') policy on a ''guaranteed issue'' basis. (Generally, this term means that the Medigap insurer cannot deny the application, delay the issuance or effective date of the policy, or charge an additional amount based on the individual's health status.) This opportunity occurs only during the 6-month period beginning with the date the beneficiary is both age 65 or older and enrolled in Medicare Part B.

Section 4031 of the BBA amended section 1882(s) of the Social Security Act to specify additional situations in which beneficiaries are able, as of July 1, 1998, to buy specific types of Medigap policies on a guaranteed issue basis, if they apply within 63 days of losing certain other types of health coverage, and if they submit evidence of the date that the prior coverage terminated. The law also requires that the entity that provided the prior coverage advise the beneficiary of these rights. While the M+C regulations do not implement the Medigap provisions of the BBA or the BBRA, it is important to understand the implications for M+C organizations, since some situations addressed by the Medigap provisions involve beneficiaries who leave M+C plans and return to original Medicare.

The situations that give rise to the obligation to notify the beneficiary include, for example, termination of

coverage by an M+C plan, reduction in an M+C plan's service area, termination of the M+C plan's contract by us, or loss of coverage under an M+C plan due to a change in the beneficiary's place of residence. As mentioned previously, section 501(a) of the BBRA amended section 1882(s)(3) of the Act to allow an individual to choose between two options: (1) Voluntarily disenrolling before coverage under the M+C plan is terminated involuntarily, and applying for a Medigap policy no later than 63 days after being *notified* by the M+C organization of the impending termination or service area reduction; or (2) waiting and applying no later than 63 days following the date of the involuntary termination or service area reduction. In these instances, the beneficiary is guaranteed the right to buy Medigap plans A, B, C, or F, subject to availability of those policies from insurers selling in the State.

With regard to availability, we note that not all 10 standardized Medigap plans may be available in all States, and all plans available in a State might not be offered by every insurer. Wisconsin, Minnesota, and Massachusetts have alternative forms of standardized policies under a waiver granted them by the Omnibus Budget Reconciliation Act of 1990 (OBRA). Federal law does not generally require sale of Medigap policies to beneficiaries under age 65 (eligible for Medicare by reason of disability or ESRD). However, State law may require insurers to sell to these populations under certain circumstances. Also, some insurers voluntarily sell policies to the disabled, usually on an underwritten basis. Where an insurer has filed in a State to sell to the under 65 population, these policies are subject to the BBA guaranteed issue protections.

The beneficiary may also have the right to guaranteed issue of a broader selection of Medigap policies if he or she either: (1) Directly enrolls in an M+C plan upon first becoming entitled to Medicare at age 65; or (2) enrolls for the first time in an M+C plan after previously having been covered under a Medigap policy, and, in both instances, later disenrolls from the M+C plan within 12 months of the effective date of the M+C enrollment. Beneficiaries who were previously enrolled in original Medicare and who purchased a Medigap policy, who disenroll from the M+C plan before the 12-month ''trial'' period has expired, are guaranteed the right to return to their old Medigap policy, if it is still available from their former insurer; (otherwise they have the choice of plans A, B, C, or F from any insurer). Alternatively, if an M+C plan was their first choice as newly entitled Medicare beneficiaries at age 65, and they disenroll during the first 12 months after enrolling, they have their choice of all 10 Medigap plans, including plans H, I, and J, which provide some outpatient prescription drug coverage. This broader array of choices for beneficiaries who elected an M+C plan when they first became entitled to Medicare at 65, in effect, compensates them for having forgone their 6-month Medigap open enrollment opportunity, which began when they reached age 65.

In all these cases of voluntary or involuntary terminations from an M+C plan, beneficiaries must apply for the Medigap policy of their choice, from among the options available to them, within 63 days. If they fail to act within this time period, they lose both their guaranteed issue right to purchase the policy of their choice at the standard premium rate, and their protection from pre-existing exclusion periods. Outside of this guaranty issue period, they may be able to find some Medigap insurers who are willing to sell to them, but they may not be able to purchase the policy they want. Additionally, the insurer can apply a pre-existing condition exclusion period of up to 6 months and/or charge them an additional amount based on their health status.

Because the Medigap provisions establish specific deadlines for beneficiaries who wish to take advantage of these new rights, prompt action by the M+C organizations to notify beneficiaries of their rights, or by us to provide accurate evidence of recently terminated coverage, is essential. We are committed to providing beneficiaries whose M+C coverage is terminated with timely and accurate evidence of the recently terminated coverage. To this end, we will provide M+C plans with, among other things, a model final termination letter that must be sent 90 days prior to termination of a contract. This letter will contain detailed information about beneficiaries' rights to Medigap under BBA and the BBRA.

We urge M+C organizations to keep in mind that they are obligated to notify beneficiaries whose coverage terminates of their rights under the Medigap provisions. Those provisions are complex, and beneficiaries will be entitled to guaranteed issue of Medigap policies at standard premium rates and with no preexisting condition exclusion periods only under certain circumstances. As noted above, their choice of Medigap policies will depend on the precise reason for, and timing of, the termination of their coverage under the M+C plan. It also matters whether they disenroll voluntarily or wait to be involuntarily disenrolled. However, if their initial 12-month trial period will expire before the M+C plan's contract will terminate, they have the option of disenrolling before the 12-month period has expired if they wish to obtain the broader selection of Medigap policies that may be available to them.

Further guidance is available to beneficiaries from their State Health Insurance Assistance Program (SHIP) or State insurance department.

Comment: A commenter has asked whether Medigap coverage is still applicable when a beneficiary chooses to privately contract for health services.

Response: Medigap policies cover two basic types of costs. The first includes costs such as deductibles and coinsurance that apply with respect to services *covered by Medicare.* The second includes costs of non-covered items and services such as outpatient prescription drugs. Medigap insurers are only required to make payment for the first type of services if a bill is submitted to and processed by Medicare. When a beneficiary privately contracts with a physician or practitioner under section 1802(b) of the Act to receive services that would otherwise be covered under Medicare, the services are excluded from Medicare payment under section 1862(a)(19) of the Act, and the beneficiary agrees not to submit a bill. As the beneficiary acknowledges in the private contract, as required by section 1802(b)(2)(B)(iv) of the Act, the Medigap policy will not pay for costs related to these services.

The policy may, however, be required to make payment with respect to the types of costs that are not otherwise covered by Medicare.

Comment: Commenters asked for clarification of the effective date of the BBA guaranteed issue requirements for Medigap A, B, C, and F plans, and for clarification of the rights of disabled beneficiaries with regard to guaranteed issue.

Response: As discussed above (and in greater detail in the **Federal Register** on December 4, 1998 and February 17, 1999, 63 FR 67078 and 64 FR 7968, respectively), the BBA's guaranteed issue provision took effect for all insurers on July 1, 1998. In addition, as noted previously, any Medigap policy that is available to beneficiaries under age 65 under any other circumstances must be offered to beneficiaries under age 65 who meet the criteria for BBA guaranteed issue protections.

Comment: One commenter was concerned about the wide variation in premiums of the 10 Medigap plans, and

was worried about beneficiaries being overcharged.

Response: It is true that there is wide variation in the premiums charged for the 10 standardized Medigap policies, both within States and from State to State. Regulation of Medigap insurance rates is ultimately within the discretion of the States, although federal Medigap law imposes some general requirements. In particular, Medigap policies must meet certain loss-ratio standards that are intended to ensure that policies provide refunds or credits if aggregate premiums exceed aggregate benefits by too high a margin. In addition, during the initial open enrollment period, and when the BBA guaranteed issue situations are in effect for a beneficiary, the insurer cannot increase the premium based on the beneficiary's health status.

Comment: Commenters voiced concern over the possibility of a beneficiary being penalized when a health plan terminates without timely enough notice for the beneficiary to find the appropriate Medigap insurance. Commenters also believe that we should provide plans with information as to which States have Medigap policies without pre-existing condition limitations as of January 1, 1999, and in general that plans need more information on Medigap.

Response: We have developed a clear termination policy and systems to provide for timely beneficiary notification, so that beneficiaries will be aware of their rights and protections if a plan terminates. In addition to developing internal processes, we are working with the States and M+C organizations to develop model language that will clearly and timely inform beneficiaries of their rights and protections.

In addition, we are working with the NAIC and the States to develop the Medigap Compare database, which will identify available Medigap policies and allow beneficiaries to compare costs and benefits. Beneficiaries and M+C plans will be able to access this database to gain the appropriate information a beneficiary needs when seeking Medigap insurance.

J. Subpart J, Part 422

Subpart J of part 422 has been reserved for future use.

K. Contracts with M+C Organizations (Subpart K)

Subpart K sets forth provisions relating to the contracts that are entered into by M+C organizations, including a description of terms that must be included in the contract, the duration of contracts, provisions regarding the nonrenewal or termination of a contract, and minimum enrollment, reporting, and prompt payment requirements.

1. Definitions (§ 422.500)

Comment: As discussed above in section II.F.2, we received comments suggesting that we impose requirements on providers to cooperate with M+C organizations in their collection of encounter data to be used in implementing risk adjustment.

Response: As discussed in section II.F.2, in response to this comment, we have taken several steps to facilitate the cooperation of providers in supplying valid data that can be used by M+C organizations to comply with encounter data requirements. In the case of contracting providers, we have specified under § 422.257 that M+C organizations may include in their provider contracts provisions requiring submission of valid data. Therefore, an M+C organization could provide in its contract that it will not make payment if claims do not meet the standards specified. In the case of noncontracting providers, however, § 422.520 requires M+C organizations to pay 95 percent of ''clean claims'' within 30 days, or pay interest on the amount. Also, based on the existing definition of ''clean claims,'' an M+C organization could not withhold payment based on a failure to submit a claim in the form required for use in complying with encounter data requirements. As noted in section II.F.2, we are revising the definition of ''clean claim'' in § 422.500 to require that clean claims include the substantiating documentation needed to meet the requirements for encounter data submission, and meet the original Medicare ''clean claim'' requirements. This change will, in effect, also require noncontracting providers submitting claims to an M+C organization to provide the organization with the information it needs to be able to use the claim in encounter data submissions, by exempting claims that do not meet these requirements from application of the 30-day ''prompt payment'' standards articulated at § 422.520. M+C organizations will therefore be able to withhold payment longer than the 30-day prompt payment standard in cases where noncontracting providers submit claims that do not contain substantiating documentation necessary for encounter data submissions or have other deficiencies (for example, inadequate coding). We believe that this clarification of the clean claim definition at § 422.500 is consistent with section 1957(f)(1) of the Act, which incorporates the Medicare fee-for-service prompt payment provisions in sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act, and simply fleshes out the concept in the existing definition that a claim is not clean if it lacks ''any required substantiating documentation.'' Providers should note that submission of claims with complete and accurate encounter data is ultimately in their best interest, since M+C organizations must submit complete and accurate encounter data in order to get the full payment to which they are entitled under the risk adjustment system. While HCFA does not regulate payments to providers by M+C organizations, we believe that M+C organizations should share appropriately with providers any gains under the risk adjustment system.

2. National Contracting

The BBA does not specifically define or directly address the issue of national contracting. It facilitated such contracting, however, when it provided in section 1857(a) of the Act that an M+C contract ''may cover more than 1 Medicare+Choice plan,'' and, in section 1851(h)(3) of the Act, provided that marketing material need only be approved once to the extent it is consistent from area to area. While we are interested in national contracting, we similarly have not expressly provided for it in the regulations. One national contracting approach we would be willing to consider would permit an M+C applicant to request that we enter into a national contract with the applicant if the applicant holds license as a risk-bearing entity in each State where it intends to operate. The applicant would have the option of adopting a single M+C plan across the country, with one service area and a national ACR proposal, or offering different M+C plans in different areas under the same national contract.

While we have not at this time entered into a national contract with any M+C organization, HCFA has entered into national ''agreements'' with national chain organizations that hold M+C contracts. These arrangements apply to those chain organizations that enter into separate contracts in multiple States. These agreements allow a chain organization to establish a uniform policy across all of its States as to marketing, quality assurance, utilization review, claims processing, etc. HCFA pre-approves these national policy procedures. We continue to contract separately with individual, albeit related, M+C organizations affiliated through common ownership or control. We likewise continue to monitor operational activities for each organization in each State, but, having approved national policy, the need for

review at the State and local level is reduced.

Nine commenters addressed national contracting for M+C organizations. While most of the public comments favored extending the option of national contracting to M+C organizations and applicant organizations, commenters generally linked their support for the concept to a request that we provide additional information on the specifics of any national contracting policy.

Comment: While several commenters that supported national contracting raised individual concerns, (in most instances related to the need for HCFA to provide additional information), one commenter raised concerns that national contracting would undermine our ability to adequately monitor the performance of M+C organizations. Another commenter raised concerns that national contracting would provide M+C organizations the ability to bypass existing limits pertaining to the provision of cross-state and national radiology services.

Response: We continue to believe that national contracting has potential advantages for Medicare beneficiaries, M+C organizations, and HCFA. Indeed, we have already observed the benefits of allowing M+C organizations that operate in many markets throughout the county to establish uniform operational functions in the areas of marketing, quality assurance and claims processing. However, some issues pertaining to national contracting, (for example, monitoring and oversight, enforcement actions, etc.), require additional study. While HCFA continues to explore these issues, we are not able to provide detailed guidance. At such time as additional guidance is developed, we anticipate notifying the public through an operational policy letter.

3. Compliance Plan (§ 422.501(b)(3)(vi))

As a condition for entering into an M+C contract with HCFA, applicant organizations must demonstrate that they have certain administrative and management arrangements in place. There are six specific administration and management requirements at § 422.501(b)(3). One of these requirements is that M+C organizations have in place a compliance plan for meeting all applicable Federal and State standards. The regulations list the required elements of the compliance plan, which generally follow the standards applied under the U.S. Sentencing Commission's Federal Sentencing Guidelines in determining whether the existence of a compliance plan should mitigate penalties. We received nine public comments on the M+C compliance plan requirement.

Comment: Although some commenters agreed with the spirit of the compliance plan requirement, most objected to its mandatory nature, especially in light of OIG guidance on compliance plans for M+C organizations.

Response: We believe that the unique financial incentives and health care delivery systems of M+C organizations justify the compliance plan requirement. Medicare beneficiaries who enroll in plans are essentially ''locked in'' to that plan's benefit structure and provider network and may not obtain services under original Medicare. M+C organizations are responsible for a significantly broader range of program activities than original Medicare providers, including marketing, enrollment, appeals and grievances, utilization management, and claims payment. Each of these activities presents the potential for noncompliance that could directly and adversely affect a beneficiary's rights under the Medicare program. For example, an M+C organization's failure to report enrollment data properly to HCFA may result in incorrect payments to that organization.

While HCFA and the OIG conduct ongoing M+C program monitoring and enforcement activities, the number and variety of M+C operational requirements presents a significant regulatory challenge to both of these agencies. As a result, we believe that the additional level of scrutiny imposed by a compliance plan is a reasonable requirement.

While the OIG stated in its November 1999 guidance that the document was intended only to provide assistance for M+C organizations, the OIG did note that it ''believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, and ensuring the provision of high-quality cost-effective care.'' The OIG also stated that a compliance plan is a tool for an M+C organization ''to ensure that it is not submitting false or inaccurate information to the Government or providing substandard care to Medicare beneficiaries * * *.'' We agree with the OIG's judgement with respect to the utility of the compliance plan tool and have adopted this requirement to protect the integrity of the M+C program.

Comment: Several commenters asked when M+C organizations are responsible for meeting the compliance plan requirements stated at § 422.501(b)(3)(vi), and noted that no detailed guidance on compliance has been issued by HCFA in connection with the interim final rule.

Response: The requirements in § 422.501(b)(3)(vi), as revised in this final rule, are in effect and must be met by M+C applicants and M+C organizations. Pending any further guidance, M+C organizations are free to reasonably interpret the provisions in § 422.501(b)(3)(vi), and should be prepared to demonstrate, upon request, how the organization meets each compliance plan element, as specified at § 422.501(b)(3)(vi), *et seq.*

Comment: Many commenters addressed the requirement at § 422.501(b)(3)(vi)(H) that M+C organizations develop ''an adhered-to process for reporting to HCFA and/or the OIG credible information of violations of law by the M+C organization, plan, subcontractor, or enrollee for determination as to whether criminal, civil, or administrative action may be appropriate.'' Commenters generally stated that this requirement was too vague, and should be more clearly defined to enable organizations to demonstrate compliance to HCFA. Several commenters requested that we specify what ''credible information'' means within the context of requiring M+C organizations to submit information to HCFA and/or the OIG. Commenters also requested that we specify: (1) Exactly what information must be self-reported; (2) to which agency; and (3) pursuant to violations of which laws. Commenters also noted that while paragraphs (A) through (G) correspond to provisions found in the Federal Sentencing Guidelines, paragraph (H) appears to be an M+C requirement only. These commenters believe that it is unfair to subject M+C organizations to a self-reporting requirement that does not apply to other sectors of the health care industry.

Response: Commenters correctly point out that the first seven elements of the mandated compliance plan guidance at § 422.501(b)(3)(vi) *et seq.* reflect the areas identified in the U.S. Federal Sentencing Guidelines. We previously added the eighth element in an attempt to ensure an enhanced level of program safeguard through self-reporting. We recognize, however, that it is arguably unfair to impose a self-reporting requirement on M+C organizations but not on other types of health care providers and suppliers participating in the Medicare program, and we have eliminated any requirement of self-reporting.

Nevertheless, we believe that the existence of voluntary self-reporting procedures of potential misconduct is an appropriate part of an M+C organization's compliance program. While this rule does not make any type of self-reporting mandatory, M+C organizations may wish to consider the following suggestions, as a matter of voluntary good business practice. These suggestions are not mandatory. Where the M+C organization discovers evidence of misconduct related to payment or delivery of health care items or services under the M+C contract, the M+C organization may conduct a timely, reasonable inquiry into the misconduct. After the reasonable inquiry, if the organization has determined that the misconduct resulted in an overpayment, the M+C organization is encouraged voluntarily to report the overpayment to HCFA. If the M+C organization has determined that the misconduct may violate the statutes of direct concern to the HHS Office of Inspector General, it is encouraged voluntarily to report the existence of the misconduct to that office. Finally, the M+C organization is encouraged voluntarily to initiate and implement appropriate corrective actions to ensure the problem does not recur.

While we are withdrawing all requirements for self-reporting in this rule, we believe that the required reporting of overpayments is an effective tool for promoting Medicare program integrity generally. Accordingly, HCFA intends to develop policies through separate notice and comment rulemaking in cooperation with the HHS Office of Inspector General that would require all Medicare providers, suppliers and contractors to report overpayments to HCFA.

Comment: Some commenters considered the M+C compliance plan requirements at § 422.501(b)(3)(vi) to be overly prescriptive, and asserted that they would result in M+C organizations being forced to ''reinvent the wheel,'' even though they may have existing compliance structures in place that meet the intent of the regulations. Many of these same commenters questioned our authority to prescribe these requirements in the M+C final rules.

Response: It is not our intent through these rules to require M+C organizations with effective compliance plans in place to make major changes. We believe that the requirements in § 422.501(a)(3)(vi) based on the Federal Sentencing Guidelines are sufficiently broad and general in nature that an effective compliance plan currently in place should satisfy M+C requirements. However, we do want some assurances that M+C organizations will have procedures in place to ensure compliance with Federal laws and requirements. We believe that our compliance plan requirements include the basic framework required for organizations to prevent and detect activities that will render the organization out of compliance. Moreover, the elements of the Federal Sentencing Guidelines from which these requirements are drawn are present in other guidances issued by the OIG over the last several years and should be familiar to most M+C compliance officials.

M+C organizations and contract applicants have broad discretion under § 422.501(b)(3)(vi) to design their compliance plan structure to meet the unique aspects of each organization. We recognize that there is no one best way for an organization to take steps to ensure that it is operating in compliance with all applicable regulations and requirements. Thus, we intend to work with M+C organizations and contract applicants to apply a flexible standard in reviewing M+C compliance plans, while still ensuring that these compliance plans serve their intended purpose: to detect and prevent compliance problems, in addition to identifying aspects of the organization that may be vulnerable to such problems.

We believe that one way for us to determine if an organization's corporate compliance plan is effective is to evaluate and audit the performance of the organization according to the M+C requirements articulated in the M+C contract and regulations. Since we have an established monitoring process for M+C organizations, we believe that the infrastructure is already established that may assist HCFA in its efforts to assess the effectiveness of organizations' compliance plans based in part on the results of our monitoring efforts.

4. Access to Facilities and Records (§ 422.502(e))

Under § 422.502(e) of the regulations, an M+C organization must agree to allow access to HHS or the Comptroller General to evaluate the quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract; the facilities of the M+C organization; and the enrollment and disenrollment records for the current contract period, and 6 prior contract years. We received two comments regarding access to M+C organization records.

Comment: A commenter asked what an M+C organization's obligations are in relation to information concerning nonplan providers, with whom an M+C organization has no contract. The commenter questioned how M+C organizations could be expected to provide access to governmental entities for nonplan provider records in order to meet the requirements of § 422.502(e).

Response: We recognize that HHS, the Comptroller General or their designees can require only M+C organizations and their subcontractors to make available their facilities and records. If an M+C organization does not have a contract or other suitable written arrangement with a provider, it cannot compel the provider to provide the same access that an M+C organization or its subcontractors must provide under the terms of their M+C contract with HCFA. In order for HHS or the Comptroller General to gain access to the facilities and records of noncontracting providers, these agencies would be required to resort to other available legal remedies, such as subpoenas.

We would add, however, that as a general principle, if Federal funds are going to a provider of Medicare or Medicaid services, appropriate Federal officials have a right to review that provider's facility or books as a condition of receipt of those Federal funds.

Comment: A commenter suggested that the 6-year time period for which data must be retained under the regulations should be tied to the end of the year in question, and not the date of the completion of the audit, as provided in § 422.502(e)(4).

Response: The 6-year period specified for retention of records was established in reliance on the 6-year ''statute of limitations'' that generally governs the initiation of a civil action by the Government, either under the False Claims Act (FCA) or the Civil Monetary Penalties Law (CMPL). A statute of limitations specifies the time period during which the Government may initiate an action. Generally, a statute of limitations begins to run on the date that an audit was completed. For this reason, we are requesting that books and records be kept for at least 6 years from either the end of a contract or the completion of an audit, whichever is later.

For purposes of clarity, we also point out that the 6-year record retention requirement requires M+C organizations to keep a specific year's records for 6 years, after which the organization is free to dispose of any records they deem appropriate. This is to clarify one misconception that M+C organizations must maintain 6 years of records for an additional 6-year period. We instead

envision the obligation for M+C organizations to retain records to expire on a rolling basis, with M+C organizations having the right to discard each year the records from more than 6 years earlier. For example, in 2000, M+C organizations could discard records from 1993 or earlier. In 2001, M+C organizations could discard records from 1994, etc. Under this system of record retention, if the Government has not audited or determined any wrongdoing within a 6-year period following the year when records were developed, the Government would be otherwise precluded under law from taking any action against an M+C organization.

5. Disclosure of Information (§ 422.502(f)(2)(v))

Pursuant to authority at section 1851(d) of the Act, § 422.502(f)(2) describes the information that M+C organizations must submit to HCFA. We specify that this information is necessary for us to fulfill our responsibilities in evaluating and administering the program. Our dissemination of some of this information to current and prospective Medicare beneficiaries enables them to exercise informed choice in obtaining Medicare services. We received one comment on this section of the interim final rule.

Comment: One individual commented on the requirement in § 422.502(f)(2)(v) that M+C organizations submit to us information about beneficiary appeals and their disposition. The commenter recommended that we amend this section of the regulations to include the additional requirement that M+C organizations disclose to HCFA information regarding beneficiary grievances and their disposition.

Response: Consistent with section 1852(c)(2)(c) of the Act, § 422.111(c)(3) of the regulations distinguishes between information that an M+C organization must provide to a Medicare enrollee annually, and information that the M+C organization must disclose to any M+C eligible individual upon request. The requirement states that M+C organizations must disclose to M+C eligible individuals, upon request, the aggregate number of disputes, and their disposition, including both grievances and appeals. Thus, Medicare beneficiaries have access to information on M+C organization grievances.

Also, pursuant to both sections 1851(d)(3) and 1852(c)(2)(C) of the Act, § 422.502(f) requires that M+C organizations disclose to us the appeal data that they are required to disclose upon request to beneficiaries. We believe that this is necessary so that we can begin to capture important baseline data on the appeals process. Our contractor (the Center for Health Disputes Resolution) is responsible for making reconsideration decisions when an enrollee files an appeal, and these decisions are appealed to HHS administrative law judges and the Departmental Appeals Board. In addition, HCFA enforces decisions made by these entities, which necessarily involve the critical question of whether services will be covered by the M+C organization.

While the regulations provide for beneficiary access to information on an M+C organization's grievance process, we do not at this time believe that it is necessary for HCFA to collect this information for administrative purposes. We would advise M+C organizations, however, that while we are not requiring that M+C organizations disclose grievance data to us at this time, we intend to propose additional requirements pertaining to M+C grievances, including quality of care grievances, in a notice of proposed rulemaking to be published later this year. Thus, we anticipate that M+C organizations may be required to report grievance data in the future.

6. Beneficiary Financial Protection (§ 422.502(g))

In the interim final rule, we addressed enrollee financial protection provisions at § 422.502(g). These provisions are designed to protect enrollees from incurring liability for payment of any fee for which M+C organizations are legally obligated. Section 422.502(g) incorporates enrollee financial protections that were in place before the BBA in § 417.122(a)(1), which applies to all section 1876 contractors under § 417.407(f). Section 422.502(g)(1) is intended to protect enrollees from being held financially responsible for fees for which the M+C organization is legally liable; § 422.502(g)(2) addresses M+C organizations' obligation to provide for continued coverage of health care benefits, and § 422.502(g)(3) sets forth the mechanisms M+C organizations can employ to provide the required enrollee protections. We received three comments regarding § 422.502(g).

Comment: A commenter suggested that we provide appropriate ''hold harmless'' language for inclusion in M+C organizations' contracts because different States have different requirements regarding hold harmless language. (By ''hold harmless'' language, the commenter is referring to language included in an M+C organization's contract with a provider that protects enrollees from being charged for services, (other than pursuant to M+C plan provisions that allow for cost-sharing), furnished by the provider, even if the provider has not received payment from the M+C organization for the services.)

Response: Implicit in the commenter's request is recognition that many States have adopted hold harmless contract language requirements for managed care organizations operating within a given State. We generally recommend that M+C organizations adopt the National Association of Insurance Commissioners' (NAIC) model hold harmless language. However, given the wide variety of individual State requirements loosely categorized under member or enrollee protections, we do not believe that it is prudent to *require* M+C organizations to adopt the NAIC model language, because that requirement may well place some M+C organizations at odds with State provisions. The NAIC-approved language is available through most State insurance commissioners' offices, or by contacting the NAIC directly.

Comment: One commenter recommended that we strengthen the beneficiary protection provisions in subpart K by explicitly prohibiting providers from bringing ''collection actions'' against M+C enrollees, as a means of preventing providers from billing beneficiaries enrolled in M+C plans for fees that are the legal obligation of the M+C organization. The commenter also suggested that we define the word ''fees'' for purposes of this section of the regulations.

Response: Section 422.502(g)(1) is designed to ensure that beneficiaries are not held liable for fees for which the M+C organization is legally responsible. As discussed above, under § 422.502(g)(1)(i), contracts with M+C plan providers must contain language that prohibits these providers from holding beneficiary enrollees liable for payment of fees that are the obligation of the M+C organization. (This language is commonly referred to as ''hold harmless'' language.) Under § 422.502(g)(1)(ii), M+C organizations are responsible for indemnifying enrollees for payment of any fees that are the legal obligation of the M+C organization to pay when services are furnished by providers that do not have a contract or other acceptable written arrangement with the M+C organization. We believe that these two provisions generally are adequate to ensure that M+C enrollees are not held responsible for fees for which an M+C organization is liable.

In instances where providers do bill M+C enrollees for amounts beyond those approved in an M+C plan, we believe that it is the responsibility of the M+C organization to take appropriate steps, such as recovering these amounts from the providers, to see that beneficiary enrollees are made financially whole. If they fail to do so, we would take appropriate action against the M+C organization. We believe it would be inappropriate for us to engage in activities directed at individual providers.

We note, however, that even in situations, (such as insolvency or other financial difficulties), where an M+C organization fails to satisfy its responsibility to pay a provider for services furnished to an M+C enrollee, the principle that the beneficiary is protected still applies. Although we believe this principle is inherent in the existing regulations, to clarify this point, we are revising § 422.502(g)(1) to indicate that the applicable beneficiary financial protections apply in situations such as insolvency or other financial difficulties.

We believe that the term ''fee'' is commonly understood, and does not need a special definition. In this context, the term refers to the fees charged by a provider (for example, a physician's fee for services provided). M+C organizations are responsible for payment of such fees, except for applicable enrollee cost-sharing amounts specified under the M+C plan, which are the obligation of the Medicare enrollee.

Comment: A commenter contended that there is an inconsistency in the language in §§ 422.502(g)(2), (g)(3), and (i)(3)(i)(B). Section 422.502(g)(3) gives M+C organizations several options for meeting requirements in § 422.502(g) (other than the ''hold harmless'' requirement in § 422.502(g)(1)(i)), including the options of providing for continuation of benefits through contractual arrangements, insurance, financial reserves, or other arrangements acceptable to HCFA. Section 422.502(i)(3)(i)(B), however, effectively requires that continuation of benefits be provided for in contract language.

Response: We agree with the commenter that the language in these sections is inconsistent. Accordingly, we are revising §§ 422.502(i)(3)(i) to eliminate the requirement that the continuation of benefits protection be addressed through contractual arrangements. In conjunction with this technical change, we also are revising § 422.502(g)(3) to clarify that the alternative arrangements spelled out there are linked only to the indemnification provision in § 422.502(g)(1)(ii) and to the continuation of benefits provision in § 422.502(g)(2).

7. Requirements of Other Laws and Regulations (§ 422.502(h))

Section 422.502(h) requires that contracts reflect the M+C organization's obligations under other laws, specifically, the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans with Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.

Comment: Several commenters wanted us to define ''other laws applicable to recipients of Federal funds'' and ''other applicable laws and rules'' as used in § 422.502(h).

Response: These references are intentionally broad and all-encompassing. We have already identified various specific laws. These references are intended to encompass laws that may be enacted in the future, or current laws that we might inadvertently omit if we were to attempt to be more specific in this regulation. It is important to note, however, that these references only apply to laws that are, by definition and by their own terms, ''applicable'' to an M+C organization. Thus, these provisions of the regulations do not result in an organization being required to comply with any laws that do not already apply to them. Rather, they simply call for a commitment to comply with these laws.

8. Contracting/Subcontracting Issues (§ 422.502(i))

The requirements found at § 422.502(i)(3) pertaining to M+C contracting requirements with providers, suppliers, and administrative service entities were developed pursuant to our authority under section 1856(b)(1) of the Act to ''establish'' M+C ''standards.'' We developed these rules in recognition of the fact that managed care organizations commonly enter business relationships with entities that they place under contract to perform certain functions that would otherwise be the responsibility of the M+C organization. Section 422.502(i)(3) establishes these requirements in three broad categories: enrollee protection provisions, accountability provisions, and a provision that assures that services performed by other entities are carried out in a manner that complies with the M+C organization's contractual obligations to us. We received three comments concerning the subcontracting issues addressed in § 422.502(i)(3).

Comment: Two commenters believe that HCFA should provide additional guidance on its contracting/subcontracting requirements; they suggested that HCFA apply a flexible standard in holding M+C organizations accountable for meeting these requirements in a timely manner. A third commenter wanted to know if our subcontracting guidance would compel entities with whom M+C organizations contract to comply with HCFA's Y2K systems compliance requirements.

Response: We are cognizant of the importance of providing detailed contracting guidance to M+C organizations, and to individuals and entities that might choose to contract with them. We have issued significant guidance in the past and intend to continue doing so as needed in the future. For example, in OPL 98.077 we addressed two major issues. First, we clarified the contracting requirements that affect M+C organizations, applicant organizations, contractors, and subcontractors. Second, we addressed implementation guidance for organizations that wished to begin operation as an M+C-contracting organization. We believe that this OPL sufficiently addresses concerns raised by the managed care industry concerning the need for a higher degree of specificity regarding contracting and subcontracting requirements. We likewise believe that OPL 98.077 established flexible implementation standards in recognition of the labor-intensive nature inherent in activities aimed at amending or otherwise establishing contracts and subcontracts that follow the standards specified in the M+C regulations and elsewhere in OPL 98.077. Commenters and other interested parties may access OPL 98.077 on the Internet at http://www.hcfa.gov.

Regarding the question on Y2K requirements, this issue is moot, since all contracting M+C organizations appear to have succeeded in avoiding related problems. We would note, however, that to the extent an M+C organization provided services through subcontractors, it was responsible for ensuring the Y2K compliance of those subcontractors to the extent necessary to ensure overall Y2K compliance.

Comment: Some commenters expressed confusion regarding use of the terms ''related entities, contractors, and subcontractors'' in § 422.502(i)(1), and the applicability of these terms. Some have pointed out that although the term ''related entity'' is defined at § 422.500, the terms ''contractor'' and ''subcontractor'' are not defined.

Response: In response to the confusion suggested by this comment, we now recognize that the terms ''contractor'' and ''subcontractor'' are somewhat amorphous, and could mean different things to different parties. For instance, a contract between an M+C organization and members of an IPA might be considered a ''contract'' by one party and a ''subcontract'' by another party. Likewise, organizations or individuals might sometimes call a contract between the IPA and its member physicians a ''subcontract,'' while in other instances call it a ''provider participation agreement.'' We have consulted with the managed care industry about terms that may be universally recognized, and have also considered developing new terminology with clear definitions.

As a result, and in response to the comment, we have added two terms—''first tier'' and ''downstream''—to the list of definitions at § 422.500. We believe these definitions will clarify the types of entities to which the M+C contracting requirements described at § 422.502(i) apply. We began using the terms ''first tier'' and ''downstream'' in OPL 98.077, and believe that both terms satisfactorily enhance the description of entities or individuals that are the intended audience for satisfying the requirements found at § 422.502(i).

9. Certification of Data That Determine Payment/Certification of the Accuracy of ACR Information (§ 422.502(l))

Under § 422.502(l), M+C organizations must certify to the accuracy, completeness, and truthfulness of the data used to calculate payments to the organizations. These data include enrollment information, encounter data, and the information included in an M+C organization's ACR proposal. In the preamble to the interim final rule, we noted that in submitting these data, M+C organizations are making a ''claim'' for payment from HCFA, since this information directly affects the calculation of payment rates and amounts. We stated that the certifications would help ensure accurate data submissions and assist us in maintaining the integrity of the Medicare program.

Comment: Several commenters suggested that the certification requirement should include a ''good faith'' standard. Given the significance of the penalties that HCFA, OIG, and the Department of Justice (DoJ) may potentially impose in the case of a ''false claim,'' and the complexity of the data required, these commenters believe that it would be unfair and unrealistic to hold M+C organizations to a ''100 percent accuracy'' certification standard.

Response: We first addressed this issue during the drafting of the 1999 M+C coordinated care plan contract. In developing the certification forms M+C organizations would use to meet the payment data certification requirement, we consulted with OIG and DoJ in drafting language that requires the M+C organization to certify the accuracy, completeness, and truthfulness of this data based on ''best knowledge, information, and belief.'' This language was included in the 1999 contract forms in recognition of the fact that M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce.

In presentations to industry, HHS representatives have emphasized that simple mistakes will not result in sanctions. Generally, the Federal government can bring an action only when one of three states of mind exists: (1) Actual knowledge of falsity of a claim or information; (2) reckless disregard; or (3) deliberate ignorance of information supporting the truth or falsity of a claim or other information (42 CFR 1003.101). However, no specific intent to defraud is required. The ''best knowledge, information, and belief'' standard of the M+C contract certification forms is consistent with these standards.

It is appropriate that the M+C regulations be consistent with the standard of knowledge reflected in Federal fraud statutes. Therefore, we are modifying § 422.502(l) as needed to reflect the ''best knowledge, information, and belief'' certification standard.

Comment: Several commenters suggested that the signatory authority for payment certifications should not be limited to the chief executive officer (CEO) and chief financial officer (CFO) of an M+C organization. The commenters noted that as a practical matter, it is difficult to obtain a CEO or CFO signature on a monthly basis, given the workload and travel obligations of these officers. Therefore, the regulations should permit a CEO or CFO to designate another individual in the M+C organization to sign the certifications.

Response: We agree that the CEO/CFO signature requirement can create operational difficulties for M+C organizations in their efforts to comply with the payment certification requirements of § 422.502(l). However, we believe that it is important that certifications be made by a high level individual who has authority to obligate the M+C organization, or someone who has been delegated the authority of such an individual. Therefore, we are modifying § 422.502(l) to require the ''CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such an officer,'' to certify the M+C organization's enrollment data, encounter data, and ACR proposal information.

Comment: A commenter contended that M+C organizations should not be required to certify the accuracy of the encounter data they receive from third parties. Rather, this commenter believes that organizations should be required to certify only that they have not altered the data, and that they have transmitted it to HCFA as they received it from the provider. The commenter asserted that M+C organizations do not control the operations of those providing encounter data, and that the volume of data is such that no M+C organization has the resources to verify the accuracy of these submissions.

Response: Under the M+C program, encounter data will be used as a factor in calculating payments to M+C organizations. Therefore, encounter data submissions, like enrollment data and ACR information, represent a ''claim'' for payment. As such, M+C organizations have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data.

We acknowledge that encounter data come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake ''due diligence'' to ensure the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a ''best knowledge, information, and belief'' standard. Therefore, M+C organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.

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

Section 1857(c)(3) of the Act provides that the effective date of an M+C contract is to be specified in the M+C contract, and section 1857(c)(1) requires that contracts be for a term of at least one year. The Secretary was provided the discretion under section 1857(c)(1) to provide for contracts to be ''automatically'' renewable in the absence of notice.

Section 1857(c)(2) of the Act authorizes us to terminate an M+C contract if we determine that an M+C organization substantially fails to carry out its M+C contract, carries out the contract in a manner that is inconsistent with the effective and efficient administration of the M+C program, or fails to continue to meet the M+C requirements.

Section 422.504 of the June 1998 interim final rule implements section 1857(c)(1) and (3) of the Act. Section 422.504(b) provides that contracts generally are for a 12-month period beginning January 1 and ending December 31. Section 422.504(d) provides for a limited exception to this rule, permitting HCFA the discretion, prior to January 1, 2002, to approve a contract for longer than 12 months beginning on a date other than January 1. This decision permits us to accept M+C applications on a continuous ''flow'' basis until the beginning of the lock-in periods contemplated under the BBA starting in 2002. We received one comment pertaining to the effective date and term of the M+C contract.

Comment: A commenter expressed concerns regarding the effect of open enrollment requirements on our requirements governing the effective date and term of M+C contracts. In particular, the commenter had concerns about the elimination of the right to disenroll (and enroll) in an M+C plan at any time. The commenter believes that this shift in enrollment policy contributed to our decision no longer to approve contract applications on a continuous ''flow'' basis after 2002, since most Medicare beneficiaries, (excluding newly eligible beneficiaries and those beneficiaries eligible to make an election based upon a special enrollment period), would not otherwise be able to enroll in the new M+C organization until the beginning of the next annual open enrollment period. The commenter suggested that M+C organizations retain the ability to enroll Medicare beneficiaries on an ongoing basis without regard to the annual lock-in periods contemplated by the BBA at section 1851(e).

Response: This comment raises two related issues. The first pertains to enrollment and disenrollment policies, and the second pertains to HCFA's rationale for considering a policy that would establish a cutoff date for making contracts effective on a date other than January 1. We believe the statute clearly indicates that continuous open enrollment and disenrollment may continue only through the end of 2001. Currently, M+C organizations are only required to be open for enrollment in November of each year, to newly Medicare-eligible individuals, and during specified ''special election periods.'' (See § 422.60(a).) Thus, it is not necessarily the case even now that there is ''continuous'' open enrollment, though the right to disenroll exists all year. During the first 6 months of the transition year of 2000, a beneficiary will be able to disenroll without cause, and enroll in any M+C plan open for enrollment, with a limit of one change in enrollment status during this period. This same situation will apply to the first 3 months of every year after 2002, with a limit of one change in elections during this 3-month period. Other than this, beneficiaries will only be permitted to enroll or disenroll during the annual November open enrollment period, a special election period, or upon first becoming eligible for Medicare (with the exception of institutionalized individuals, consistent with section 501 of the BBRA). These enrollment limitations will, in effect, limit the number of Medicare beneficiaries that an M+C organization can enroll mid-year. Yet, after considering the comments, we do not believe that the enrollment policies pursuant to the BBA necessarily preclude us from entering into contracts on dates other than January 1 beginning 2002. While we recognize the inherent enrollment limitations for M+C organizations that will result from a mid-year enrollment eligibility pool that will be comprised largely of individuals that become newly eligible for Medicare, we nevertheless believe that enrollment and the term of an M+C contract are distinct issues that can be considered independent of each other. Regarding the term of an M+C contract, we further believe that the statute permits us to continue to approve mid-year contracts post-2002. Since section 1857(c)(1) requires that contracts be for a term of at least one year, HCFA may continue to enter contracts that may begin on dates other than January 1 for terms longer than 12 months. We have modified § 422.504 to reflect this policy.

11. Nonrenewal of M+C Contracts (§ 422.506)

Section 422.506 specifies the process that M+C organizations and HCFA must use should HCFA decide not to renew the organization's contract, or should the organization give HCFA notice that it does not want its contract to be renewed. We received four comments addressing our M+C contract renewal policy.

Comment: Some commenters believe that requiring M+C organizations to notify HCFA of their intent to nonrenew their M+C contract(s) by May 1 does not provide enough time for organizations to conduct the requisite analysis necessary to decide whether the organization should remain in the M+C program.

Response: We agree with the commenter that the May 1 deadline does not provide organizations enough time to decide whether to remain in the M+C program. We recognize that the May 1 deadline affords organizations only 60 days from the date such organizations received the upcoming year's M+C payment rates to make business decisions affecting their participation in the M+C program. Congress recently recognized this problem when it amended section 1854(a)(1) of the Act to change the deadline for submitting an ACR from May 1 to July 1. (See section 516 of the BBRA and section I.C of this preamble.) In light of the commenter's concern, and the change in the ACR deadline enacted by Congress, we are revising § 422.506(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year. An M+C organization that does not signify its intent not to renew its M+C contract by July 1, and that has not otherwise been notified by HCFA of our intent not to renew the M+C organization's contract by May 1, will be obligated to contract for the upcoming contract year.

Comment: One commenter questioned our authority under § 422.506(b)(ii) to decide not to renew M+C contracts based on our assessment that an M+C organization's level of enrollment or growth in enrollment threatens the viability of the organization under the M+C program. This commenter likewise questioned the authority under which we could decide not to renew a contract based upon our assessment that lack of enrollment could be viewed as an implied measure of dissatisfaction with a particular M+C organization.

Response: We believe that HCFA should be a prudent purchaser of health care services on behalf of Medicare beneficiaries. This entails a fiduciary responsibility to Medicare beneficiaries and tax payers to maintain contracts with organizations that display a sustained and ongoing commitment toward meeting the highest quality standards, and that offer a product attractive enough to attract Medicare beneficiaries to enroll. In promulgating § 422.506(b)(1)(ii), we determined that it might not be worth the costs associated with contracting with an M+C organization if that organization fails to attract or keep at least some level of Medicare enrollment.

However, in response to the commenter's concern, we have determined that the standard outlined at § 422.506(b)(1)(ii) for declining to renew an M+C contract may be too vague to enforce; therefore, we are deleting § 422.506(b)(1)(ii).

12. Provider Prior Notification and Disclosure (§§ 422.506(a), 422.508, 422.510(b), and 422.512)

We address M+C contract determinations in several sections throughout subparts K and N of the M+C regulations. As noted above, § 422.506 contains provisions governing our decisions and M+C organization decisions concerning whether to renew an M+C contract. Section 422.508 specifies that HCFA and an M+C organization may together elect, upon mutual consent, to modify an M+C contract. Sections 422.510 and 422.512 describe M+C contract termination procedures when initiated by either HCFA or an M+C organization. When M+C contract determinations occur, either the organization initiating the determination, or the organization impacted by the determination, must meet certain notification requirements described in §§ 422.506, 422.508, 422.510, and 422.512. The notice requirements compel either HCFA or the M+C organization to notify: (1) The party affected by the contract determination (for example, if HCFA elects to terminate a contract, HCFA must notify the M+C organization of our determination); (2) the Medicare beneficiaries from the affected M+C organization's M+C plans; and (3) the general public.

Comment: Several commenters suggested that we consider developing a requirement that would compel HCFA and/or an M+C organization to notify providers affected by M+C contract determinations about the contract determination, regardless of which party initiates the contract determination action. The commenters contended that the notice is necessary to grant providers sufficient time to react to contract determinations that may adversely affect them. (A related section of regulations that the commenters did not reference, but would logically be affected by the recommendations of the commenters, is § 422.641 of subpart N.)

Response: We believe there are several reasons why separate provider disclosure and notification is unnecessary. First, we do not believe that notifying an M+C organization's network providers of an M+C contract determination is feasible for HCFA, since we do not routinely maintain this information at a level of specificity that would be necessary to provide such notice. Further, we do not believe that it is necessary to require M+C organizations to provide such notice, since we believe that they would necessarily have to notify affected providers that their contracts were being nonrenewed.

In any event, since M+C organizations and/or HCFA are already required to disclose specified information to the general public, a subset of which are the M+C organization's providers, pursuant to an M+C contract determination, we believe that any additional notification requirements may be duplicative and unnecessary.

13. Mutual Termination of a Contract (§ 422.508)

Section 422.508 provides that M+C organizations and HCFA may mutually agree to modify or terminate an M+C contract. When a contract is terminated by mutual consent, M+C organizations must provide notice to affected Medicare enrollees and the general public. If the contract terminated by mutual consent is replaced on the following day by a new M+C contract, the notice requirements do not apply.

Comment: One commenter expressed concerns that our policy, as outlined at § 422.508, does not provide enough beneficiary protection, and may potentially compromise beneficiary continuity of care. Further, the commenter recommended that mutual contract termination should automatically trigger a special enrollment period for affected Medicare beneficiaries, as outlined at § 422.62(b).

Response: We believe that § 422.508 provides Medicare beneficiaries affected by mutual consent contract termination with the protections necessary for affected beneficiaries to choose new Medicare health service delivery options. In particular, the requirement that M+C organizations provide Medicare beneficiaries and the general public with a notice of termination to conform to the 60-day notice requirement in §§ 422.512(b)(2) and (3) should enable affected Medicare beneficiaries to arrange for alternative health care coverage, such as returning to original Medicare, or choosing a different M+C plan before the effective date of termination.

We agree with the commenter that a termination (and not modification) of an M+C contract by mutual consent should trigger a special election period as described at § 422.62(b), and we believe that the existing language at § 422.62(b)(1) supports this position. In stating ''HCFA has terminated * * * or the organization has terminated * * * the [M+C] plan in the service area or continuation area in which the [Medicare eligible] individual resides * * *,'' we believe that termination of a contract by mutual consent of the two aforementioned parties is consistent with the intent of the provision at § 422.62(b)(1). Thus, we believe that any change to the regulation language at § 422.508 or § 422.62(b)(1) is unnecessary.

14. Termination of Contract by HCFA (§ 422.510)

Section 422.510 implements the provisions in section 1857(c)(2) of the Act pertaining to our authority to terminate an M+C organization's contract if we determine that the organization: (1) Fails to substantially carry out the contract; (2) is carrying out the contract in a manner inconsistent with the efficient and effective administration of Medicare Part C; and/or (3) no longer substantially meets the applicable conditions of Part C. In § 422.510(a), we set forth the above standards, as well as several specific circumstances that we believe constitute a substantial failure to carry out the contract, justifying termination. The procedures under which we would take action to terminate an M+C contract are described in section 1857(h) of the Act. In general, we may terminate an M+C contract after: (1) We provide the M+C organization with an opportunity to correct identified deficiencies; and (2) we provide the organization with notice and opportunity for a hearing, including the right to an appeal of an initial decision.

We received three comments on § 422.510. One commenter requested further explanation regarding the termination process, for which we refer the commenter to subpart N of the regulations. The other comments are addressed below.

Comment: Two commenters requested that we define what we mean by the term ''substantially fails to comply,'' as used throughout § 422.510(a).

Response: In the June 1998 interim final rule, and at § 422.510(a)(4) through (11), we identify circumstances that we believe constitute examples of what the statute identifies as substantially failing to carry out an M+C contract. They are: the M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program; the M+C organization substantially fails to comply with requirements in subpart M relating to grievances and appeals; the M+C organization fails to provide us with valid encounter data as required under § 422.257; the M+C organization fails to

implement an acceptable quality assessment and performance improvement program as required under subpart D; the M+C organization substantially fails to comply with the prompt payment requirements in § 422.520; the M+C organization substantially fails to comply with the service access requirements in §§ 422.112 or 422.114; or the M+C organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

We have longstanding compliance standards for Medicare managed care contractors. In addition to those set forth in the statute and regulations, compliance standards are set forth in our Medicare Managed Care Performance and Monitoring protocol. We use this document when conducting performance/monitoring evaluations of contracting Medicare managed care organizations, including M+C organizations. Pursuant to these reviews, each contracting organization must demonstrate that it again complies with all applicable statutory, regulatory and contract requirements that apply to M+C organizations. These reviews result in findings as to whether a failure to comply with requirements constitutes a ''substantial failure'' for purposes of § 422.510(a). In determining whether a failure is ''substantial,'' we consider both the frequency and the seriousness of the noncompliance. In the case of a serious violation that could put the health of an enrollee at risk, even a single violation might be considered substantial. In the case of a less serious violation, the noncompliance would have to be more pervasive or systematic in order to be considered substantial.

Comment: Some comments reflected confusion regarding § 422.510(c), and its reference to subpart N of part 422. Section 422.510(c) indicates that if we make a determination to terminate an M+C contract, we must first allow the affected M+C organization the opportunity to submit a corrective action plan in accordance with ''time frames specified at subpart N'' of part 422. The commenter noted that subpart N does not contain any time frames that apply specifically to activities related to corrective actions.

Response: We agree that subpart N does not contain time frames that appear applicable to an opportunity to take corrective action, and that this reference is an error. We accordingly are deleting this reference from § 422.510(c).

15. Minimum Enrollment Requirements (§ 422.514)

Section 1857(b) of the Act specifies that we may not enter into a contract with an M+C organization unless the organization has at least 5,000 enrollees (or 1,500 if it is a PSO), or at least 1,500 enrollees (or 500 if it is a PSO) if the organization primarily serves individuals residing outside of urbanized areas. Section 1857(b)(3) creates a transition standard for meeting this requirement by allowing us to waive the minimum enrollment requirement during the M+C organization's first 3 years.

Comment: A commenter asked if we would consider a permanent minimum enrollment waiver for ''smaller scale service models.''

Response: A review of both the statute at section 1857(b) of the Act and the Conference Committee report indicates that the Congress intended for the minimum enrollment waiver to apply only during the first 3 contract years for any organizations. The minimum enrollment thresholds themselves are necessary to enable organizations to adequately spread risk across enrolled populations.

16. Reporting requirements (§ 422.516)

The M+C regulations contain various provisions that specify information disclosure requirements. The requirements address both information to be provided by M+C organizations to HCFA (see §§ 422.64, 422.502, and 422.512), by M+C organizations to beneficiaries (see §§ 422.80 and 422.111), and by HCFA to beneficiaries (under existing § 422.64). Section 422.516 specifies requirements that M+C organizations must meet regarding disclosure of statistics and information to HCFA, M+C enrollees, and the general public.

Comment: A commenter requested that we expand the reporting requirements specified at section § 422.516 to require M+C organizations to report the statistics and other information specified in § 422.516 *et seq.* directly to the organization's network health care providers.

Response: The commenter seeks to carve-out a separate category of individuals, providers, to receive statistics and other information that M+C organizations are already obligated to disclose to HCFA, to M+C plan enrollees, and to the general public. We believe that it is unnecessary for M+C organizations to report statistics and other information separately to providers. Since M+C organizations (or HCFA) are already required to disclose specified information to the general public, (a subset of which is the M+C providers), any additional requirement to disclose information separately to an organization's providers is duplicative and unnecessary. Moreover, we are concerned about the administrative burden that such a requirement could impose upon M+C organizations, which may contract with thousands of providers. Further, we suspect that many organizations already voluntarily furnish providers with much of the information required under § 422.516, such as information on health plan benefits, premiums, quality and performance measurements, and utilization control mechanisms.

17. Prompt Payment by M+C Organization (§ 422.520(a))

Section 422.520 indicates that contracts between M+C organizations and HCFA must specify that the M+C organization agrees to provide prompt payment of claims that have been submitted by providers for services and supplies furnished to Medicare enrollees when these services and supplies are not furnished by an organization-contracted provider. Specifically, 95 percent of ''clean claims'' must be paid within 30 days of receipt. While this provision closely follows requirements already in place for section 1876 contractors, (including provisions pertaining to interest to be paid if timely payment is not made), section 1857(f) of the Act extends similar prompt payment requirements to claims submitted by Medicare beneficiaries enrolled in M+C private fee-for-service plans. Section 422.520(a) incorporates this requirement of new section 1857(f), as well as the general 30-day requirement that applied to noncontracting providers under section 1876. In the preamble to the June 1998 interim final rule, we indicated that pursuant to our authority under section 1856(b)(1) to establish standards under Part C, M+C organizations would be required to act upon (either approve or deny, not necessarily pay) all claims not subject to the 30-day standard within 60 calendar days from the date of request.

Comment: Commenters noted that the ''approve or deny'' language in § 422.520(a)(3) was inconsistent with rules regarding M+C organization determinations and reconsiderations as described in subpart M. Also, it has been brought to our attention that the requirement that ''non-clean'' claims (and up to 5 percent of clean claims) be ''approved or denied,'' but not necessarily paid, within 60 calendar days from the date of the request for payment, is inconsistent with the

standard that applied to contractors under section 1876 of the Act. Under the Medicare risk program, HCFA traditionally required that HMOs or CMPs with Medicare risk contracts *pay* or deny non-clean claims within 60 calendar days from the date of the request for payment. The ''approve or deny'' language may permit gaps of time between when an organization approved a claim for payment and when the organization actually paid a claim.

Response: After further review of this issue, we agree that M+C organizations should be required to either pay or deny non-clean claims (and clean claims not subject to the 30-day standard) within 60 calendar days from the date of the payment request. This standard removes the possible ambiguity associated with ''approving'', but not necessarily paying, a claim for payment, and any related ambiguities pertaining to M+C organization determination and reconsideration policies articulated in subpart M of this final rule. Thus, we are revising § 422.520(a)(3) to indicate that claims for services that are not furnished under a written agreement between M+C organization and its network providers, and that are not paid within 30 days, must be either paid or denied within 60 calendar days from the date of the request.

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

The provisions set forth in subpart L of part 422 by the June 1998 interim final rule merely constituted a redesignation of the provisions in part 417 on change of ownership or leasing of facilities. However, since the June 1998 interim final rule was published, it has come to our attention that M+C organizations have serious concerns about language in the italicized title to § 422.550(a)(2) which has been construed to present an impediment to an asset sale by one corporation to another. Section 422.550(a) sets forth what constitutes a ''change of ownership'' for purposes of provisions in § 422.552 which permit an M+C contract to be transferred to a new owner under certain circumstances (for example, the new owner must meet the requirements to qualify as an M+C organization). Because this italicized title refers to an ''unincorporated sole proprietor,'' it suggests that a ''[t]ransfer of title and property to another party'' does not constitute a change of ownership if the assets are transferred by a corporation, rather than a sole proprietor. This has presented problems in cases in which transactions that would benefit Medicare beneficiaries by keeping a M+C plan option available do not appear to fall within the definition of change of ownership. If an M+C contract accordingly could not be transferred as part of an asset sale, this could prevent the sale from going forward, or limit the sale to commercial or Medicaid lines of business, in either case, potentially depriving Medicare beneficiaries of an M+C plan option they would otherwise have.

The italicized language in question was adopted from rules in section 1876 of the Act, which in turn were adopted from longstanding original fee-for-service Medicare change of ownership regulations containing identical language (see § 489.18(a)). These original Medicare change of ownership regulations apply to a change of ownership in the case of a Medicare provider, and address the assumption of a Medicare provider agreement, rather than an M+C contract. However, the language in § 489.18(a)(2) is identical to that in § 422.550(a)(2). In the original Medicare context, this language has consistently been interpreted to encompass an asset sale from one corporation to another. This interpretation was applied by the U.S. Court of Appeals for the Fifth Circuit in *U.S.* v. *Vernon Home Health Care Inc.,* 21 F.3d 693 (5th Cir.), *cert. denied,* 115 S. Ct. 575 (1994). While we have determined that the current M+C change of ownership regulation containing identical language should similarly be interpreted to encompass an asset sale by a corporation, we believe that it would be helpful to eliminate the reference in the title of § 422.550(a)(2) to a ''sole proprietorship'' in order to avoid confusion. We therefore are changing this title in this final rule to read ''Asset sale.''

M. Grievances, Organization Determinations, and Appeals (Subpart M)

1. Background and General Provisions (§§ 422.560 through 422.562)

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

For the grievance, organization determination, and appeal requirements, an M+C organization must establish procedures that satisfy these requirements with respect to each M+C plan that it offers. These requirements generally are the same for each type of M+C plan—including M+C non-network MSA plans and M+C PFFS plans. (Please refer to the preamble material on M+C appeals and grievances in the June 26, 1998 interim final rule (63 FR 35021) for a detailed discussion of the specific requirements under Subpart M.)

Additional regulatory improvements to the M+C appeal and grievance processes are currently under development. We included in the M+C interim final rule those improvements that were practical within the short time frame allotted for completing that interim final rule. As we indicated in the preamble to the M+C interim final rule (63 FR 35030), we intend in the near future to publish a proposed rule implementing a variety of other improvements to the M+C dispute resolution process, including both appeals and grievances.

Sections 422.560 and 422.561 contain the basis and scope and the relevant definitions for subpart M. Section 422.562, General Provisions, provides an overview of the rights and responsibilities of M+C organizations and M+C enrollees with respect to grievances, organization determinations, and appeals. The responsibilities of M+C organizations, under § 422.562(a), essentially parallel those applicable to

HMOs under § 417.604(a), with the added provision that, if an M+C organization delegates any of its responsibilities under subpart M to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the applicable grievance and appeal requirements are still met.

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

Like the part 417 regulations, § 422.562(b) contains provisions addressing the applicability of other regulations that implement Social Security appeals procedures under title II of the Act.

2. Grievance Procedures (§ 422.564)

Section 1852(f) of the Act requires that each M+C organization provide ''meaningful procedures for hearing and resolving grievances.'' We have defined this term in § 422.561 as any complaint or dispute other than one that involves an ''organization determination'' (as described under § 422.566(b)). (This definition retains the meaning of grievance used in part 417.) An enrollee might file a grievance if, for example, the enrollee received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, as specified under §§ 422.570(d)(2)(ii) and 422.584(d)(2)(ii), grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to grant an enrollee's request to expedite an organization determination or a reconsideration.

Under § 422.564(a), an M+C organization must resolve grievances in a timely manner using procedures that comply with any guidelines which we establish. Section 422.564(c) clarifies that the PRO complaint process under section 1154(a)(14) of the Act addresses quality issues, but is separate and distinct from the M+C organization's grievance procedures. Thus, there are three different complaint processes (grievance, appeals and PRO processes) available to an enrollee in an M+C organization.

3. Organization Determinations (§§ 422.566 through 422.576)

Section 1852(g) of the Act requires an M+C organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations. In accordance with section 1852(g)(1) of the Act, § 422.566 specifies that an M+C organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. Also, an M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization is an action that constitutes an organization determination. Disputes involving additional benefits, as well as mandatory and optional supplemental benefits, also constitute organization determinations and are subject to the appeals process.

Section 422.566(b) lists actions that are organization determinations, and with two exceptions, follows the previous HMO regulation at § 417.606(a). The exceptions involve the inclusion as organization determinations of decisions involving—(1) optional supplemental benefits, and (2) payment for post-stabilization services.

Section 422.568 includes the standard time frame and notice requirements for organization determinations. Under § 422.568(a), an M+C organization must make a determination with respect to an enrollee's request for service as expeditiously as the enrollee's health status requires, and in no case later than 14 calendar days after the organization receives the request. An M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee; (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must include a written justification for the extension in the case file.

Section 422.568(b) specifies that time frames for requests for organization determinations on payment issues are identical to the ''prompt payment'' requirements set forth under § 422.520. Thus, for issues relating to payment, the requirements are as follows: (1) For ''clean claims,'' an M+C organization must make a determination regarding the claim within our current ''clean claim'' rules, that is, 95 percent of clean claims must be paid within 30 calendar days after receipt of the request for payment; (2) for all other claims, an M+C organization must make a determination regarding the claim within 60 calendar days after receipt of the request for payment. (Under existing § 422.500, ''clean claims'' are claims that have no defect, impropriety, lack of any required substantiating documentation, or particular circumstances requiring special treatment that prevents timely payment. See section II.K of this preamble for a further discussion of rules regarding clean claims and prompt payment.)

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

Sections 422.570 and 422.572 set forth the requirements for M+C organizations with respect to expedited determinations. Sections 422.570(a) (for expedited organization determinations) and 422.584(a) (for expedited reconsiderations) allow either an enrollee or a physician to request an expedited organization determination or reconsideration, regardless of whether the physician is affiliated with the M+C organization. Under § 422.570(a), any physician can request an expedited organization determination. Section 422.584(a) provides that a physician who requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

Section 422.570(b)(2) specifies that a physician may provide written or oral support for a request for expedition, and under § 422.570(c)(2)(ii), requests for expedited organization determinations that are made or supported by a physician must be granted by the M+C organization if the physician indicates that the enrollee's health could be jeopardized.

Under § 422.568(d)(1), an M+C organization must automatically transfer a denied request for an expedited organization determination to the standard 14-day time frame described in § 422.568(a), and § 422.570(d)(2)(ii) requires an M+C organization to inform the enrollee of the right to file a grievance if he or she disagrees with the

M+C organization's decision not to expedite. We also require under § 422.570(c)(1) that an organization establish an efficient and convenient means for individuals to submit oral or written requests for expedited organization determinations and document any oral requests. We clarify under § 422.570(b)(1) that procedures may involve submitting a request to another entity responsible for making the determination, as ''directed by the M+C organization.''

Section 422.572(a) requires an M+C organization to notify the enrollee (and the physician involved, as appropriate) of an expedited determination as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. Under § 422.572(b), an M+C organization may extend the 72-hour deadline for expedited review by up to 14 calendar days if the enrollee requests the extension or if the organization finds that additional information is needed and the delay is in the interest of the enrollee. Also under this section, an M+C organization must notify an enrollee of a determination as expeditiously as the enrollee's health care needs require but no later than upon expiration of the extension.

Provisions in both §§ 422.570(f) and 422.584(f) prohibit an M+C organization from taking or threatening to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited organization determination or reconsideration.

Section 422.574 identifies the parties to an organization determination, which include the enrollee, certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and any other entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

4. Reconsiderations by an M+C Organization or an Independent Review Entity (§§ 422.578 through 422.616)

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

Section 422.590(a)(1) requires that, with respect to standard reconsiderations concerning requests for service, an M+C organization must issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the request for reconsideration. As with organization determinations, § 422.590(a) also provides that the M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information, and how the delay is in the interest of the enrollee. Under § 422.590(b)(1), for standard reconsiderations involving requests for payment, the M+C organization must issue any fully favorable determination no later than 60 calendar days from the date it receives the request for the reconsideration.

In the case of expedited reconsiderations (which involve only requests for services), § 422.590(d)(1) requires that an M+C organization issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 72 hours after it receives the request for expedited reconsideration, again with the possibility of a 14-day extension as described in § 422.590(d)(2). If, however, the M+C organization's reconsideration results in an affirmation, in whole or in part, of its original adverse organization determination, this decision is automatically subject to further review by an independent entity contracted by us. (Again, the time frame within which an M+C organization must reconsider a standard or expedited case has been tied to the enrollee's health needs for service requests, subject to either a 30-day or 72-hour maximum (with a possible 14-day extension), while the time frame remains at 60 days for reconsideration requests involving payment.)

Section 1852(g)(4) of the Act requires us to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm, in whole or in part, an M+C organization's denial of coverage. Thus, unless an M+C organization completely reverses its coverage denial, it must prepare a written explanation, and refer the case to the independent review entity for a new and impartial determination concerning the payment or service at issue.

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

Section 422.590(g)(2) requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by a physician with expertise in the field of medicine that is appropriate for the services at issue.

For the most part, the procedures outlined above were carried over into the M+C requirements from the existing part 417 standards. We also implemented several changes in the reconsideration requirements that are analogous to those described for organization determinations, such as the requirement under § 422.584(d)(1) that an M+C organization automatically transfer a denied request for an expedited reconsideration to the standard 30-day time frame described in § 422.590(a). In addition, § 422.590(e) requires that if an M+C organization refers a case to the independent entity, it must concurrently notify the enrollee of that action.

Consistent with section 1852(g)(4) of the Act, §§ 422.592 and 422.594 address reconsiderations by an independent entity. If the independent review entity's reconsidered determination is not fully favorable to the enrollee, subsequent review possibilities include ALJ and Departmental Appeals Board (DAB) hearings, as well as judicial review. Provisions addressing these forms of review are set forth in §§ 422.600 through 422.616.

5. Effectuation of a Reconsidered Determination (§ 422.618)

Section 422.618 established effectuation requirements for payments

and services. For reconsiderations of requests for payment, when an M+C organization reverses its adverse organization determination, it must pay for the service no later than 60 calendar days after the date that the M+C organization receives the request for reconsideration. For reconsiderations of requests for service, when an M+C organization reverses its adverse organization determination, it must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the M+C organization receives the request for reconsideration, or no later than upon expiration of a 14 calendar day extension. When the M+C organization is reversed by the independent review entity or higher review level, the M+C organization must pay for, authorize, or provide the service as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date the M+C organization receives notice reversing its organization determination.

6. Notification of Noncoverage in Inpatient Hospital Settings (§§ 422.620 and 422.622)

Sections 422.620 and 422.622 pertain to M+C organizations' responsibilities in connection with inpatient hospital care. The existing provisions clarify that inpatient services continue to be covered only until written notice of noncoverage in situations in which the hospital admission was authorized in the first instance by the M+C organization, or in which the admission constituted urgent or emergent care. This notice now is issued to enrollees by the M+C organization, either directly or through the hospital, with the concurrence of the attending physician responsible for the enrollee's hospital care. Section 422.622 provides enrollees with the right to seek PRO review by noon on the day after the receipt of the notice if the enrollee believes that he or she is being discharged too soon. The enrollee bears no additional financial liability for care furnished during the period of PRO review, regardless of the proposed date of discharge. If the enrollee misses the noon deadline for requesting PRO review, the enrollee may file an expedited appeal with the M+C organization. Unlike the PRO review process, there is no financial protection afforded to the beneficiary while the M+C organization conducts its review.

Subpart M Comments and Responses

7. Definitions and General Provisions

Comment: One commenter suggested that the definition of appeal should read as follows: ''Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care or health care services an enrollee is entitled to receive, including delay in providing or approving the health care or health care services. * * *''

Response: We generally agree with the commenter and are revising the definition in § 422.561 to incorporate most of the commenter's suggested language. We are omitting ''health care'' as we believe the language duplicates and is inferred in the meaning of ''health care services.'' We are adding the term ''arranging for'' to the definition. Therefore, we are adopting the following revision to the appeals definition: ''Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.''

8. Grievances (§§ 422.564, 422.570, and 422.584)

Comment: Two commenters contended that we should not establish prescriptive grievance procedures, while several supported establishing standards. One commenter stressed that any grievance requirements we imposed should be consistent with those applied by accrediting organizations, so that M+C organizations would not have to change current procedures to a great extent. The commenter expressed concern about State privacy requirements, as M+C organizations currently are prevented under State law in some cases from providing specific information on how grievances have been resolved. Rather, in these cases, organizations are only allowed under State law to inform enrollees that the complaint has entered the tracking system. One commenter stated that grievance procedures should be flexible, given our interpretation of preemption provisions. One commenter strongly encouraged establishing mandatory time frames for the resolution of grievances as soon as possible, and suggested that the time frames and notices mirror those applicable to organization determinations (including expedited time frames). Two commenters suggested a 30-calendar day time frame to render a grievance decision, with an opportunity for a 14-calendar day extension for peer review. Both commenters stated that for non-quality of care grievances, both oral and written, M+C organizations should be encouraged to provide personalized service. One commenter believes that if a denial of expedited consideration is considered a grievance, then the grievance procedure must have a mechanism to resolve the dispute within 24 hours, so that an inappropriately denied request for expedited consideration can proceed quickly. Additionally, a commenter asserted that M+C organizations should be required to provide clear, accurate and standardized information concerning grievance and appeal procedures. One commenter asked who will determine which route is more appropriate for the beneficiary in pursuing a remedy to a complaint, since we acknowledge that the same claim or circumstances that give rise to an appeal may have elements of a grievance. This may cause the beneficiary to be unclear as to which route is most appropriate.

Response: Currently, M+C organizations are required under section 1852(f) of the Act and § 422.564 to provide ''meaningful procedures'' for hearing and resolving grievances. In the interim final rule (63 FR 35030), we requested comments on whether to establish requirements for grievance procedures, and indicated that we would consider prescribing specific requirements for grievances through a forthcoming notice of proposed rulemaking. As anticipated, commenters indicated varying approaches to organization-level grievance procedures. As noted in the interim final rule, we believe that all parties would benefit from subjecting proposed grievance procedures to public notice and comment, and we will do so as part of the notice of proposed rulemaking we are in the process of developing. Thus, we are not including additional grievance requirements in this final rule.

Comment: One commenter disagreed with treating a denial of an expedited determination as a grievance rather than permitting an appeal of such a denial. The commenter argued that such a denial should be considered an adverse organization determination on the

health care services an enrollee is entitled to receive, and should be appealable. This commenter contended that denying a request for an expedited determination is not analogous to the example of a grievance provided in the preamble to the interim final rule.

Response: The preamble to the interim final rule cites the regulatory definition of a grievance at § 422.561—that is, a grievance is ''any complaint or dispute other than one involving an organization determination.'' The revised definition of organization determination at § 422.566(b) (discussed in detail below) includes determinations regarding payment or services that the enrollee believes should be furnished or arranged for by the M+C organization, and discontinuations of a service if the enrollee believes that the service continues to be medically necessary. In this context, we believe that the term ''services'' clearly refers to health care services, as opposed to member or customer services, that the M+C organization provides under its contract. Expedited review is a process provided by the M+C organization versus a health care service which is subject to appeal, such as mandatory and optional supplemental benefits. We believe there is a clear distinction between a substantive decision whether benefits should be covered and a procedural decision as to the timing of making such a substantive decision. Indeed, we do not believe that the latter type of determination falls within the statutory language establishing the reconsideration and appeals process, which refers to situations in which the enrollee believes he or she is entitled to services, and to the amount of enrollee liability for services. Therefore, we will continue to require that an organization's denial of expedition generally will be subject to the organization's grievance procedures. We intend to monitor the frequency with which M+C organizations deny requests for expedited determinations.

Comment: One commenter believes that a beneficiary should be able to appeal a disenrollment by an M+C organization, rather than simply being able to utilize the grievance process, as provided in § 422.74(d)(2)(ii). In addition, the commenter asserted that decisions on disenrollment should not be left to the M+C organization. Another commenter suggested that we permit a beneficiary to appeal a decision as to whether he or she is entitled to a special enrollment period, and that an M+C organization's decision regarding enrollment or disenrollment, based on the circumstances in § 422.62, should be considered an organization determination subject to appeal.

Response: While we do not believe all disenrollment decisions require an appeals process, we recognize the need in some instances, in particular, when a M+C organization disenrolls an individual for disruptive behavior. Accordingly, in § 422.74(d)(2), M+C organizations must forward all proposed disenrollments for disruptive behavior to HCFA for administrative review. M+C organizations may not disenroll an individual unless HCFA approves of the decision. With respect to the other, limited circumstances under which a M+C organization has the option to disenroll an individual (that is, failure to pay premiums, or fraud), the enrollee has a right to file a grievance if he or she disagrees with an M+C organization's decision. We believe that this approach to these issues has been proven to be sufficient over the years. As indicated above, we will monitor M+C organizations' implementation of their grievance procedures to ensure that they are meaningful. Our monitoring will include investigating a complaint from a beneficiary who believes that the M+C organization did not properly handle a complaint about one of the issues discussed by the commenters above.

9. Organization Determinations (§ 422.566)

Comment: We received numerous comments on various aspects of the definition of an organization determination, including requests for clarification of whether specific types of situations constitute organization determinations. For example, several commenters suggested that reductions in service should be included in the list of actions that constitute organization determinations. The commenters asserted that when services are reduced, beneficiaries receive no notice and are completely unaware of their ability to contest this reduction through the appeals process. Some commenters noted that the vacated 1997 *Grijalva* order expressly required written notice for a reduction of services. One commenter believes that notice of a reduction in services is of particular importance in the delivery of home care and therapy services. Some commenters believe that § 422.566(b)(4), which provides for notice of a termination only if the enrollee disagrees with the determination that the service is no longer medically necessary, is inconsistent with other Medicare regulations, which the commenter believes require written notice for discontinuation of inpatient services both in a hospital or a skilled nursing facility, regardless of whether the beneficiary agrees with the decision. One commenter suggested that the regulations require M+C organizations to send notices one day in advance of termination, reduction, suspension or delay in services. One commenter suggested that § 422.566(b) should include a fifth category indicating that the failure of the M+C organization to approve or provide health care or health care services in a timely manner, or to provide the enrollee with timely notice of an organization determination, constitutes an organization determination. Additionally, some commenters suggested that if, in the future, we require that notices of appeal rights must be given in instances in which the current definition of organization determination is not met, we should incorporate the requirement into the regulations.

Response: As these commenters suggested, we believe there is a need to revise § 422.566(b) to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights. Therefore, we are revising § 422.566(b) as follows:

- Paragraph (b)(1), which concerns payment for out-of-plan services, is revised by adding payment for out-of-area renal dialysis to the existing list of such services (which already included emergency, urgently needed, and post-stabilization services);
- Paragraph (b)(3) includes additional language to clarify that an organization's refusal to pay for or provide services ''in whole or in part, including the type or level of services'' can constitute an organization determination if the enrollee believes they should be furnished or arranged for;
- Paragraph (b)(4) is restructured to indicate that a discontinuation of services when an enrollee believes that the services continue to be medically necessary constitutes an organization determination (thus eliminating any implication that an organization must make a formal determination as to medical necessity to give rise to appeal rights); and
- New paragraph (b)(5) is added to specify that another situation that constitutes an organization determination is an MC organization's failure to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or failure to provide the enrollee with timely notice of a determination, if such a delay would adversely affect the health of the enrollee.

Thus, we agree that a reduction in services can be considered an

organizational determination that is subject to appeal. To the extent that a reduction results in an enrollee no longer receiving services to which the enrollee believes he or she is entitled, this would be subject to appeal under the language in the first sentence in section 1852(g)(5) of the Act, which addresses appeals based on failure to receive a health service. Also, since a reduction in services could constitute a ''[d]iscontinuation'' of services to the extent they were no longer being provided, these cases could fall within the language in § 422.566(b)(4). Finally, to the extent that the organization was refusing to continue to provide all or part of the services the enrollee believes should be furnished, and the enrollee has not received the services, this would also fall within the language in § 422.566(b)(3).

Examples of other situations that are intended to fall within the clarified definition of an organization determination include:

- A physician requests approval of 10 home health visits, but the organization approves only five visits (even though Medicare allows more than five visits);
- An organization approves a referral to a specialist, but the specialist it designates does not have experience in treating the enrollee's rare condition;
- A physician requests inpatient surgery for a patient because of the patient's history of complications with anesthesiology, but the organization will approve only outpatient surgery; or
- Although an organization agrees to pay for an in-network service, it imposes greater cost-sharing than the enrollee believes is permissible.

We believe that each of these examples fit within the statutory language at section 1852(g)(1)(A) and (B) of the Act that establishes that an M+C organization must have an appeals procedure for determinations as to whether an enrollee ''is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service.'' Thus, the purpose of the revisions to § 422.566(b) is not to expand on our interpretation of what types of situations constitute organization determinations but rather to provide additional insight into how we continue to interpret the intent of the applicable statutory provisions.

As we explained above, we are developing a proposed regulation that would provide additional specific guidance as to when a reduction in services gives rise to the obligation to provide a written notice. This has been an extremely difficult issue to resolve, and despite extensive consultations with beneficiary advocates, industry representatives, and State officials, we still have not been able to reach conclusions as to standards beyond those already in the statute and regulations and quoted above. Again, we will address the issue in connection with a separate rulemaking that is being developed in close consultation with all affected groups. Finally, as commenters suggested, if in the future we believe that it is necessary to require notices of appeal or other rights for situations other than organization determinations, we would do so through notice and comment rulemaking.

Comment: Some commenters requested confirmation that a discontinuation on grounds other than medical necessity is not an organization determination.

Response: As noted above, we have made a minor change to § 422.566(b)(4) to clarify that any discontinuation situation in where the enrollee believes that the services continue to be medically necessary constitutes an organization determination, rather than only those situations where a formal medical necessity determination is involved. Moreover, § 422.566(b)(3) continues to cover any refusal to provide services (including a refusal to *continue* to provide services) that the enrollee believes should be provided. While many cases may involve a medical necessity judgment, others may involve a question of how a limit on benefits (including additional or supplemental benefits) applies to given facts. In some cases, the case for noncoverage on grounds other than medical necessity may be so clear-cut that an appeal would not be requested. For example, in a case in which a service is expressly limited to a fixed number of days, and there is no dispute as to how many days the service has been provided, it is unlikely that the enrollee would ''believe'' that the M+C organization is obligated to cover days beyond the limit. In other cases, however, there may be ambiguities as to how a limit on benefits is to be interpreted, or applied to a given set of facts, or there may be a dispute as to facts relevant to whether the benefit is covered. In these cases, the beneficiary should have the right to a reconsideration of a denial, so that these issues could be addressed on appeal.

10. Written Notice (§§ 422.566, 422.568, 422.572, and 422.620)

Comment: Several commenters believe that the regulations at §§ 422.566 and 422.568 do not make clear that a written notice is required for discontinuations of services.

Response: Except in the case of inpatient hospital care, written notice currently is not required for all discontinuations in services. We believe that our policies on what constitutes a denial in the case of a discontinuation of service (other than in the case of inpatient hospital care) are set forth in the regulations concerning organization determinations. According to revised § 422.566(b)(4), discontinuation of a service is considered to constitute an organization determination ''if the enrollee believes that continuation of the services is medically necessary.'' Therefore, if an M+C organization discontinues coverage, and an enrollee indicates that he or she believes that the services continue to be necessary, this action would constitute an organization determination for which a written notice must be provided. We recognize that there may be circumstances that make it difficult to tell whether a written notice is required in a particular case. We therefore are developing a notice of proposed rulemaking that would address this issue, and clarify rules for M+C organizations and beneficiaries.

Comment: Several commenters suggested that written notice should take place in all instances where services are reduced or discontinued, not only in instances where the enrollee has indicated disagreement. One reason provided for this suggestion is that it would ensure that enrollees always would receive notice of their appeal rights, even if they have not formally objected to the reduction or discontinuation. Another reason given was that this would make the rule consistent with the rule that applies to hospital inpatient discharges. Other commenters suggested that M+C organizations should provide written notice when services actually terminate, or when services discontinue prior to the time for which the M+C organization initially authorized services. Two commenters suggested that we require notice when there are financial implications to the enrollee.

Other commenters supported the current requirement that the M+C organization provide notice when the enrollee disagrees that the services are no longer medically necessary. One commenter stated that where there is no disagreement, it is wholly inappropriate to provide notice and appeal rights. Instead, it is more appropriate to provide notice at the beginning of a course of treatment. One commenter recommended that we provide advance notice for reductions and terminations in writing, describing the basis for the decision and appeal rights. Some

commenters stated that providing detailed notice in all situations would be confusing, burdensome, and intrusive upon the physician/patient relationship. Two commenters recommended we include in this subpart notice requirements for discharge from a SNF.

Response: We recognize that the issue of when it is appropriate for M+C organizations to issue written notice for organization determinations that involve reductions and discontinuations of services is a controversial one. As stated in the preamble to the June 26, 1998 interim final rule (63 FR 35030), we are developing proposed regulations that would further clarify these requirements. At this time, however, we believe that the current regulations serve to balance the need for adequate notice with the potential for inappropriate burdens or beneficiary confusion that might ensue if notice were provided in all cases.

To eliminate confusion, we want to point out that written notice is always required for inpatient hospital discharges regardless of whether the enrollee agrees with the discharge decision. The issuance of a notice to an enrollee prior to an inpatient hospital discharge required under § 422.620 is a separate requirement that should not be confused with the provisions at §§ 422.566(b)(4) and 422.568(c). We will address the SNF issue in the forthcoming proposed rule.

Finally, as the commenters suggested, we recognize the potential compliance difficulties and burden associated with existing § 422.568(c), which requires that if an M+C organization denies services or payment, in whole or in part, it must give the enrollee a detailed written notice that meets the content requirements of § 422.568(d) (such as stating the specific reason for the denial and describing the available appeals procedures). We understand that in practice, plan practitioners generally are responsible on behalf of M+C organizations for issuing these detailed notices to their patients, given that most care decisions about future care are made at the practitioner level; and we agree that this practice may be unnecessarily burdensome and intrusive on the practitioner/patient relationship. Moreover, we can understand that requiring M+C organizations to ensure that appropriately detailed notices are given to enrollees in practitioners' offices may be difficult to monitor and enforce in all circumstances.

Therefore, we have revised the provisions at §§ 422.568(c) through (e) to establish a process under which—(1) practitioners routinely notify enrollees at each patient encounter of their right to receive a *detailed* notice about their services from the M+C organization itself, and (2) when an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, the M+C organization must give the enrollee a detailed written notice of the determination, consistent with existing content requirements.

The practitioner's notification must inform enrollees of their right to receive a detailed notice from the M+C organization and provide enrollees with all information necessary in order to contact the M+C organization. Consistent with other notification requirements set forth in subpart M (for example, under existing § 422.568(d)(4) or under § 422.572(e)(2)(ii)), we also specify that the content of the practitioner's notification must comply with any other requirements established by HCFA. We are now developing standardized language for use by affected practitioners, and will provide an opportunity for public comment through OMB's Paperwork Reduction Act process. Once that process is completed, we intend to provide further guidance on the content and form of the required practitioner notice. We believe that this requirement will serve to improve M+C organizations' ability to assure implementation of the requirement for detailed written notices while at the same time reducing the administrative burden on practitioners by freeing them from the obligation to routinely provide such detailed notices to their patients.

11. Time Frames (§§ 422.568, 422.572, 422.590, 422.592, 422.618)

Comment: Several commenters asserted that the standard determination time frames are too long, with some commenters specifically suggesting the time frame of 5 working days that was adopted by a district court judge in a since-vacated March 3, 1997 order in *Grijalva* v. *Shalala* (a class action lawsuit filed by Medicare HMO enrollees in 1993, challenging, among other things, the appeals procedures that applied under section 1876 of the Act and part 417). One commenter suggested that upon receipt of complete information, a decision should be rendered within 2 business days. Other commenters stated that the M+C time frames are too short. One commenter suggested that we require M+C organizations to make a good faith effort to meet time frames as opposed to a requirement that M+C organizations must meet absolute time frames. A number of other commenters supported the time frames established through the M+C interim final regulation.

Response: Before deciding to incorporate into the interim final rule reductions in the time frames within which M+C organizations are expected to render standard organization determinations and reconsiderations for service requests, we consulted with representatives of the managed care industry and beneficiary advocacy community, and conducted extensive research on the subject of organization-level resolution time frames. All groups with which we consulted agreed that the 60-day time frames provided for under the HMO regulations in part 417 were too long. Reports from independent organizations, such as the Physician Payment Review Commission, the General Accounting Office, and medical journals also advocated the reduction of standard time frames. Additionally, we realized the 60-day time frames in part 417 were based on the original fee-for-service Medicare appeals process, which is mostly retrospective. We were aware that new time frames needed to account for the fact that pre-service requests for organization determinations exceed the number of retrospective requests, and that reduced time frames are of critical importance when an individual is awaiting prior authorization for a service. Further, public comments received prior to publication of the M+C interim final rule indicated strong support for a reduction in time frames.

In view of the range of opinions contained in the comments on the M+C interim final rule, we believe that we succeeded in establishing an appropriate middle ground for the maximum time frames. It has also been reported to us that the majority of organizations make decisions within our reduced time frames. Only one commenter contended that the 14-day time frame could not be met as a general rule. We believe that the opportunity for up to a 14-day extension to the time frames for service-related requests allows the M+C organization adequate time in which to render a determination. We also believe that the new 14 and 30 calendar day time frames are appropriate from both consumer protection and industry feasibility standpoints. The medical exigency standard, which requires that decisions be rendered as expeditiously as an enrollee's health requires, provides for a quicker response where appropriate. Likewise, the opportunity for up to a 14-day extension for both organization determinations and reconsiderations

permits M+C organizations additional time to make a coverage decision when appropriate; for example, an M+C organization may extend the time frame at an enrollee's request, or if additional medical documentation is necessary and the M+C organization justifies the reason for the extension.

Comment: Another commenter who advocated reductions to reconsideration time frames suggested that we also reduce the time frame within which M+C organizations are permitted to forward case files to the independent review entity under the standard appeals process.

Response: M+C organizations must forward standard reconsideration cases to the independent review entity within the time frames permitted for resolution of standard requests. That is, when an M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must make the determination and send the case file for external review as quickly as the enrollee's health condition requires but no later than within 30 calendar days for service requests, or within 60 calendar days for payment requests. Time frames begin on the date the organization received the request for a standard reconsideration. Since time frames for submitting case files to the independent entity are incorporated into the resolution time frames, and we are not reducing time frames for standard reconsiderations, it would not be appropriate to reduce the time frames for submitting information to the independent review entity.

Comment: One commenter stated that we should provide a definition of ''good cause'' for extensions of time frames. Another commenter suggested that we should clarify that a 14-day extension may be granted in any instance where an organization determination demonstrates a need for additional information.

Response: The regulations for both expedited and standard requests for organization determinations (§§ 422.568(a) and 422.572(b)) permit an M+C organization to obtain an extension ''if the organization justifies a need for additional information and how the delay is in the interest of the enrollee''. We believe that this standard is largely self-explanatory. As indicated in the preamble to the M+C interim final rule, the M+C organization must include written justification of the extension in the enrollee's case file. Although forthcoming operational instructions will provide further clarification of the M+C organization's ability to grant itself an extension, we would like to clarify that a 14-day extension for service-related requests may be granted where an organization finds and notes in the enrollee's case file that it needs additional information to make a determination.

Moreover, to further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both §§ 422.568(a) and 422.572(b) that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision. Relatively few enrollees utilize the appeals process, and most organizations are able to make determinations on requests for services within 30 days. Therefore, we do not foresee that requiring M+C organizations to notify enrollees upon initiating an extension will create an undue burden on M+C organizations.

Comment: Some commenters supported the requirement that M+C organizations must make decisions ''as expeditiously as the enrollee's health requires'' (the ''medical exigency'' standard). In contrast, other commenters stated that the medical exigency standard was vague and uncertain, and likely to cause every reconsideration to become expedited.

Response: We believe that the ''medical exigency'' standard is needed to ensure that M+C organizations will not routinely avail themselves of the maximum time frames for all decisions. Although the expedited review process incorporates the medical exigency standard, this standard is separate and distinct from the process M+C organizations use to handle cases in which a physician or the M+C organization determines that an enrollee's life, health or ability to regain maximum function could be jeopardized in applying the standard time frames.

In our consultations with the public before publishing the M+C interim final rule, industry representatives advised us that each request is different; where some organization determinations are likely to require a 14-day time frame, and possibly 14 additional days, other decisions require less resolution time. Likewise, resolution of some reconsiderations will take up to 30 calendar days, and may require more time to gather additional information. The medical exigency standard requires M+C organizations to prioritize those cases where waiting for a decision is more likely to affect an enrollee adversely. We interpret this standard as requiring that the M+C organization or the independent entity apply, at a minimum, established, accepted standards of medical practice in assessing an individual's medical condition. Evidence of the individual's condition can be demonstrated by indications from the treating provider or from the individual's medical record (including such information as the individual's diagnosis, symptoms, or test results). We established the medical exigency standard by regulation to ensure that M+C organizations would develop a system for determining the urgency of both standard and expedited requests for services, and give each request priority according to that system. That is, we intend that M+C organizations treat every case in a manner that is appropriate to its medical particulars or urgency, rather than systematically use the maximum time permitted for service-related decisions.

Also, as indicated in the preamble to the interim final rule (63 FR 35028), we continue to believe that the emphasis on the health needs of the individual enrollee is consistent with the statutory requirement that determinations be made on a timely basis. Thus, the fact that an organization makes a determination on a service-related issue within 14 days does not necessarily constitute compliance with the law or regulations if there is evidence that an earlier determination was necessary to prevent harm to the enrollee's health.

We intend to issue additional guidance on the medical exigency standards in a future operational policy letter.

Comment: Several commenters suggested shortening the maximum time frame for M+C organizations to pay for, or provide, services once the independent review entity has ruled in the beneficiary's favor. One commenter suggested the effectuation time frame should be reduced to 15 days. Another commenter expressed concern that the effectuation requirements in § 422.618 do not provide for shorter implementation periods for expedited appeals. One commenter observed that if an M+C organization completely reverses its organization determination on reconsideration of a request for service, the organization must authorize, or provide the service; however, given the fact that the enrollee must seek the service, it may prove difficult to ensure that the service has actually been provided. Thus, this commenter suggested that a letter authorizing the service should be sufficient.

Response: We agree with the commenters concerning the need for a reduction of effectuation time frames for both standard cases overturned upon review by the independent review entity, and expedited cases overturned by the M+C organization or the independent review entity. However, we believe that since M+C organizations are permitted to authorize, provide or pay for the service in order to effectuate the decision, there is no need to establish a separate requirement for an authorizing letter. Based on these comments, we are revising § 422.618 to reduce the time frame within which M+C organizations must pay for, authorize or provide services to enrollees following a decision rendered by the independent review entity. For service-related requests, the revised language states that ''the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date.'' For requests regarding payment, we are reducing the time frame to effectuate the independent review entity's determination from ''no later than 60 calendar days'' to ''no later than 30 calendar days.'' We continue to maintain a distinction for payment-related appeals because most billing practices are on a 30-day cycle.

We also agree with the comments that expedited effectuation requirements should be incorporated into the regulations. To promote consistency in implementation, and to ensure enrollees receive the services they need as quickly as possible, we are establishing a new § 422.619 to require M+C organizations to effectuate overturned, expedited determinations as quickly as necessary, but no later than within 72 hours. Under the new provision, if the M+C organization reverses its original adverse organization determination, in whole or in part, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date it receives the request for the determination.

Where the independent entity reverses, in whole or in part, the M+C organization's initial expedited determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date it receives notice reversing the determination. In instances where the independent review entity expedites certain cases on its own accord (for example, where an enrollee or physician did not originally request an expedited appeal at the M+C organization level, but the independent review entity determines an expedited appeal is warranted), the expedited effectuation requirements of § 422.619 still apply.

If the ALJ or higher level reviewer reverses the independent review entity's expedited reconsidered determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health requires, but no later than 60 calendar days from the date of the decision.

Comment: Several commenters urged that we incorporate the review time frames for the independent review entity into the regulations text. Section 422.592(b) provides that an independent outside entity must conduct reconsideration reviews ''as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.'' One commenter noted that the contract with the independent outside entity may change each time it is negotiated, and that the general public is not informed of such negotiations, or the time frames produced by these negotiations. Thus, this commenter believes that regulations should specifically impose appropriate time limits on the independent review entity, and the time limits should be consistent with those specified in the vacated 1997 *Grijalva* order. One commenter expressed concern that the public has no remedy when the independent review entity fails to comply with time frames in the contract. This commenter added that the public plays no role in contract negotiation through which the independent review entity's time limits will be determined; and therefore, there is no assurance that an appropriate time limit will be imposed. One commenter recommended that we contract with PROs for the expedited review process instead of our current contractor, the Center for Health Dispute Resolution (CHDR). (PROs are organizations under contract with us to perform utilization and quality review of Medicare services generally, and review of the quality of services furnished by M+C organizations to their enrollees.) There was also concern about the notices provided by the independent review entity. Some commenters suggested that § 422.594 specify that the notice should be written in ''understandable language,'' as provided in § 422.568. Additionally, these commenters believe that the notice should also inform the enrollee about the PRO complaint process under section 1154(a)(14) of the Act.

Response: The time frames for the independent entity's review currently are the same as those time frames within which M+C organizations are required to decide standard and expedited cases, as detailed in the chart provided in the interim final rule (63 FR 35024). The time frames appear in our contract with the independent entity (as opposed to the regulation), however, to provide flexibility in the case of an unanticipated increase in the volume of appeal cases—since the independent contractor reviews cases from organizations nationwide. We have provided public notice of the time frames in the interim final rule and again in this rule. We agree with the commenters that beneficiaries should be informed of any changes that we might make to the current time frames, and will inform beneficiaries if these time frames are changed.

Additionally, we agree with one of the recommended changes to the independent entity's reconsideration notice, and are amending § 422.568 to require that the notice be written in ''understandable language.'' We also will consider issuing instructions to require the independent entity to advise an enrollee of his or her right to review by the PRO for quality of care concerns; (the same requirement on M+C organizations is set forth via model notice instructions).

12. Expedited Organization/ Reconsidered Determinations (§§ 422.570, 422.572, 422.584, and 422.590)

Comment: Several commenters expressed concern with § 422.572(d), which provides that the 72-hour time period under § 422.572(a) does not begin until medical information is received from noncontract providers where such information is required. One commenter stated that such an open-ended requirement poses an unreasonable risk of delay for the enrollee; especially in cases where time is of the essence, this provision could allow a decision to be postponed indefinitely. Another commenter suggested that M+C organizations should be required, at a minimum, to contact the noncontract provider within 24 hours of the initial request for an expedited reconsideration in order to request the necessary information from the noncontract provider and provide a fax number where the information can be submitted. Additionally, the commenter suggested that the enrollee, the representative, and the physician should be contacted to: Explain the

delay, inform them of the information needed, and provide them with a fax number. One commenter stated that the regulations should place the burden on the M+C organization to make prompt, good faith efforts to communicate with the noncontract provider to obtain the needed information. Additionally, information from noncontract providers should be provided within the 14-day extension period and under the same conditions that an extension would be granted in other circumstances. However, one commenter stated allowing an M+C organization to grant itself a 14-day extension beyond the 72-hour time frame gives the M+C organization too much additional discretion. This commenter stressed that an M+C organization will always state that it needs more than 72 hours, particularly if treatment will be expensive.

Response: We largely agree with the commenters, and are revising the regulation text to ensure that M+C organizations must make determinations within the same expedited time periods for cases involving noncontract providers. Accordingly, we are revising §§ 422.572(d) and 422.590(d)(4) to eliminate the provisions indicating that the 72-hour period begins when the organization receives information from the noncontracting provider. Instead, the regulations will require the organization to meet the same time frames set forth in §§ 422.572(a), (b), and (f) for expedited organization determinations and §§ 422.590(d) and (f) for expedited reconsiderations regardless of whether the M+C organization must request information from noncontracting providers. We agree that in situations where either a physician or the M+C organization has already determined that an expedited decision is crucial, open-ended time frames may put the enrollee at risk. We likewise are incorporating into § 422.572(d) the recommended provision for expedited reviews that requires the M+C organization to request any necessary information from the noncontract provider within 24 hours of the initial request for expedition. We continue to require noncontract providers to make ''reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required time frames.'' We believe an opportunity for an M+C organization to take up to a 14-day extension under the 72-hour expedited review process provides the M+C organization with a reasonable opportunity to obtain information from non-contract providers. We will monitor M+C organizations to ensure M+C organizations do not routinely, or unnecessarily, avail themselves of the 14-day extensions. Where appropriate, M+C organizations must notify the physician involved; M+C organizations are always required to notify enrollees of the decision, whether the decision is adverse or favorable to the enrollee, in accordance with the regulation. However, we do not agree that the M+C organization must always contact or notify the enrollee's physician.

Comment: Several commenters stated that the criteria for deciding whether a determination must be expedited may be too rigorous. Some commenters suggested that we revise §§ 422.570(c)(2) and 422.584(c)(2) to reflect language from the district court's vacated order in the *Grijalva* case, under which reconsiderations were to be expedited ''when services are urgently needed.'' The district court provided the examples of when acute care services are being denied or terminated, certain types of nursing facility care, certain types of home health and therapy services, and denials of certain types of non-cosmetic surgery. This commenter suggested that the regulation state that expedited consideration may be granted, in certain circumstances, upon lay evidence and without a request by the physician. One commenter contended that the regulations should clearly articulate what constitutes ''seriously jeopardizing the enrollee's life, health, or ability to regain maximum function.'' The commenter argued that a more specific definition should be provided that takes into account both a substantial risk of an adverse outcome, and a small (but significant) risk of a serious and adverse outcome such as permanent disability or death. Some commenters expressed concern that if an enrollee does not obtain physician support to expedite a determination, the M+C organization has broad discretion in deciding whether to expedite.

Response: We do not believe that the adoption of the ''urgently needed'' standard from the vacated *Grijalva* order would be appropriate. First, we believe it is too broad and vague. Second, the term ''urgent'' is already used in connection with ''urgently needed services'' (for which enrollees do not need to obtain prior authorization). Using the same term here could cause unnecessary confusion. We also believe that the ''serious jeopardy'' standard is sufficiently clear. It is unclear how we could expand on what is meant by ''serious jeopardy'' to an enrollee's ''life'' (that is, could put his or her life in serious jeopardy), ''health'' (that is, could put his or her health in serious jeopardy), or ''ability to regain maximum function'' (that is, could put his or her ability to regain maximum function in serious jeopardy). We believe that the commenter's suggestion that the requirement to expedite a case in which there is a ''significant'' risk of a ''serious and adverse outcome such as permanent disability'' is already addressed in language referring to ''seriously jeopardizing the enrollee's * * * ability to regain maximum function.'' With respect to the commenter's suggestion that the regulations provide for cases to be expedited based on ''lay evidence'' (that is, in the absence of the involvement of a physician), this is already required under section 1852(g)(3)(B)(ii) of the Act ''if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.'' The interim final rule and this final rule similarly provide for expedition without the need for a physician's involvement. (*See* §§ 422.570(a) through (b), and 422.584(a) through (b).) Although this decision is made by the M+C organization in the absence of a physician's involvement, the decision is subject to the grievance process, and we will monitor M+C organizations closely to ensure that they are expediting cases where appropriate.

Comment: Several commenters strongly urged the removal of the requirement that physicians requesting an expedited appeal must be acting as an enrollee's authorized representative. Commenters contended that the regulation as written is inconsistent with their view of statutory intent, intrudes in the doctor-patient relationship, and could present a problem for incapacitated enrollees.

Response: We agree that a physician who requests an expedited reconsideration on behalf of an enrollee should not have to be formally appointed as the enrollee's authorized representative. We initially included this provision based on our belief that the physician served a different role in the context of an organization determination versus an appeal. In the case of an organization determination, we regarded the physician as a provider who is requesting a service for his or her patient. On the other hand, in the context of a reconsideration, we viewed the physician as serving as the enrollee's representative in the first

level of the appeals process. Thus, we believed the physician would need to be appointed by the enrollee in the same manner as any one else who served as a representative. However, in response to the above comments, we have reconsidered our position, and recognize the operational problems with requiring that physicians be authorized representatives when requesting expedited reconsiderations on an enrollee's behalf. For example, under the M+C program, each appeal request requires completion of a separate authorized representative form, which may cause an undue burden on physicians. For this reason and those set forth in the comment above, we have decided to revise § 422.584(a) by eliminating this requirement. Therefore, physicians may request expedited reconsiderations on a patient's behalf without being appointed as the enrollee's authorized representative.

We want to make clear, however, the distinction between a physician acting on behalf of the enrollee, and a physician who meets the conditions for being a party in his or her own right. When a physician seeks either a standard or expedited organization determination for services on behalf of the enrollee, the physician does not need to be an authorized representative. But, if the physician seeks a standard reconsidered determination for purposes of obtaining payment, then the physician must sign a waiver of liability, consistent with § 422.574(b).

Comment: One commenter suggested that the ability to request an expedited organization determination should be expanded. The commenter suggested the following options for expansion: (1) All health care professionals, (2) health care professionals that have been designated by a physician to carry out such tasks, or (3) all health professionals providing care in medically underserved areas. Another commenter suggested that we should permit an ''authorized representative'' to request an expedited determination.

Response: The statute explicitly lists enrollees and physicians as those permitted to request expedited organization determinations and expedited reconsiderations, (*see* sections 1852(g)(3)(a)(1) and (2) of the Act). We note that authorized representatives may request expedited determinations or reconsiderations, since the definition of ''enrollee'' in § 422.561 includes the enrollee's authorized representative. Therefore, the regulations already permit health care professionals who enrollees authorize as their representatives to request expedited organization determinations and expedited appeals. As described in the previous comment, physicians now may make requests without being authorized representatives. We do not believe it would be appropriate, however, to grant health care professionals other than the enrollee's physician the right to make requests on the enrollee's behalf absent an authorization. There are so many potential health care professionals involved in a patient's care, this could create confusion, and potentially cause duplicate or conflicting requests.

Comment: One commenter suggested that we incorporate a separate notice requirement provision whereby, before deciding whether to expedite a determination, the M+C organization must notify the enrollee of the M+C organization's obligation to expedite any request for a determination that was accompanied by a physician's statement that ''applying the standard time frame for making a determination could seriously jeopardize the life of the enrollee or the enrollee's ability to regain maximum function.'' Several commenters requested that we define ''prompt oral notice'' of a denied request for expedition, as provided in § 422.570(d)(2). This section provides that, if the M+C organization denies a request for an expedited determination, it must give the enrollee prompt oral notice of the denial and follow up within 2 working days with a written letter explaining their right to file a grievance. One commenter asked whether this meant the enrollee is supposed to receive the written notice within 2 working days of the decision, or that the organization is to mail it within 2 working days. Additionally, the commenters suggested that this section also specify that the enrollee be given the right to make an oral, immediate request for a reconsideration when given oral notice of denial, followed by written verification of the reconsideration request.

Response: M+C organizations are required under § 422.111(a)(8) to provide notice of grievance and appeal rights upon enrollment and at least annually thereafter. Thus, all enrollees should receive notice of the right to automatic expedition of determinations and reconsiderations when a physician supports the request. However, in a case in which an enrollee submits a request for an expedited organization determination or an expedited appeal, but does not indicate that the request was supported by a physician, we recognize that the enrollee may not have read the required notice carefully, and thus be unaware that a physician's support would make the expedition of the request automatic. We therefore are revising §§ 422.570(d)(2) and 422.584(d)(2) to require that when an M+C organization denies a request for an expedited determination or reconsideration, its notification letter must inform the enrollee of the right to resubmit the request with a physician's support.

As noted above, upon denial of an enrollee's request for expedited review, existing regulations require an M+C organization to provide the enrollee with ''prompt oral notice'' of the denial, and follow up with a written letter within 2 working days. We believe that this is a reasonable requirement which indicates that an M+C organization must contact and advise the enrollee of the denial without delay. As suggested by the commenter, we are clarifying the regulations to indicate that subsequent to providing oral notice of the denial, M+C organizations must ''deliver'' to the enrollee, within 3 calendar days, a written letter that includes the information listed in the regulation at §§ 422.570(d)(2) and 422.584(d)(2). We interpret this provision as requiring an M+C organization to first orally notify an enrollee of a denial, and subsequently deliver written notice to the enrollee within 3 days after the decision. Note that we have revised the regulations at §§ 422.570(d)(2), 422.572(c), 422.584(d)(2), and 422.590(d)(3) to establish a requirement of 3 calendar days, rather than 2 working days. We believe this is a reasonable amount of time within which to require M+C organizations to deliver written notice enrollees (following the oral notice) of a denied expedited request, and that the change to calendar days will eliminate confusion over what constitutes a working day. This change is consistent with the general replacement of standards related to ''working days'' with ''calendar day'' standards throughout the M+C regulations.

We also wish to clarify that if an enrollee's request for an expedited organization determination is denied, the M+C organization will automatically transfer and process the enrollee's request under the standard process. If the M+C organization denies the request in whole or in part, the enrollee (or a physician on the enrollee's behalf) then has a right to orally request expedited reconsideration. The M+C organization continues to be responsible for documenting all oral requests in writing and maintaining the documentation in the case file.

13. Authorized Representative (§§ 422.561 and 422.574)

Comment: A commenter suggested that § 422.574, which addresses parties to the organization determination, should include surrogates under State law as a possible party to an organization determination. This commenter added that by excluding such surrogates, enrollees who are incapacitated and cannot appoint representatives may lack persons authorized to handle appeals on their behalf. Similarly, two other commenters stated that the ''authorized representative'' definition should be expanded to allow individuals who can act on behalf of an individual under State law to be authorized representatives. This commenter believes that the current definition is limited to an individual appointed under the Social Security Act, and requires completion of the Appointment of Representative form. The commenter believes that this requirement makes it difficult for those who have written Durable Power of Attorney to act in place of the beneficiary. Several commenters suggested that the definition of ''enrollee'' should not include an authorized representative. One commenter argued that an authorized representative is not the enrollee, since an enrollee is someone who is entitled to health services. Further, the commenter recommended that an authorized representative receive copies of all communications sent to the enrollee concerning the appeal.

Response: We agree with the commenters concerning the need to include those individuals appointed under State law (such as surrogates) in M+C requirements, as well as those with Durable Power of Attorney. For this reason, we are amending the definition of authorized representative at § 422.561 to include an individual authorized by an enrollee, ''or under State law,'' to act on his or her behalf in obtaining an organization determination, or in dealing with any of the levels of the appeals process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in subpart M. We believe that the revised definition of an authorized representative includes those individuals with Durable Power of Attorney. Therefore, an individual authorized to act as a surrogate of an enrollee and those who have written Durable Power of Attorney are permitted to act on behalf of an enrollee in the organization determination, reconsideration and appeal processes. By adding individuals authorized under State law to the definition of authorized representative, such individuals are included as one of the parties to an organization determination listed at § 422.574, since the definition of an enrollee (who is a party) includes the enrollee's authorized representative. Thus, a surrogate authorized by the State is not only a party to the organization determination, but is permitted to act on behalf of the enrollee under all provisions of subpart M.

We disagree with the commenters who requested that the definition of ''enrollee'' exclude an authorized representative. Although we recognize that an authorized representative is not an enrollee in the literal sense of being entitled to health services, we believe that to ensure authorized representatives are always permitted to act on behalf of an enrollee, the regulations should include an authorized representative in the definition of ''enrollee'' under subpart M. We note that § 422.561, which sets forth the definitions used in the appeals regulations contained in subpart M, specifies that the definitions are only ''as used in this subpart, unless the context indicates otherwise.''). An authorized representative thus would not be considered an enrollee for general M+C program purposes, such as under enrollment or financial liability provisions, but would be able to exercise the rights available to an enrollee for appeal and grievance purposes, such as the right to act on behalf of an enrollee in requesting an appeal or to receive applicable notifications.

Comment: One commenter commended our appeal and grievance rights as providing substantial protection, yet expressed concern over access for enrollees with special health care needs (the disabled and/or chronically ill). One commenter stated that M+C organizations will face a challenge in serving the increasing population of beneficiaries with questionable, fluctuating or diminished capacity, and further stated that M+C organizations need to identify enrollees who have surrogates in order to keep them informed. This commenter stated that the regulation should require information and notices be sent to surrogates of incapacitated beneficiaries, and surrogates should be listed as requesters of expedited decisions.

Response: As noted above, to the extent that such a surrogate is authorized under State law to act on the beneficiary's behalf, he or she would be considered an authorized representative who is included in the definition of enrollee and permitted to make requests on the beneficiary's behalf. With respect to other additional procedural protections for enrollees with special health care needs, we believe that such additional protections for enrollees with special health care needs should be included in a notice of proposed rulemaking to provide the public with ample opportunity for input on final standards. We plan in this rulemaking to address the issue of special protections for beneficiaries with limited capacity, and consider possible additional notice requirements for surrogates in such cases.

14. Other Appeal Rights (§§ 422.596, 422.600, 422.602, 422.608, 422.612, and 422.616)

Comment: One commenter suggested that we revise § 422.596 to clarify that an M+C organization cannot appeal to an Administrative Law Judge (ALJ). However, two commenters argued that M+C organizations should have the right to appeal to an ALJ.

Response: Section 422.600 addresses the ''Right to a hearing.'' Section 422.600(a) provides that ''any party to the reconsideration (*except the M+C organization*) who is dissatisfied with the reconsidered determination has the right to a hearing before an ALJ.'' (Emphasis added.) Section 422.600(a) then expressly states that ''[t]he M+C organization does not have the right to request a hearing before an ALJ.'' While we believe that the regulations thus are already clear on this point, we have no objection to the commenter's suggestion that § 422.596 be revised to also reflect this restriction.

The policy limiting ALJ appeal rights to Medicare enrollees has been in place since the inception of the Medicare risk contracting program under section 1876 of the Act. As noted above, under section 1856(b)(2) of the Act, M+C standards are to be based on standards established under section 1876 of the Act to the extent consistent with M+C rules. More importantly, the M+C statute expressly grants a right to a hearing only to an enrollee, with the M+C organization given the right to: (1) Be made a party to such a hearing; and (2) appeal from an ALJ. Section 1852(g) of the Act sets forth a three step process for appeals of coverage determinations. Section 1852(g)(1) of the Act establishes the process for making initial organization determinations and providing notice of appeal rights. Section 1852(g)(2) of the Act provides for the reconsideration process, which is conducted initially by the M+C organization. (Section 1852(g)(3) of the Act provides for M+C organizations to

expedite certain organization determinations under section 1852(g)(1) of the Act and reconsiderations under section 1852(g)(2) of the Act; and section 1852(g)(4) of the Act provides for review by an independent review entity as part of the reconsideration process established under section 1852(g)(2) of the Act). It is section 1852(g)(5) of the Act which provides for the ALJ level of review if the amount in controversy is at least $100, and for ultimate judicial review. Under section 1852(g)(5) of the Act, ''[a]n *enrollee* with a Medicare+Choice organization * * * is entitled (if the amount in controversy is $100 or more) to a hearing before the Secretary * * * and in any such hearing the Secretary shall *make the [M+C] organization a party*.''

Comment: A commenter suggested that some denied services that do not reach the $100 threshold represent legitimate disputes that could adversely affect patients. This commenter believes that patients should be able to request ALJ hearings for denials of services needed to maintain or regain health or physical functions, without regard to the cost involved. Another commenter similarly asserted that an enrollee's ability to obtain an ALJ hearing and seek judicial review should not be based on the amount in controversy, because this could arbitrarily prevent some enrollees with legitimate disputes from appealing. This commenter suggested modifying the provision to allow a decision to be appealed if the amount in controversy meets the identified threshold, or if the patient's life or health may be jeopardized as a consequence of the decision.

Response: Although we are sensitive to the concerns of the commenters, amount in controversy (AC) requirements in the case of appeals under the M+C program are set forth in the statute at section 1852(g)(5) of the Act. A statutory change would be required to alter the current threshold levels; therefore, we are not modifying the M+C regulations.

Comment: A commenter expressed concerns about the process for obtaining judicial review. The commenter also requested clarification as to what constitutes the ''final decision of HCFA.'' The commenter believes that some enrollees may not have the resources to pursue their rights in court. This commenter recommended that the reimbursement of attorney fees or associated court costs be left to the discretion of the judge performing the judicial review.

Response: A decision by our agent, the independent review entity, becomes ''final'' and binding on all parties unless a party other than the M+C organization files a request for an ALJ hearing, or unless the decision is reopened and revised by the independent entity. This is the earliest ''final'' decision that involves us (through our agent), since organization determinations are made by M+C organizations. If this decision is not appealed or re-opened, it is in essence, a ''final decision of HCFA.'' A failure to appeal this decision, however, would mean that the right to further administrative and judicial review has been forfeited. An ALJ decision is similarly final and binding if it is not appealed by a party; (unlike a reconsidered determination, an M+C organization has the right to appeal an ALJ decision). If a timely appeal is filed, the ALJ decision is subject to further review by the Departmental Appeals Board (DAB). At this point, if the DAB declines to review the case, under § 422.612(a), the ALJ's decision becomes a ''final'' decision for purposes of the right to judicial review. If the DAB agrees to hear the case on appeal, the DAB's decision is the ''final decision of HCFA'' for purposes of judicial review.

We believe that the commenter's confusion about what constitutes a ''final decision of HCFA'' may be due to some confusing regulatory text in § 422.612(b). Section 422.612(b) provides that a decision of the DAB may be appealed to Federal court if ''(1) It is the final decision of HCFA; and (2) The amount in controversy is $1,000 or more.'' This implies that there is a distinction between a DAB decision and a ''final HCFA decision.'' In fact, a DAB decision constitutes a ''final decision'' on our behalf, since it is not subject to any further administrative review. We therefore are revising § 422.612(b) to provide that a DAB decision may be appealed to district court if the amount in controversy is $1,000 or more.

Comment: One commenter suggested that we include other rights found in State managed care laws, such as requiring M+C organizations to provide beneficiaries, on request, with clinical guidelines upon which a denial is based.

Response: M+C organizations must provide enrollees with written notice of the reasons for a denial, as set forth at §§ 422.568(c) and (d). This includes providing all the information necessary for the beneficiary to understand why the service was denied, including any Medicare coverage criteria or policies applied in making the decision, as well as specific clinical rationales if applicable. To the extent that particular guidelines or screens are used in the determination process, but are not determinative of coverage (for example, services falling outside certain screens will be given closer review, but still covered if coverage standards are met), we do not believe it is critical for beneficiaries to have access to these documents. We note that Medicare does not make similar documents used by carriers and intermediaries under the fee-for-service program available to the public.

15. Inpatient Hospital Notice of Discharge (§§ 422.580, 422.586, 422.620 and 422.622)

Comment: Two commenters urged that we simplify the language used in the notice of noncoverage (hereafter referred to as the Notice of Discharge & Medicare Appeal Rights (NODMAR)). One commenter suggested working with us to craft a notice outlining beneficiary rights of appeal while avoiding unnecessary paper work, especially since most of the NODMAR information is already contained in the ''Important Message From Medicare'' issued upon admission to a hospital. One commenter stated that the notice should be on a clear and readable form, in at least 12-point font, and in understandable language. One commenter stated that beneficiaries are confused by the content and intent of the notice, and that the notice should include a contact person at the M+C organization. Two commenters stated that this should be a form developed by HCFA.

Response: Shortly after the promulgation of the notice requirement, which is reiterated in § 422.620, we began receiving comments that the notices of noncoverage being issued to beneficiaries were confusing, contained a great deal of sophisticated ''legalese,'' were too long (the notices were ranging from five to nine pages), and that the many variations of the document posed administrative burdens. Therefore, we committed to drafting a more comprehensive and beneficiary-friendly notice.

We began consulting with industry groups, beneficiary advocacy groups, and peer review organizations in support of drafting a notice that would serve the intended purpose. On February 11, 1999, we issued OPL 99.082. This OPL conveyed: (1) Our new notice, the NODMAR; (2) our intent to consumer test and standardize the model language; and (3) our continued effort to find the best balance of beneficiary protections with administrative burden. The model language conveyed in the OPL contains language that is in 12 and 14-point fonts, is written in understandable language, and is only three pages in length.

The Important Message from Medicare (IMM) and the NODMAR are two documents that contain similar information. The IMM is currently given to the Medicare beneficiary at or about the time of admission, while the NODMAR is given in advance of the patient's discharge. We recognized the burden associated with issuing two notices with similar information. Therefore, we have developed a single document and process that allows patients to be informed about their inpatient hospital rights at a time and in a form that will be most beneficial to them and in a manner that reduces administrative burden. This single document is a revision to the existing Important Message from Medicare.

Accordingly, we have revised the IMM to provide for the inclusion of information on patients' inpatient hospital discharge rights. All Medicare beneficiaries will receive a revised notice, the ''Important Message About Medicare Rights: Admission, Discharge, & Appeals,'' as required under section 1866(a)(1)(M) of the Act.

This revised standardized form will be issued to all Medicare beneficiaries who are inpatients of a hospital at or about the time of their admission. Once a Medicare beneficiary's time of discharge is determined, an amended notice that includes the reasons for the discharge would again be provided to the beneficiary prior to his or her actual discharge. The revised Important Message About Medicare Rights: Admission, Discharge, & Appeals has been consumer-tested, and has received favorable feedback. (Pursuant to the Paperwork Reduction Act of 1995 (PRA), a notice outlining this document was published in the **Federal Register** on April 12, 2000, with public comments accepted through June 12, 2000. See 65 FR 19783.) The content of the revised notice (and amended follow-up notice) will meet the requirements of the PRA and section 1866(a)(1)(M) of the Act (the Important Message from Medicare), and the notice requirements set forth at § 422.620 that are now contained in the NODMAR.

Comment: One commenter stated that the notice should include standardized language that indicates that review by PROs is usually preferable to a plan review, and should clearly explain that the enrollee is obligated to make a request in this fashion under these tight time restraints in order to be protected from financial liability.

Response: As explained in the preamble to the June 26, 1998 interim final rule, there are advantages to filing for immediate PRO review. The most significant advantage in utilizing the immediate PRO review process is protection from financial liability for a continued hospital stay until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. In addition, the immediate PRO review process offered the enrollee direct communication with the PRO and a decision that is generally rendered more quickly than an M+C organization's determination.

Therefore, when the model language, NODMAR, was drafted, we included language that would allow the enrollee to understand the significance of meeting the immediate PRO review deadline. Likewise, the revised Important Message stipulates that if the enrollee meets the deadline for filing for immediate PRO review, the enrollee's M+C organization continues to be responsible for paying the costs of the enrollee's hospital stay until noon of the day after the PRO notifies the enrollee of its official decision.

In addition to stating that the enrollee has financial protection if he/she meets the immediate PRO review deadline, we have included a section that explains what happens to the enrollee if he/she misses the deadline and has to appeal to the M+C organization.

Comment: One commenter strongly supported the M+C regulations that improve notice requirements for hospital discharges. The commenter stated that the requirement that hospitals provide notice at the time of discharge instead of at admission gives M+C enrollees an additional protection against premature discharges. One commenter stressed the importance of always issuing a notice with respect to termination of any form of inpatient care, even when the enrollee has not expressed disagreement, because these are such significant changes in circumstances. The commenter suggested that these notices must be given in advance of the termination, and inpatient care must continue, without financial liability to the enrollee, until the appeal is resolved.

Response: We agree with the commenter that a notice of appeal rights should be issued at discharge without regard to whether the beneficiary expresses disagreement with the termination of care. Section 422.620(a) already provides that an M+C enrollee has the right to continued coverage of inpatient hospital services unless a proper discharge notice is provided. We are concerned that the commenter appears not have understood the existing regulations to require a notice in all cases. This misinterpretation of our current requirements is consistent with what we have heard from beneficiaries discharged from hospitals during the year prior to consumer testing conducted on the NODMAR, who reported that they were unaware that they had the right to appeal the decision that it was time to leave the hospital, and left based on the belief that they had no choice in the matter. Given that the existing regulations text may not be sufficiently clear, we are responding to this comment by revising § 422.620(a) to expressly require that written notice be issued to enrollees in the case of all discharges and by revising the introductory clause in § 422.620(c) to provide that ''In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, each enrollee must receive a written notice that includes the following * * * .''

With respect to the commenter's suggestion that the enrollee not be financially liable until an appeal is resolved, as noted above, if the enrollee disagrees with a discharge decision, the enrollee may file for immediate PRO review by noon the day after a discharge notice is received. If such a timely request for review is filed, the enrollee is protected from financial liability until at least noon on the day after notice of the PRO's decision, if the PRO upholds the decision to discharge the enrollee. If the PRO decides that hospital services are still necessary, coverage would continue until a new discharge notice is issued.

Comment: Several commenters did understand the current regulations to require issuing the NODMAR to every enrollee prior to being discharged from an inpatient hospital setting, and indicated that they found this requirement difficult to administer. One commenter believes that M+C organizations need the cooperation of hospitals to fulfill this requirement, and contended that such cooperation was not always possible to obtain. Therefore, this commenter suggested that we reconsider our decision to require that a NODMAR be provided to every M+C organization member prior to discharge, or that we at least articulate this requirement as a ''good faith effort'' versus an absolute requirement. Two commenters said that in cases in which the responsibility for providing the notice has not been delegated by the M+C organization to the hospital, or where hospitals refuse to assist in this process, M+C organization staff would have to be available to visit each hospital on an ongoing basis 7 days each week, thereby creating a significant increase in the level of staffing. One commenter reported that in some cases,

hospitals are demanding compensation from M+C organizations for providing the notice to enrollees. Another commenter contended that it is inappropriate and unhelpful for hospitals to issue the notice, since there is no reimbursement from M+C organizations or Medicare, and it is impossible for hospital staff to explain decisions they did not make.

Response: We understand the burdens associated with an M+C organization directly providing notices in a hospital setting, and agree with the commenters who stated that hospitals are in the best position to give the discharge notice required under § 422.620. In light of the above comments, we have completed development of a single document that combines the NODMAR with the ''Important Message.'' (The Important Message is the document we have determined that hospitals are already required, under section 1866(a)(1)(M) of the Act, to issue to all Medicare beneficiaries, including M+C enrollees.) While this regulation is not the appropriate vehicle to impose requirements on hospitals, some of which do not contract with M+C organizations, we intend, through a more appropriate vehicle, to require that all hospitals provide discharge notices for all Medicare patients. Thus, we are revising § 422.620 to eliminate the existing requirement that M+C organizations issue the notice of noncoverage to M+C enrollees.

Lastly, we note that it is the responsibility of the entity that made the discharge decision to ensure that an enrollee's questions about the discharge decision be directed to someone within that entity who can provide assistance. Thus, where a discharge decision is made by an M+C organization, that organization should be available to answer questions, even though the notice is issued on the organization's behalf by a hospital.

Comment: Several commenters suggested that the requirement to issue a NODMAR to all enrollees prior to discharge should be repealed or significantly modified. Four commenters suggested that the NODMAR should be given only if the enrollee or the physician disagrees with the hospital's decision to discharge. One commenter contended that issuing a notice in cases where the enrollee agrees with the discharge decision is unnecessary, will confuse the enrollee, and may result in the delay of appropriate discharge or the increase in hospital costs.

Response: The intent of the notice requirement set forth at § 422.620, as with all notice requirements, is to provide enrollees with information that will help them make an informed decision about their health care at a time when it would be most needed and effectively received. The notice requirement is an important and necessary beneficiary protection.

Again, the revised Important Message has undergone extensive consumer testing. This has helped us to improve the content of the notice to make it less confusing to the beneficiary. Since the revised notice will be used to satisfy the requirement for notice of discharge/termination of coverage, beneficiaries will have the benefit of the consumer testing in this context as well.

Comment: One commenter supported an extension of the notice requirement to original Medicare beneficiaries, that is, all Medicare beneficiaries would receive a notice prior to being discharged from the hospital regardless of whether the beneficiary agrees with the decision. The commenter stated that until this requirement is extended, it will be very difficult to achieve full compliance, and urged that we defer any evaluation of plan compliance with this requirement until such an extension is secured.

Response: We have received many inquiries as to whether the M+C policy of issuing NODMARs in all cases will also apply to original Medicare beneficiaries. Currently, the practice has not been for hospitals to issue notices (that is, the Hospital-Issued Notices of Noncoverage (HINN)) to all original Medicare beneficiaries in advance of their hospital discharge, but to do so only in cases in which the beneficiary disagrees. We believe that it is in the best interests of all Medicare beneficiaries and the entities responsible for distribution of such notices to implement a uniform policy for M+C program and original Medicare purposes, and we intend to provide for this through an appropriate vehicle. This final rule, however, sets forth only those requirements that apply in the case of M+C enrollees.

Comment: One commenter contended that our inpatient hospital notice requirement generates ill will among M+C organizations, contracting providers, and beneficiaries. Two commenters opposed the notice requirement because they believe it would raise costs to hospitals.

Response: The intent of the notice requirement is not to supplant the doctor/patient relationship nor to harm the working relationships among M+C organizations, contracting providers, and/or beneficiaries. We believe that standardized instructions, and the eventual implementation of a uniform policy for original Medicare beneficiaries, will help to alleviate a great deal of contention between the various entities. In the long run, this should make the referenced relationships function more smoothly.

Comment: One commenter suggested that the regulation should make clear that if a notice is not issued, the M+C organization (not the hospital) is liable for services.

Response: We agree that if proper notice is not provided, the M+C organization is liable for coverage, unless the hospital has been delegated the authority to make coverage decisions on behalf of the M+C organization. This liability is provided for under § 422.622(c), which expressly addresses liability for services, and § 422.620(a), which makes clear that the enrollee is entitled to coverage until noon the day after notice is given.

Comment: One commenter suggested that the only information that should be reviewed in an appeal of a decision not to admit a patient to a hospital, or to discharge a patient, is that which was available at the time that the decision was made.

Response: We disagree with the commenter. We believe that the entity reviewing an inpatient hospital discharge decision, or decision not to admit an enrollee to the hospital, should base its review on all the facts and evidence available—regardless of whether such information was available at the time of the decision not to admit or to discharge. In particular, in the case of review by the M+C organization, § 422.586 provides the parties to the reconsideration with an opportunity to present related evidence and allegations of fact or law in person as well as in writing; (the regulation notes that such an opportunity may be limited in the case of expedited reconsideration). Further, § 422.580 defines a reconsideration as a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or we obtain. Thus, there is ample precedent for not limiting information to be reviewed in the case of an appeal, and we plan to continue that policy.

Comment: One commenter suggested that, in order to avoid stalemates, the M+C regulations (like the original Medicare regulations) should provide a process to resolve cases in which the physician and the M+C organization disagree about the discharge decision.

Response: We agree with the commenter that the existing regulations do not provide for a clear resolution process in situations where an M+C

organization determines that inpatient care is no longer necessary, but the physician who is responsible for the patient's hospital care does not agree. We are currently examining different methods to resolve these situations, such as a method comparable to the existing Medicare fee-for-service system. Under that system, if a hospital believes that an inpatient is ready for discharge, but cannot obtain the concurrence of the attending physician, the hospital may request PRO review of the case. We intend to discuss this issue in our forthcoming notice of proposed rulemaking.

16. Other Comments

Comment: As alluded to above, several commenters suggested that we modify the subpart M regulations to reflect the provisions of the 1997 district court order in *Grijalva* that was vacated by the Ninth Circuit on appeal in 1999. For example, several commenters suggested we provide for the continuation of coverage during the pendency of an expedited appeal as provided under that district court order. Two commenters suggested that we clarify the enrollee's right to submit evidence in person. Additionally, several commenters suggested that the regulation should state that the enrollee has the right to informal, in-person communication with the reconsideration decision maker and that telephone hearings could be conducted if appropriate. One commenter opposed the implementation of the provisions in the vacated *Grijalva* order as too burdensome on M+C organizations.

Response: In general, we intend to implement regulatory changes that stem from the *Grijalva* order through upcoming notice and comment rulemaking. Thus, several of the commenters' suggestions are not addressed here. We note, however, that in some respects, we believe that the improvements to the appeals process that have been made under the M+C program already incorporate several of the provisions in the vacated *Grijalva* order, and in many instances are stronger. For example, the *Grijalva* order would have required that organization determinations be rendered within 5 working days, with the possibility of a 60-day extension. Under this regulation, we require that when an enrollee requests a service, the M+C organization must respond as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days. The M+C organization may not extend the time frame beyond an additional 14 calendar days. More significantly, unlike under the *Grijalva* order, the M+C program provides an expedited 72-hour time frame for organization determinations in some cases that is shorter than the *Grijalva* time frame, and a similar expedited 72-hour time frame for the resolution of certain reconsiderations, while the *Grijalva* order provides neither. In another example illustrative of how our current M+C regulations meet or exceed the *Grijalva* order, at § 422.586, the M+C organization is required to provide parties to the reconsideration with a ''reasonable opportunity to present evidence and allegations of fact or law * * * in person.''

Comment: One commenter urged that we eliminate the phrase in § 422.574(b) which reads ''and formally agrees to waive any right to payment from the enrollee for that service,'' because this language demeans the role of physicians as patient advocates for medically necessary services.

Response: We do not believe changes are needed in § 422.574(b), which requires a physician or other provider who has furnished a service to an enrollee to formally agree to waive any right to payment from the enrollee for that service. The waiver is only required in the case of retrospective payment denials, where an enrollee has *already* received medically necessary services, but the noncontract physician or provider is seeking payment for furnishing those services; therefore, this phrase does not affect the role of physicians as patient advocates for medically necessary services. In the context of receipt of payment, the role of the physician or provider is no longer as a patient advocate for medically necessary services. Therefore, the M+C regulation does not adversely affect or demean a physician's role as an advocate in prospective instances where an enrollee has not yet received health care services.

Comment: A commenter asked whether we would offer clarification of respective Medicare/Medicaid authorities, particularly with respect to New York State's existing 1115 Medicaid demonstration project. Additionally the commenter wondered if we will establish an administrative linkage between the States and the Medicare review authority for the provision of reports on reviews of adverse determinations in M+C organizations also operating as a State-defined managed long term care plan. (The commenter noted that managed long term care plans will predominantly serve the dually eligible.)

Response: We agree that access of dual eligibles to both the Medicare and Medicaid external hearing process should be clarified. The external hearing process accessed depends upon the type of services being provided. For example, in original Medicare, enrollees who are dually eligible access Medicare services through the Medicare system. Therefore, appeals of Medicare services may be appealed through the Medicare external hearing process, if the beneficiary chooses to do so. Medicaid-only wraparound services (such as pharmacy services) must be accessed through Medicaid. Therefore, appeals of Medicaid-only services must be appealed through the Medicaid external hearing process. Likewise in capitated managed care, when a dually eligible enrollee is enrolled in a Medicaid MCO, the capitated rates are set based on an assumption that Medicare services are accessed through the Medicare system. Therefore, the Medicaid fair hearing system is accessed only for the Medicaid capitated services. The Medicare external hearing is accessed for the Medicare services outside of the Medicaid capitation contract. If a dually eligible individual is enrolled in an M+C organization, then the Medicare external hearing is accessed for the Medicare services within the capitation contract. The enrollee accesses the Medicaid State Fair Hearing only for services outside of the Medicare contract. The key to this example is that the enrollee and the M+C organization need to know whether the service provided is a Medicare- or Medicaid-covered service.

Comment: A commenter suggested that § 422.568(e), which addresses the effect of failure to provide timely notice of an organization determination, should be revised to specify that: (1) Failure to give timely and proper notice shall result in an automatic authorization/approval; and/or (2) failure to give timely and proper notice shall result in automatic sanctions by us. Furthermore, the commenter stressed that if an M+C organization fails to give proper notice, the M+C organization should be required to submit the file directly to an independent organization as described in § 422.590(c). Another commenter suggested that M+C organizations that fail to comply with grievance and appeal requirements should be subject to other intermediate sanctions.

Response: If we determine that an M+C organization substantially fails to comply with the notice requirements relating to grievances and appeals in subpart M, we have the option to terminate the contract under the requirements of § 422.510(b), impose intermediate sanctions as described in §§ 422.756(c)(1) and (c)(3), and/or

impose civil money penalties as described in § 422.758. We note that, depending on the seriousness of a violation (for example, in terms of the degree of risk to an enrollee's health), failure to comply with notice or appeal requirements in only one or two cases could constitute a substantial failure. Intermediate sanctions include the suspension of enrollment and marketing. We believe that these sanction requirements are most appropriately set forth in the sections of the M+C regulations dedicated to contract provisions (subpart K) and intermediate sanctions (subpart O).

We do not agree that we should add the requirement that an M+C organization's failure to give timely and proper notice shall result in an automatic authorization/approval, or that failure to give timely and proper notice shall result in *automatic* sanctions. In fact, we believe the first recommendation could seriously jeopardize the enrollee's health if, for example, an enrollee requested service that could be harmful to his or her health. We note that in the case of hospital and nursing home services already being provided, we have in part implemented the commenter's suggestion, in that the M+C organization is obligated to continue to cover the services until notice of noncoverage is provided. Also, as mentioned earlier, our sanction authority includes cases where we determine an M+C organization substantially fails to comply with the requirements relating to grievances and appeals in subpart M, including the organization's failure to provide the enrollee with timely and proper notice. Finally, where an M+C organization fails to give proper notice within the time frames required for resolution, § 422.590 requires the M+C organization to submit the file to the independent entity for review. We expect M+C organizations to provide enrollees with written notice for all denials (including the case of a discontinuation of a service where the enrollee disagrees (that?) the services are no longer medically necessary) according to the time frames and notice requirements set forth under subpart M and in operational instructions. However, we do not agree that it is practical, nor does the law mandate, that we require M+C organizations to automatically forward cases for independent review when content of the notice is at issue, and there has not been an adverse organization determination (that is, a coverage denial).

Comment: A commenter suggested that M+C organizations should be required to establish an independent appeals procedure for denials of care.

Response: The M+C statute requires that we contract with an independent review entity to independently review plan denials of care. We believe that this arrangement, along with the other M+C appeal requirements, provide Medicare enrollees with the rights they need, and the rights to which they are entitled.

Comment: Two commenters did not believe that the physician reviewing the reconsideration needed to be of the same specialty or sub-specialty as the treating physician. Requiring the same specialty as the treating physician unduly complicates the reconsideration process in this commenter's view. One commenter pointed out that the BBA Conference Report states that ''It is not the conferees intent to require that a physician involved in the reconsideration process in all cases be of the same specialty or sub-specialty as the treating physician.'' One commenter suggested that *expertise* should be defined in terms of board certification in the specialty, years of experience practicing in the specialty, and active practice. One commenter also suggested that physicians have qualifications other than expertise in the field of medicine that is appropriate for the services at issue. The commenter believes that the reviewing physician should also be formally qualified in the specialty treatment (licensed and actively practicing in the same jurisdiction) as the practitioner providing (or who would provide) the services, and have the appropriate level of training and experience to judge the necessity of the service. To ensure greater professional accountability, a commenter recommended that the reviewing physician's identity be accessible to the physician who recommended, rendered, or would have rendered the treatment under review. One commenter suggested that we also include other rights found in State managed care laws, such as requiring initial (organization) determination denials to be made or approved by a physician.

Response: We agree that a physician involved in the reconsideration process need not in all cases be of the exact same specialty or sub-specialty as the treating physician; therefore, we are revising § 422.590(g)(2) to make this clear. For example, we believe that there may be situations where only one specialist practices in a rural area, and therefore, it would not be possible for the M+C organization to obtain a second reviewer with expertise in the same specialty. In addition, we recognize that there may be some situations where there are few practitioners in highly specialized fields of medicine. Under these circumstances, it would not be possible to get a physician of the same specialty or sub-specialty involved in the review of the adverse organization determination.

With respect to the commenter who specified training that the commenter believes reviewing physicians should have, we believe that our standard of ''appropriate'' expertise addresses this comment. Nor do we believe that it would be appropriate for the reviewing physician's identity to be provided to the treating physician being reviewed. The treating physician has the right to challenge the M+C organization's decision on the merits through several levels of an appeals process. We believe that sufficient accountability exists for reviewing physicians through the appeals process, since a physician whose decisions are reversed on appeal would be accountable to his or her M+C organization. Providing the name of the physician making the initial decision for the M+C organization could result in needless personal harassment of that physician by the physicians he or she reviews.

Finally, we do not agree with the comment that organization determinations should be made or approved by a physician. We do not believe that it is necessary to require physician involvement in all organization determinations that are adverse. Nevertheless, we expect that where adverse determinations are based on a lack of medical necessity, M+C organizations will ensure that appropriate health care professionals will be involved in the decision-making. For example, a nurse practitioner could render an adverse organization determination without the need to involve a physician. Furthermore, if an enrollee believes that the lack of physician involvement was a central factor in an adverse organization determination, then the enrollee need only request a reconsideration since the reconsideration requirements (§ 422.590(g)(2)) specify that a denial of coverage based on a lack of medical necessity must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. (We note that we have made a minor technical change to § 422.590(d) to clarify that the term ''medical necessity'' includes any substantively equivalent term used by an M+C organization to describe the concept of medical necessity.)

Comment: Several commenters provided suggestions on elements for grievance and appeal data.

Response: We appreciate the variety of comments we received concerning categories of meaningful data elements. The comments have provided valuable insight as we continue to work with the public to develop collection and reporting requirements related to organization-level appeals and grievances. Please note that OPLs 99.081 and 2000.114 provide guidance on the manner and form in which M+C organizations will be expected to comply with the requirement under § 422.111 for disclosing grievance and appeal data upon request to M+C-eligible individuals. Collection began April 1, 1999, and the first reporting went into effect on January 1, 2000.

N. Medicare Contract Appeals (Subpart N)

Subpart N of Part 422 addresses M+C contract determinations. There are three types of contract determinations addressed under Subpart N: (1) A determination that a contract applicant is not qualified to enter into a contract with us under Part C of title XVIII of the Act; (2) a determination to terminate a contract with an M+C organization; and (3) a determination not to authorize a renewal of a contract with an M+C organization. Regarding item (1), above, this type of contract determination likewise applies to service area expansion applications.

As indicated in the June 1998 interim final rule, pursuant to section 1856(b)(2) of the Act, most of what comprises subpart N was drawn from regulations in part 417 governing similar contract determinations involving contracts under section 1876 of the Act. We received nine public comments concerning subpart N of the interim final rule.

Comment: We received one comment on § 422.641. The commenter objected to the fact that subpart N, and § 422.641 in particular, does not provide for an appeal mechanism when we and an M+C organization disagree over a term of the organization's M+C contract. The commenter believes that because the Federal Acquisition Regulations (FAR) and contract disputes procedure in Subpart 33.2 of that regulation do not apply to M+C contracts, the M+C final rule should address how these disputes or disagreements will be resolved.

Response: The M+C statute does not contemplate a contract disputes procedure akin to the contract disputes procedure contained in Subpart 33.2 of the FAR. Unlike acquisition contracts subject to the FAR, the terms of M+C contracts are dictated by statute and regulations. M+C organizations have an opportunity for input on the regulations that govern what is included in M+C contracts through the notice and comment process. Ultimately, however, as a matter of Federal administrative law, we are charged with implementing the M+C statute in regulations, and with interpreting and applying its regulations. We attempt, through Operational Policy Letters and other means, to provide guidance to M+C organizations on our interpretations of regulatory provisions, and ultimately, M+C contract terms. In some cases, M+C organizations, or associations representing M+C organizations, have objected to our interpretations of the regulations or to M+C contract terms. In some of these cases, we have taken these objections into account, and we have made modifications. To the extent that an M+C organization remains uncomfortable with the terms of the M+C contract, or of our interpretation of these terms, it ultimately is free not to renew its contract for the following calendar year. We believe that this informal process has worked well, and that there is no need to create a formalized adjudicatory process for addressing disagreements between an M+C organization and us about an M+C contract issue.

Comment: We received several comments about the terminology used throughout subpart N. In particular, commenters noted that the terms used in describing the two categories of entities to which the subpart applies, that is, entities that hold M+C contracts and entities that apply to become M+C contractors, vary throughout the subpart. For example, §§ 422.650(c), 422.650(d), 422.656(a), and 422.660 use three different terms to describe contract applicants: ''entity,'' ''M+C contract applicant,'' and ''applicant entity.'' The commenter recommended that we standardize our use of terminology concerning contract applicants.

Response: We agree with the commenter that the varied use of terms to describe contract applicants is confusing and unnecessary. Therefore, we are revising the regulation text throughout subpart N to refer to organizations applying to become M+C organizations as ''contract applicants.''

Comment: One commenter indicated that in some instances, subpart N refers only to M+C organizations when it presumably should refer to contract applicants as well. For example, § 422.648(b) states that we will reconsider a contract determination if the *M+C organization* files a written request. Presumably, this provision should likewise apply to contract applicants since we also afford these organizations reconsideration rights under subpart N.

A similar issue exists at § 422.656 of the interim final rule. Paragraph (a) discusses giving both the M+C organization and the contract applicant written notice of the reconsidered determination, while paragraph (b)(1) refers only to the M+C organization. Paragraph (b)(3) returns to using both M+C organizations and contract applicants.

Response: We agree with the commenter that contract applicants are also entitled to seek reconsideration pursuant to a Medicare contract determination. Thus, we are revising § 422.648(b) to specify that we will reconsider a contract determination if a contract applicant or M+C organization files a written request for one. We likewise agree that § 422.656(b)(1) should be revised to specify that the provision applies to contract applicants as well as existing M+C organizations, and we are making the needed changes to the regulation text.

Comment: One commenter pointed out that subpart N appears to grant different rights to contract applicants than those available to M+C organizations. This is due, in part, to the provision at § 422.648(b) that states—in error—that we will reconsider contract determinations for M+C organizations, but not contract applicants. In conjunction with the § 422.660 citation mentioned above, this section indicates that applicant entities must seek reconsideration before requesting an appeal, while M+C organizations can appeal a termination or nonrenewal without first seeking a reconsideration. This too stands in contrast to the provision at § 422.662 that contemplates hearings taking place after the initial determination and reconsideration occur.

Response: As mentioned earlier, correcting the language at § 422.648(b) to include contract applicants correctly realigns the language in subpart N to convey that applicant entities and M+C organizations must first seek a reconsideration before proceeding to the hearing stage.

Comment: A commenter believes that the language provided at § 422.662(b) is confusing, because it appears to indicate that contract applicants who are denied a contract by us must file a request for a hearing within 15 days of the date of the contract determination without first receiving notice of our initial determination.

Response: We agree that the language at § 422.662(b) confuses our intent to provide for a contract appeals process that includes—in this order—(1) a

contract determination, (2) an opportunity for reconsideration of the initial contract determination, (3) a reconsidered determination, as necessary, (4) the right to a hearing, as applicable, and (5) for contract terminations, a review by our Administrator. We therefore are changing the language at § 422.662(b) to clearly specify that the affected party must file a request for a hearing within 15 days after the date of the reconsidered determination.

Comment: We received one comment on § 422.668 regarding the disqualification of a hearing officer. Paragraph (b) of this section states that the person designated to be the hearing officer must consider objections from any party to the hearing that relates to any potential bias of the hearing officer. The hearing officer may then proceed with the hearing or withdraw. The commenter suggested that allowing a hearing officer whose impartiality has been questioned the discretion to continue with the hearing is ill-advised. The commenter asserted that if a party believes that the officer is biased, it would be more expedient to resolve that issue immediately instead of proceeding with the hearing.

Response: We believe that in selecting an individual to serve as a hearing officer, the individual's ability to be fair and impartial would be taken into account. Should there be a suggestion of a possible bias, we believe that such an individual would be in a position to evaluate the situation, and determine whether he or she in fact could be impartial with regard to the case in question. Vesting the decisionmaker with this authority to make his or her own determination, subject to appeal only after the matter is heard on the merits, is the same approach used with respect to judges in court proceedings, and we believe is appropriate in this context as well. The alternative could permit an appealing party to delay hearings indefinitely by repeatedly challenging the impartiality of the hearing officer and appealing any rejection of such a challenge.

We believe that § 422.668 provides an adequate remedy to situations where bias of the hearing officer is questioned. This section states that the objecting party may, at the close of the hearing, present objections, request that the decision of the hearing officer be revised, or request a new hearing before a different hearing officer.

Comment: Commenters noted that § 422.692 limits the right to a review by our Administrator to situations involving M+C contract terminations. The commenters questioned whether we intended to deny this level of review in instances in which we nonrenew an M+C contract, or we deny a contract application.

Response: The additional layer of review by our Administrator is intended to apply only to contract termination decisions. This extra level of administrative review was included in the case of termination decisions in order to implement the requirement in section 1857(h)(1)(B) of the Act that M+C organizations have the ''right to appeal an initial decision'' following a termination decision. In providing for review of a hearing officer's decision by our Administrator, we have adopted procedures similar to those used for the Administrator's review of decisions of the Provider Reimbursement Review Board found at § 405.1875.

Comment: A commenter questioned the provision at § 422.696 under which reopening a contract or reconsideration determination is limited to our discretion, the Administrator, or the hearing officer. The commenter asked if the aggrieved party can petition for reopening in any instance.

Response: If an applicant or M+C organization believes it has a basis for re-opening a decision, it may request that the decisionmaker re-open the matter. The decision whether to act on such a request, however, is committed to the decisionmaker's discretion, and is not subject to appeal or further review of any kind. This is consistent with our general policies on re-opening decisions. See, for example, 42 CFR Part 405, Subpart R.

O. Intermediate Sanctions (§§ 422.750 through 422.760)

As stated in the interim final rule, M+C organization actions that are subject to intermediate sanctions include those specified at § 417.500 for contracts under section 1876 of the Act. The BBA also contained additional sanction authority not found in § 417.500, which we have implemented in subpart O. Specifically, section 1857(g)(3) of the Act provides that the Secretary can impose intermediate sanctions and civil money penalties based on a finding that the grounds in section 1857(c)(2) of the Act for terminating a contract are met. These grounds for termination are reflected in § 422.510(a), and are discussed in section II.K and II.N above. While intermediate sanctions based on the grounds for termination at § 422.510 generally are imposed on the same terms as sanctions for the violations specified in § 422.750(a), in the case of all grounds except a finding of fraud or abuse under § 422.510(a)(4), HCFA, rather than the OIG, imposes civil money penalties.

We received 3 comments on subpart O.

Comment: A commenter contended that the intermediate sanctions provisions do not provide Medicare contracting organizations with sufficient appeal rights before intermediate sanctions are imposed. Another commenter argued that the Congress originally intended intermediate sanctions to be an intermediate step less severe than a termination, and that instead suspension of payment for enrollees can be a worse penalty than termination. This commenter believes that the use of intermediate sanctions and civil money penalties has been incorporated as a program management tool, rather than an intermediate step to termination, which the commenter believes should follow sanctions.

Response: In the case of the imposition of a civil money penalty, extensive appeal rights are afforded, including the right to a hearing before the departmental appeals board (DAB). In the case of an ''intermediate sanction,'' however, the entire point of this authority is to allow the Secretary to take swift action to respond to a finding of a serious violation of M+C requirements. Since the sanction is temporary, and only remains in place until corrective actions have been taken, elaborate appeal rights were not contemplated by the Congress, and would not be appropriate. The Congress has demonstrated in section 1857(h) of the Act that it knows how to require specific appeal rights when it wishes to do so. We believe that an M+C organization's interests are sufficiently protected by giving the organization an opportunity to seek reconsideration of a decision to impose intermediate sanctions by demonstrating that the basis for the decision is incorrect, and giving the organization an opportunity to have the sanctions lifted when corrective action is taken. This approach is consistent with what is provided with respect to intermediate sanctions in the nursing home enforcement area. With respect to the second comment, we believe that intermediate sanctions are an ''intermediate step'' between no action and the drastic step of termination, yet do not agree that termination necessarily would follow, unless the organization fails to take corrective action in response to sanctions. Our experience generally has been that organizations respond favorably to sanction letters. The commenter's opinion that an intermediate sanction could be worse than termination may be based on a

misunderstanding of the nature of the sanction referenced by the commenter. The option of suspending payment for enrollees, under section 1857(g)(2)(C) of the Act, applies only to payments for individuals who enroll after the effective date of the sanction. This sanction option, which is available with respect to the violations specified in § 422.752(a), would only apply in a case in which HCFA decided not to impose the sanction of a suspension of enrollment. Finally, the commenter is correct that we view intermediate sanction and civil money penalty authorities as a program management tool that HCFA can employ in the event an organization is not meeting Medicare regulations. Through the use of this tool, HCFA can ensure compliance with regulations without depriving beneficiaries who may be happy with the M+C plan in which they are enrolled of that enrollment option.

Comment: A commenter suggested that HCFA expand intermediate sanctions to include all aspects of grievance and appeals violations.

Response: HCFA has the authority to impose intermediate sanctions for a substantial failure to comply with any grievance and appeal requirement set forth in subpart M. Specifically § 422.752(b) provides that HCFA may impose intermediate sanctions for any violation under § 422.510(a). Section 422.510(a)(6) in turn specifies a substantial failure to ''comply with the requirements in subpart M of this part relating to grievances and appeals'' as a sanctionable violation.

P. Medicare+Choice MSA Plans

1. Background

Among the types of M+C options authorized under section 1851(a)(2) of the Act is an M+C medical savings account (MSA) option, that is, a combination of a high deductible M+C insurance plan (an M+C plan) and a contribution to an M+C MSA. Section 1859(b)(3)(A) of the Act defines an MSA plan as an M+C plan that:

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

2. General Provisions (Subpart A)

Sections 422.2 and 422.4 set forth several definitions for terms connected with M+C MSA plans, including ''M+C MSA,'' ''M+C MSA plan,'' and ''MSA trustee.'' We also distinguish between a ''network'' and a ''non-network'' M+C MSA plan. These definitions consist of general meanings for these terms as used in the BBA, and do not include specific requirements in the definitions themselves. The definition for an MSA does, however, reference the applicable requirements of sections 138 and 220 of the Internal Revenue Code, while the M+C MSA plan definition references the applicable requirements of part 422.

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

a. Eligibility and Enrollment (§ 422.56)

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

- No more than 390,000 individuals may enroll in M+C MSA plans.
- No individual may enroll on or after January 1, 2003, unless the enrollment is a continuation of an enrollment already in effect as of that date.
- No individual may enroll or continue enrollment for any year unless he or she can provide assurances of residing in the United States for at least 183 days during that year.

b. Election (§ 422.62)

Section 1851(e) of the Act establishes general rules concerning the time periods when a beneficiary could elect to enroll in an M+C plan (if one is offered in the beneficiary's area), with special rules for M+C MSA plans set forth at section 1851(e)(5) of the Act. Based on these provisions, § 422.62(d) specifies that an individual may elect an MSA plan only during one of the following periods:

- An initial election period, that is, the 7-month period beginning 3 months before the individual is first entitled to parts A and B of Medicare.
- The annual coordinated election period in November of each year.

4. Benefits (Subpart C)

a. Basic Benefits Under an M+C MSA Plan (§ 422.103)

Section 422.103 incorporates the statutory requirements for M+C MSA plans defined under section 1859(b)(3) of the Act, as outlined above. Thus, § 422.103(a) specifies that an MSA organization offering an MSA plan must make available to an enrollee, or provide reimbursement for, at least all Medicare-covered services (except for hospice services) after the enrollee's countable expenses reach the plan's annual deductible. Further, § 422.103(b) then indicates that countable expenses must include the lesser of actual costs or all the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(c) provides that after the deductible is met, an M+C MSA plan pays the lesser of 100 percent of either the actual expense of the services, or of the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(d), concerning the annual deductible, is based on section 1859(b)(3)(B) of the Act. As the statute specifies, the maximum annual deductible for an MSA plan for contract year 1999 was $6,000. In subsequent contract years, the maximum deductible may not exceed the maximum deductible for the previous contract year increased by the national per capita M+C growth percentage for the year. Thus, based on a national per capita growth percentage of 5 percent, the maximum deductible for 2000 is $6,300. In calculating the maximum deductible for future years, HCFA will round the amount to the nearest multiple of $50.

b. Supplemental Benefits (§§ 422.102 and 422.104)

Section 422.102 addresses the general M+C rules on supplemental benefits.

Unlike other M+C plans, MSA plans are not permitted to include any mandatory supplemental benefits, and are limited in terms of the optional supplementary benefits that can be offered. In accordance with section 1852(a)(3)(B)(ii) of the Act, § 422.104(a) specifies that an M+C MSA plan generally may not provide supplemental benefits that cover expenses that count toward the annual deductible. In addition, section 4003(b) of the BBA added new section 1882 to the Act to prohibit the sale of most supplementary health insurance policies to individuals enrolled in M+C MSA plans. The only exceptions to this rule are spelled out in section 1882(u)(2)(B) of the Act. Further, these exceptions apply both for purposes of the prohibition on selling freestanding supplementary health insurance (or ''Medigap'' insurance), and for purposes of ''optional supplemental benefits'' offered under M+C MSA plans. These exceptions are reflected in § 422.103(b)(2).

5. Quality Assurance (Subpart D)

Consistent with section 1852(e)(2) of the Act, a network model M+C MSA plan must meet requirements similar to those that apply to all other M+C coordinated care plans (with the exception of the achievement of minimum performance levels); the statute and regulations establish different requirements for non-network M+C MSA plans. These requirements are discussed in detail in section II.D of this preamble.

6. Relationships With Providers (Subpart E)

For the most part, subpart E of new part 422 does not establish any requirements that are specific to MSA plans. However, § 422.214, ''Special rules for services furnished by noncontract providers,'' does not apply to enrollees in MSA plans. Section 422.214 implements section 1852(k) of the Act, which contains limits on amounts providers can collect in the case of coordinated care plan enrollees (section 1852(k)(1) of the Act), and private fee-for-service plan enrollees (section 1852(k)(2) of the Act). As explained in the June 1998 interim final rule preamble, it is clear that Congress intended no such limits to apply to services provided to MSA plan enrollees.

7. Payments Under MSA Plans (Subpart F)

Section 1853 of the Act describes the method to be used to calculate the annual M+C capitation rate for a given payment area. We apply the same methodology in determining the annual capitation rate associated with each M+C MSA plan enrollee, though the actual amount paid to an M+C organization offering an M+C plan is not the amount determined under section 1853 of the Act.

The special rules concerning the allocation of the M+C capitated amount for individuals enrolled in M+C MSA plans are set forth at section 1853. In general, HCFA will allocate the capitated amount associated with each M+C MSA enrollee as follows:

- On a lump-sum basis at the beginning of the calendar year, pay into a beneficiary's M+C MSA an amount equal to the difference between the annual M+C capitation rate calculated under section 1853(c) of the Act for the county in which the beneficiary resides and the M+C MSA premium filed by the organization offering the MSA plan (this premium is uniform for all enrollees under a single M+C MSA plan, or segment of a plan service area, if authorized under section 1854(h). (See section I.C.7 for a discussion of the BBRA changes in this regard). This results in a uniform amount being deposited in an M+C MSA plan enrollee's M+C medical savings account(s) in a given county, since the uniform premium amount will be subtracted from the uniform county-wide capitation rate for every enrollee in that county.

- On a monthly basis, pay to the M+C organization an amount equal to one-twelfth of the difference, either positive or negative, between the risk adjusted annual M+C capitation payment for the individual and the amount deposited in the individual's M+C MSA.

Section 422.262 contains the regulations concerning the allocation of Medicare trust funds for enrollees in M+C MSA plans.

8. Premiums (Subpart G)

Section 1854 of the Act establishes the requirements for determination of the premiums charged to enrollees by M+C organizations. Like other M+C organizations, organizations offering M+C MSA plans in general must submit by July 1 of each year information concerning enrollment capacity and premiums. For M+C MSA plans, the information to be submitted includes the monthly M+C MSA plan premium for basic benefits and the amount of any beneficiary premium for supplementary benefits. These requirements are set forth under section 1854(a)(3) of the Act and § 422.306(c) of the regulations.

9. Other M+C Requirements

The remaining requirements under subpart 422 have few, if any, implications specific to M+C MSA plans. One issue that we discussed in the interim final rule, however, involves the provision of section 1856(b)(3)(B)(i) of the Act (and § 422.402(b)) that any State standards relating to benefit requirements are superseded. We recognize that this provision means that State benefit rules will not apply (for example, State laws that mandate first dollar coverage for particular benefits such as mammograms or other preventative services). Some States may not license entities to offer catastrophic coverage, and it is possible that M+C MSA plans could not be offered in that State. We invited public comment on this issue.

10. Responses to Comments

Comment: We had requested comments on the establishment of a minimum deductible for MSA plans. We had suggested the possibility of establishing the minimum deductible equal to the projected actuarial value of the average per capita copayment under original Medicare. For 1999, that amount would have been $1000. In response, we received three comments. One commenter supported a minimum deductible but recommended that it be higher, $2000—$3000. Two other commenters opposed the minimum deductible, stating that it would be counterproductive, and would preclude organizations from offering plans feasible for lower income beneficiaries.

Response: Since that there is neither clear consensus on the issue nor any actual experience under the demonstration, we do not believe it would be appropriate at this time to set a minimum deductible. Therefore, we will continue with only a maximum deductible as specified in the Act, but will include an analysis of the deductible issue in the evaluation of this program.

Comment: One commenter requested clarification of § 422.56 specifying how an MSA should be treated in the Medicaid eligibility process.

Response: We are not planning to address the issue of Medicaid eligibility in these regulations. However, this is a valid issue that needs to be addressed in Medicaid eligibility regulations.

Comment: One commenter expressed a concern that MSA enrollees may fail to pay physician claims, based upon experiences with existing deductibles under Medicare. Further, the commenter feared that enrollees might decrease their use of noncovered

elective services, such as elective screening and initial diagnostic examinations.

Response: Assuming that an M+C organization chooses to offer an MSA plan, beneficiaries would be advised before they enroll in the plan that they are responsible for initial medical expenses for the year, and each enrollee would have an MSA account to pay at least part of those expenses. Whether they would be able to meet all of their obligations would be considered in the evaluation. The purpose of the M+C MSA program is to permit beneficiaries to play a greater role in their health care purchasing decisions. The program does provide them with incentives to discourage the overutilization of health care services. We had considered requiring first-dollar coverage for services such as certain screening procedures, but decided that would be contrary to the intent of this demonstration.

Comment: One commenter stated that the maximum enrollment of 390,000 beneficiaries would be a disincentive for organizations to participate in the MSA demonstration. This would be too small a number to permit organizations to devote the resources to developing and marketing a high-deductible MSA policy.

Response: The limit of 390,000 enrollees over the course of the MSA demonstration was specified under section 1851(b)(4) of the Act. We are not at liberty to change that requirement by regulation. Nevertheless, as we previously stated, we do not believe that number would be reached over the course of the demonstration if an M+C organization chose to offer an MSA plan.

Comment: We had solicited comments regarding the issue of whether we should establish sample standardized MSA plans similar to the limited number of Medigap plans. Two organizations commented, both opposing standardized MSA plans as unnecessary and overly restrictive.

Response: We agree with the commenters that there is no need to establish standardized MSA plans under the demonstration.

Comment: Two organizations expressed concern that some States may not license insurers to provide high-deductible policies, thus limiting the availability of MSA plans.

Response: The Act requires that an M+C organization wishing to offer an MSA plan be licensed by the State as a risk-bearing entity, and that the State determine that it can reasonably assume the risk that it would assume under the M+C plan it proposes to offer. It does not require that the organization be licensed commercially to offer a high deductible policy. Therefore, an M+C organization could offer an MSA plan in a State in which the State does not commercially license high deductible plans. The M+C organization must have the State's approval to do so, however.

Comment: Two commenters asserted that the requirement to submit encounter data would be unduly burdensome for M+C organizations offering MSA plans, particularly for non-network MSA plans. Further, M+C organizations may not have access to claims incurred under the MSA deductible.

Response: This issue was discussed at length during the development of the M+C regulations. Of particular concern was the fact that non-network MSA plans may not see enrollee claims should those claims not exceed the deductible. The possibility of requiring enrollees to submit claims regardless of whether the insurer would have liability was discussed, but dropped as burdensome for enrollees. We believe it is in the interest of the Medicare program that the encounter data submission requirement be maintained for all M+C plans, including MSAs. Should an organization approach HCFA about offering an MSA plan, we would work with the organization on its compliance with these requirements. (For example, enrollees who reach the deductible probably would be required to submit documentation of claims totaling the deductible amount. This documentation might be used to supply encounter data.)

Comment: Four commenters addressed the quality performance measures and the required data submissions. One commenter offered support for the performance improvement projects for MSAs and other M+C plans. Two commenters found the health data requirements for MSAs to be unrealistic, particularly for non-network plans, and likely to deter the offering of MSA and PFFS plans. A fourth commenter recommended that if certain quality assurance data are not available for certain categories for MSAs and PFFS plans, beneficiaries should be made aware of this lack of information.

Response: M+C organizations offering MSA plans are required by statute to adhere to specified quality standards. Quality performance standards in the June 1998 interim final rule have been modified to accommodate the particular characteristics of an MSA, and the fact that a report will be done on the MSA demonstration (assuming that an M+C organization chooses to offer an MSA plan). We recognize the fact that non-network MSAs may not have access to an enrollee's claims unless that individual's total claims exceed the deductible. In addition, MSAs may not be structured to provide incentives to beneficiaries to obtain preventive and diagnostic services. HCFA is reviewing the quality requirements to make sure that they are feasible for the specific plan for which they are specified.

Comment: One commenter questioned the ''community-rated'' MSA contributions for all beneficiaries enrolled in an MSA plan, and the lack of balance billing protections for MSA enrollees. Another commenter described the payment methodology as arcane and confusing, and the possibility of a negative premium as absurd.

Response: After lengthy discussions with industry representatives and other officials, the fixed MSA contribution for all beneficiaries in a specific plan in a specific area seemed to be the approach most consistent with legislative intent. Also, HCFA made a point of clarifying that no balance billing restrictions were included in the statute, and that Congress intended that there be none. As has been previously stated, a negative premium is not impossible, but we would expect an MSA plan to set its premium in a given market at a level to avoid such a possibility.

O. M+C Private Fee-for-Service Plans

1. Background and General Comments

As noted above, one type of M+C option available under section 1851(a)(2) of the Act is an M+C private fee-for-service (PFFS) plan. Consistent with the statutory definition of an M+C private fee-for-service plan at 1859(b)(2)(A) of the Act, the regulations state that an M+C PFFS plan is an M+C plan that: Pays providers at a rate determined by the M+C organization offering the PFFS plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide the services, and agree to accept the plan's terms and conditions of payment. The requirements M+C organizations must meet to contract with HCFA to offer an M+C PFFS plan generally are incorporated into the relevant sections of the M+C regulations. An M+C organization wishing to offer a PFFS plan must meet all of the requirements that apply with respect to offering any other type of M+C plan, except to the extent that there are special rules that apply to M+C PFFS plans.

Comment: One commenter contended that HCFA should examine alternatives to the ACR process for ensuring good value under PFFS and MSA plans. The ACR restriction on the premium may conflict with the role envisioned for these plans as paying high fees to providers to ensure unrestricted access.

Response: The commenter is mistaken in the belief that there are restrictions on premiums for M+C MSA and PFFS plans. There is no restriction on the premiums that may be charged for these plans (see § 422.306(e)(2)).

Comment: A commenter noted that the regulations create a loosely defined option in which the organization offering a PFFS plan fills in the details of the plan. The commenter questioned whether many beneficiaries would be motivated to join such a plan, whether insurers would be motivated to offer an option that could have such limited appeal. As currently constructed, the commenter believes that M+C PFFS plans are not likely to be viable, and therefore are not likely to be made available to beneficiaries. This in the commenter's view mitigates against the espoused concept of offering a meaningfully expanded range of options. The commenter suggested that HCFA work with the physician community to do demonstrations to explore what features of the M+C PFFS statute should be changed so that Medicare can offer a viable M+C PFFS defined contribution plan.

Response: We recognize that the statute created a loose structure for M+C PFFS plans, and that therefore M+C plans may vary greatly from one another in how they function. This is a direct consequence of the law. However, we believe that, as currently constituted, M+C PFFS plans are viable. We have received an application for a 30-State, largely rural M+C PFFS plan, and have reason to expect to receive more applications within the next year.

2. Beneficiary Issues

Comment: A commenter objected to the M+C PFFS plan option on the basis that the commenter believes it leaves the beneficiary vulnerable. The commenter's objections included the lack of a quality assurance program to protect beneficiaries, as well as the absence of a cap on premiums or out of pocket expenses, resulting in the possibility that beneficiaries could be charged up to 15 percent over the plan payment amounts. The commenter contended that beneficiaries would be better protected if the PFFS option were not offered.

Response: We recognize that some beneficiary protections provided for under the coordinated care plan option are not included for M+C PFFS plans. In some cases, such as certain quality assurance requirements, these protections may be less critical in an environment in which the enrollee has complete freedom of choice to use any provider in the country, and is not limited to a defined network of providers. We note that the quality assurance requirements that apply to coordinated care plans do not at this time apply to original Medicare either, which is also a ''fee-for-service'' arrangement. With regard to the absence of certain limits on beneficiary financial liability, we believe that this makes it particularly important that beneficiaries make a prudent consumer decision when choosing this option. However, we also believe that this alternative can provide a valuable alternative to original Medicare in areas that are not served by coordinated care plans, rural areas in particular. Moreover, we anticipate that, as we gain experience with M+C PFFS contracts, we will determine what changes we need to make to the regulations, or ask Congress to consider improving this M+C option, should we decide that such changes are needed. (We note that we have recently approved the first PFFS plan and intend to monitor its performance closely in order to identify and assess potential beneficiary protection issues.)

Comment: A commenter urged that marketing information to seniors and providers clearly differentiate between traditional Medicare and M+C PFFS plans, as there are substantially different payment schedules, balance billing rules, and premiums that can be charged for M+C PFFS purposes than for original Medicare.

Response: We agree that there is a significant potential for confusion between original Medicare and the M+C PFFS option, and we have tried to clarify the distinction between these options in our 1999 and 2000 Medicare handbooks (Medicare and You). We are also considering the best way to make this distinction clear in our model explanation of coverage for M+C PFFS plans. The model evidence of coverage document is created for an M+C organization to use as a model for the explanation they provide to beneficiaries about the plan's terms and conditions of coverage. We are currently adapting the existing Evidence of Coverage for coordinated care plans for use in the case of PFFS plans.

Comment: A commenter recommended that we require providers furnishing services to PFFS enrollees and MSA enrollees to give notice if they think the plan may not cover a service. The commenter believes that the same limitations on liability protection that apply in original Medicare should apply to M+C PFFS plans and MSA plan beneficiaries. Moreover, the commenter suggested providers be required to give enrollees of M+C PFFS plans a notice of the expected balance billing amounts that exceed $250 or more (not just the more than $500 notice required of hospitals).

Response: Unlike under original Medicare, the statute does not provide any protection against enrollee or provider liability for services that a M+C PFFS plan determines are not medically necessary to treat illness or injury, and the law does not require providers to give an advance notice to enrollees of the likelihood of plan noncoverage. Therefore, there is no basis in law to require an M+C organization to offer such protection in its plan. Of course, the organization may, if it chooses, build such protection into its plan, and we believe that doing so may be necessary to attract and keep enrollees. Moreover, an enrollee and provider clearly may seek an advance determination of coverage from the M+C organization under the organization determination regulations in part 422 subpart M. Thus, the enrollee and provider have the opportunity to seek a plan determination of coverage before receiving the service, and we encourage them to avail themselves of this option.

With respect to the notice of anticipated cost sharing, the law requires such a notice for hospital services, but not for other services. The M+C organization could, however require that contracting and deemed contracting providers of other types furnish such a notice in advance of providing care as a term and condition of payment, and could set whatever tolerance they chose for such a notice.

We chose the $500 threshold for a notice of out-of-pocket expenses that a hospital may collect from the enrollee because it mirrors the $500 threshold long established by law at section 1842(m)(1) of the Act. Section 1842(m)(1) of the Act requires that a nonparticipating physician who does not accept assignment on the Medicare claim must give the beneficiary advance notice if the actual charges that will be collected from the beneficiary equal or exceed $500. While the benefit to which the threshold applies is different, the concept of advance notice of amounts to be collected from the enrollee is the same, and therefore use of the same threshold is justified.

3. Provider Payment Issues

Comment: A commenter urged that HCFA establish standard payment deadlines, and contended that those for M+C PFFS plans should mirror those for original Medicare.

Response: We believe that the prompt payment provisions of § 422.520 largely accomplish this, since they apply to all claims submitted ''by, or on behalf of an M+C private fee-for-service enrollee.'' Since the benefits under a PFFS plan are the enrollee's benefits, we believe that any claim submitted on behalf of a PFFS plan enrollee is subject to the clean claim standard in § 422.520. While written agreements with PFFS plan providers must address this issue, and better terms may be negotiated, we have interpreted the reference to fee-for-service enrollees in section 1857(f)(1) of the Act to cover all claims involving PFFS enrollees. Under this standard, the M+C organization must pay 95 percent of the ''clean claims'' within 30 days of receipt, if they are submitted by or on behalf of an enrollee of the M+C PFFS plan, and are not furnished under a written agreement between the M+C organization and the provider. Moreover, the M+C organization must pay interest on clean claims that are not paid within 30 days as required by sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act for original Medicare.

Comment: A commenter argued that the prompt payment rules at § 422.520 permit payers to ''game'' the clean claim policy by building in a float between the receipt of Medicare payment and the payment to the providers, and recommended that HCFA establish a standard that would apply for PFFS network providers where an organization offering an M+C PFFS plan effectively imposes a delay as a condition of getting the contract.

Response: The prompt payment provisions that apply to all PFFS plan claims ensure against a float of more than 30 days in the case of a ''clean'' claim.

Comment: A commenter suggested that HCFA require M+C organizations offering PFFS plans to give physicians 30 days notice of changes to fee schedules, and should require them to follow CPT coding conventions in the same manner as original Medicare.

Response: M+C organizations offering PFFS plans must pay noncontracting providers at least the amounts they would receive under original Medicare (less the enrollee's cost-sharing); therefore, there is no potential for changes to the payment rates other than through the annual Medicare fee schedule changes. Also, in order to meet access requirements without having a network in place that satisfies coordinated care plan rules, an M+C organization offering a PFFS plan must pay contracting providers (both those with signed and deemed contracts) at least the Medicare payment rate. In this case, again, providers could count on Medicare payment notices. In all cases, however, providers either will negotiate rates in written and signed contracts, or have the opportunity to learn payment information before providing services under a deemed contract.

4. Noncontracting Provider Issues

Comment: A commenter contended that the regulations should clarify whether a noncontracting provider is precluded from balance billing beneficiaries, and must accept as payment in full rates that are no less than what would be paid under original Medicare. The commenter believes it is not clear: (1) If those rates would include the limiting charge of 115 percent; (2) if noncontracting providers are entitled to direct payment from the M+C organization; or (3) what amounts may be balance billed. The commenter suggested that enhanced balance billing should have been provided as an incentive to sign a contract, but because of the deemed contract provisions, this basic premise for contracting is lost.

Response: The law permits, but does not require, an M+C PFFS plan to permit contracting providers (with both signed and deemed contracts) to balance bill up to 15 percent of the PFFS plan payment rate for the service, in addition to the cost-sharing established under the plan. The statute expressly applies this to deemed contractors as well. Therefore, the balance billing that an M+C plan may permit contracting and deemed contracting providers to collect will be set by the organization offering the plan. The M+C organization will pay under its terms and conditions of payment, and the contracting or deemed contracting provider may collect the cost sharing and any balance billing permitted by the plan (which cannot exceed 15 percent of the PFFS plan payment rate).

In the case of noncontracting providers (that is, providers that neither have a written contract with the M+C organization offering the PFFS plan nor meet the criteria for a deemed contract), there is no balance billing permitted; by law, the provider may collect no more than the plan's cost sharing. Under section 1852(k)(2)(B) of the Act, the beneficiary liability limits governing payment to noncontracting providers are the same for M+C PFFS plans as for M+C coordinated care plans. We have clarified this by indicating in § 422.214 that the special rules for payment to noncontracting providers that apply for M+C coordinated care plans also apply for M+C PFFS plans. Specifically, the provider must accept as payment in full the amount that it would be entitled to receive under original Medicare, and the plan must pay the provider the amount that the provider would collect if the beneficiary were enrolled in original Medicare, less the enrollee's cost-sharing. For example, if the physician participates in Medicare, the plan would pay the noncontracting physician the Medicare allowed amount less the plan's cost-sharing. In the case of a nonparticipating physician, the plan would pay the Medicare limiting charge less the enrollee's cost-sharing. In the case of an acute care hospital, the plan would pay the diagnosis-related group (DRG) payment less the enrollee's cost-sharing. In the case of a nonparticipating durable medical equipment, prosthetic and orthotics (DMEPOS) supplier, the plan would pay actual charges less the enrollee's cost-sharing.

While the law addresses the payments to providers and the payment liabilities of beneficiaries, it does not specify whether the M+C organization must pay the provider, or whether it may function as an indemnity plan and pay the enrollee, for services for which the enrollee has paid the provider. Moreover, the discussion of prompt payment by M+C plans at section 1857(f) of the Act contemplates that the M+C organization may make payment to the beneficiary. Hence, the M+C organization may determine to whom (provider or beneficiary) it will make payment for covered services. However, we anticipate that M+C organizations will want to make payment to providers of services, rather than to beneficiaries since we believe that minimizing beneficiary paperwork and confusion is necessary to attract and keep enrollees in the plan.

5. Quality Assurance (§§ 422.152 and 422.154)

As discussed in section II.D of this preamble concerning quality assurance requirements, M+C PFFS plans and non-network MSA plans (and now PPO plans) are exempt from some of the quality assurance requirements that apply to network model M+C plans. The statute also exempts these plans from external quality review if they do not have written utilization review protocols. As with all other requirements for M+C organizations and M+C plans, those provisions of regulations that are not identified as

limited to coordinated care plans or MSA plans also apply to M+C PFFS plans.

Comment: Commenters suggested that § 422.154 affirmatively states that M+C organizations, including those offering MSA plans and PFFS plans, must coordinate with an external entity's (that is, a PRO's) investigation of beneficiary quality of care complaints. These commenters believe that beneficiary complaints are an important indicator of quality of care problems, and that all M+C plans should have to cooperate in investigating them.

Response: The statute relieves an M+C organization offering a PFFS plan of responsibility for contracting for external quality review if it does not carry out utilization review with respect to services covered under the plan.

6. Access to Services (§ 422.214)

Like other M+C plans, an M+C private fee-for-service plan must offer sufficient access to health care. Section 422.114(a) specifies that an M+C organization that offers an M+C PFFS plan must demonstrate to HCFA that it has sufficient number and range of health care providers willing to furnish services under the plan. Pursuant to the specific instructions of the law, under § 422.114(a), HCFA will find that an M+C organization meets this requirement if, with respect to a particular category of provider, the plan has: Payment rates that are not less than the rates that apply under original Medicare for the provider in question; contracts or agreements with a sufficient number and range of providers to furnish the services covered under the plan; or a combination of the above. These access tests must be met for each category of service established by HCFA on the M+C organization application. Thus, if an M+C PFFS plan has payment rates that are no lower than Medicare, it need not address if it has a sufficient number of providers of services under written contract. However, where the plan's payment rates are less than the Medicare payment for that type of provider, the M+C organization must demonstrate that the plan has a sufficient number of providers of that type under written contract.

Medicare payment amounts are established in a variety of different ways. For many of the key services for which Medicare pays, Medicare has prospectively set payment amounts or fee schedules that are established by HCFA and published in the **Federal Register** each year. These include, but are not limited to, prospective payment systems for acute care hospital services, and skilled nursing care, and fee schedules for physician services (which includes care by many nonphysician practitioners and diagnostic tests), durable medical equipment, and clinical laboratory services. Moreover, HCFA is currently developing prospective payment systems or fee schedules for other key services including home health care, ambulance services, and outpatient hospital care, which we expect to be implemented within the next year or two.

However, for some services, Medicare payments are set retrospectively or concurrently by Medicare carriers and intermediaries. For example, until the prospective payment systems or fee schedules are implemented, home health care, outpatient hospital care, and ambulance services will be paid by carriers and intermediaries based upon a HCFA-specified national methodology that they apply either upon receipt of the claim (for example, ambulance services paid on a reasonable charge basis) or long after the service is furnished (for example, retroactive cost report settlement). Moreover, there are some services for which reasonable cost and reasonable charge payment will continue indefinitely. Examples of these services are critical access hospital care (which by law must be paid actual cost without limits) and carrier priced physician services (for which the service is too new or too rare to support a national fee schedule value).

Clearly, where there are national prospective payment systems and fee schedules, M+C organizations offering PFFS plans should have no problem in paying amounts no less than the Medicare payment amount for covered services since those amounts are clearly and prospectively published by HCFA. However, the question arises as to how the access test based on Medicare payment levels can be met with regard to services that are paid by Medicare intermediaries or carriers on a reasonable cost or reasonable charge basis. Moreover, consistent with section 1852(d)(4) of the Act and § 422.214(b), M+C organizations offering PFFS plans cannot restrict providers from whom the beneficiary can acquire care. Therefore, the M+C organization must have the capacity to pay no less than the Medicare-allowed amounts for any Medicare-covered service furnished by any provider in any area of the nation. Acquiring the payment amounts from individual Medicare intermediaries and carriers would be a cumbersome and difficult task, and would be likely to result in unwanted payment delays. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish proxies for use in paying services for which no Medicare prospective payment system or fee schedule exists.

The law and regulations permit the use of HCFA-approved proxies as long as those proxies result in payment amounts that are ''not less than'' Medicare payment rates. If the payment amounts to be paid by the M+C organization are equal to or more than the Medicare payment amounts for those services, the requirement of the law and regulations are met and HCFA must find that the PFFS plan provides for adequate access to care for those categories of services. Therefore, in cases of services for which there is no prospective payment system or fee schedule amount, we will permit M+C organizations to pay proxy amounts under certain circumstances. These proxy amounts must be approved by HCFA as approximating as closely as possible what providers as a whole receive for certain services. Because we expect these payment proxies would be estimates, the M+C organization must also have a process for reviewing these amounts, if necessary, on a provider-by-provider basis. If a provider is able to demonstrate that the proxy amount is less than the amount Medicare would actually pay, the M+C organization must pay the latter amount.

Proxies will take different forms, depending upon what makes the most sense for the type of service being paid. For example, a hospital that is paid on reasonable costs subject to a limit may be paid a percent of charges that is taken from the provider's last settled Medicare cost report. Similarly, an ambulance supplier may be paid the prevailing charge adjusted for the IC that applies in the year in which the service is furnished. Where proxies are used, HCFA will require that a description of the proxy methodology must be included in the terms and conditions of plan payment for deemed contractors that must be made available to providers of services before they treat an PFFS enrollee (see § 422.216(h)(2)(iii)(B)). As nationally established prospective payment systems and fee schedules are developed and implemented by HCFA, the use of proxies should diminish. However, at this time, and for the foreseeable future, for a limited subset of Medicare-covered services, proxies will be necessary for organizations offering M+C PFFS plans that choose not to contract directly with providers. For the reasons discussed above, we believe that their use comports with both the spirit and intent of the law and regulations.

7. Physician Incentive Plans (§ 422.208)

In § 422.208(e), we specify that an M+C PFFS plan may not use capitated payment, bonuses, or withholds in the establishment of the terms and conditions of payment. This is necessary to implement that part of the definition of an M+C plan that specifies that the plan must pay without placing the provider at financial risk.

8. Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

As discussed in detail in our June 1998 interim final rule (63 FR 35040), § 422.216(a) addresses payment to providers. Specifically § 422.216(a)(1) provides that the M+C organization offering a PFFS plan must pay all contract providers (including those that are deemed to have contract under § 422.216(f)) on a fee-for-service basis at a rate, determined under the plan, that does not place the provider at financial risk. This reflects the statutory definition of an M+C PFFS plan. We also specify in § 422.216(a)(1) that the payment rate includes any deductibles, coinsurance, and copayment imposed under the plan, and must be the same for all providers paid pursuant to a contract whether or not the contract is signed or deemed to be in place. Section 422.216(a)(3) establishes the payment rate for noncontracting providers.

Section 422.216(b) addresses permissible provider charges to enrollees. Under § 422.216(b)(1), contracting providers (including deemed providers) may charge the enrollee no more than the deductible, coinsurance, copayment, and balance billing amounts permitted under the plan. Like payment rates, the plan deductible, coinsurance or copayments and other beneficiary liability must be uniform for services furnished by all contracting providers, whether contracts are signed or deemed to be in place. These two requirements are closely related, since permissible enrollee liability is linked by statute to the plan's payment rate. These cost-sharing amounts must be specified in the plan contract. The plan must have the same cost-sharing for deemed contract providers as for contract providers, and it may permit balance billing no greater than 15 percent of the payment rate for the service.

Other significant requirements set forth in § 422.216 address monitoring and enforcement of the payment and charge provisions (§ 422.216(c)), notifications to plan members concerning payment liability, including balance billing rules (§ 422.216(d)), and rules covering deemed contract providers, including enrollee and provider notification requirements associated with these providers regarding payment terms and conditions (§§ 422.216(f), (g), and (h)).

9. Deemed Contracting Providers

Comment: One commenter endorsed having the same standards for deemed and contracting providers so that an M+C PFFS plan does not become a PPO without the quality assurance standards of a PPO. Other commenters objected to the concept of deemed contracting providers, because they believe that it will reduce provider willingness to provide services in these plans, and because they believe it is unfair to physicians, particularly those who provide emergency care.

Specifically, a commenter indicated that M+C organizations offering PFFS plans will not be able to get providers to sign contracts because there is no incentive for a provider to bind itself to a contract when it is not promised a share of the market in the area, and when it will be paid like a contracting provider, whether it signs a contract or not, under the deemed contracting provisions. Commenters indicated that there will be problems determining the ''deemed contract'' vs. the noncontract status of providers, since it depends on what they knew at the time of service. A commenter said that HCFA should tighten the rules under which deeming can be presumed, and seek statutory modifications to limit the use of deeming.

Some commenters indicated that emergency department physicians should not be deemed contractors because the M+C organization could blanket an area with terms and conditions of plan payment, and thereby force them to accept terms and conditions with which they did not agree, since they must treat all patients who present in the emergency department. They commented that HCFA should stipulate that deeming is never presumed to have occurred when emergency services or urgent care are required, particularly when they are required under the Emergency Medical Treatment and Labor Act. Other commenters recommended that the deemed contract language should be amended to explicitly not apply to out of network service provided in an emergency department, and to require that all physicians who provide services in the emergency department be paid as noncontracting providers. Commenters believe that this is needed because, under the Medicare provider agreement anti-dumping rules, the hospital must ensure that all patients who present in the emergency room are seen and that, therefore, the physicians on duty have no ability to choose not to provide care to the enrollee. Under the deemed contracting provisions of the law, they are forced to accept the terms and conditions of plan payment when they treat the patient.

Response: We recognize that the law provides little or no incentive for a provider to sign a contract with an M+C PFFS plan because of the deemed contracting provisions. We also agree that the deemed contracting requirements of the law are problematic, particularly in emergency room settings, and will create disputes between M+C organizations and providers about what the provider knew and when it was known.

The statute specifies that the M+C organization must treat providers that do not have a contract with the plan as if they had such a contract, if the provider knew that the beneficiary was enrolled in the plan, and either knew the terms and conditions of plan payment, or had reasonable access to those terms and conditions.

In general, if the beneficiary has advised the provider of his or her plan enrollment (as is often requested by the provider before providing care), and the provider knows the terms and conditions of plan payment (for example, because the physician or the party to whom the physician has reassigned benefits has received the plan terms and conditions in writing), or has a reasonable opportunity to learn the terms and conditions of plan payment (for example, through a toll free phone number, a website, or by having been sent a copy of the terms and conditions of plan payment), in a manner reasonably designed to effect informed agreement by a provider, then the provider meets the statutory test of being a deemed contracting provider, and the law requires that he or she must be treated as such. The law and regulations presume that, if the provider meets the criteria as a deemed contracting provider and subsequently treats the enrollee, then the provider has implicitly demonstrated agreement to the terms and conditions of payment by treating the enrollee.

While the law does not provide an explicit exception to the deemed provider provisions for emergency or urgent care services, we acknowledge that there are special circumstances that surround services in an emergency department of a hospital that justify considering providers who have not signed a contract with the PFFS plan to be noncontracting providers when they furnish services in an emergency

department of a hospital. We have revised § 422.216(f) accordingly.

When a physician or hospital has not signed a contract with a PFFS plan but treats a plan enrollee in an emergency department of a hospital, the physician or hospital has no opportunity to refuse to treat the patient as the deemed contracting provisions of the law anticipate. Hence, we believe that it is appropriate to specify that a physician or hospital that furnishes services in the emergency department of a hospital on behalf of the hospital's obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA) cannot be deemed to be a contracting provider. Of course, if the physician or hospital has previously signed a contract with the PFFS plan, the physician or hospital is a contracting provider, and is bound by the terms and conditions of that contract. Moreover, once the services furnished in the emergency department of a hospital cease to be required under § 489.24, the criteria that determine whether the providers are deemed contracting providers or noncontracting providers would then apply.

III. Provisions of this Final Rule—Changes to the M+C Regulations

For the convenience of the reader, listed below are all significant changes to the M+C regulations that are set forth in this final rule. Please note that changes stemming from the BBRA, which—unlike those changes listed below—are subject to public comment, are all discussed in a discrete section of this preamble (section I.C) and thus are not listed here. In addition, we caution the reader that the list below is intended solely as a reference aid, rather than as a policy summary.

- In § 422.2, we are revising the definition of ''service area'', as well as making minor technical changes to several other definitions.
- We are revising § 422.50(a) to allow individuals and employer group members who become entitled to Medicare and live outside of the service area to convert to an M+C plan if they were previously enrolled in a commercial plan offered by the M+C organization, provided these individuals receive full plan benefits and M+C access and availability standards are met.
- To allow us the flexibility to vary the timeframes for the enrollment transmission schedule in the future, we are amending § 422.60(e)(6) to state ''upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization transmits within time frames specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.''
- We are revising § 422.60(f)(3) to state that ''upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA.''
- In order to avoid introducing confusion between responsibilities of M+C organizations and HCFA, we have eliminated material in § 422.64 concerning HCFA's information responsibilities and moved necessary material to § 422.111.
- We have modified § 422.66(b)(3)(i) to state that the timeframe to submit disenrollment transactions will be ''specified by HCFA,'' and have made a conforming change at § 422.66(f)(2), as opposed to within 15 days.
- At § 422.66(d) we are clarifying that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by ''an'' M+C organization to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling.
- At § 422.74(b)(3)(ii) we are permitting an M+C organization that has reduced an M+C plan's service area to offer continued enrollment in one of its M+C plans to enrollees in all or a portion of the reduced area if enrollees agree to receive ''basic benefits'' exclusively at designated facilities within the plan's new service area.
- We are adding a provision to § 422.74(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.
- We are changing the requirement at § 422.74(d)(4) to state that the M+C must disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area for over 6 months, rather than 12 months.
- We are adding wallet card instructions to the list of examples of marketing materials at § 422.80(b)(5)(v), to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services.
- We are revising § 422.80(e) to permit more flexibility for providers in distributing materials to M+C enrollees.
- We are adding a new § 422.80(e)(1)(viii) that prohibits new M+C plan names that exclude the disabled population.
- We are removing the definition of post-stabilization services in § 422.100(b)(1)(iv) and instead including all post-stabilization requirements in new § 422.113. See section II.C of this preamble for a full discussion of changes in the post-stabilization requirements.
- We are specifying at § 422.100(b)(1)(vi) and § 422.113 that M+C organizations are required to cover ambulance services dispatched through 911 or its local equivalent when use of other forms of transportation would endanger the health of the beneficiary.
- We are adding a provision at § 422.101(a) to state explicitly that services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.
- To promote beneficiary freedom of choice among providers, § 422.105 is revised to permit use of the POS option for in-network providers, rather than only for providers outside the plan network.
- To clarify our existing policy, we are clearly delineating HCFA's review authority in § 422.106 for employer group health plans and Medicaid plans.
- We are adding a new § 422.108(f) to clarify that a State cannot take away an M+C organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer.
- We are revising § 422.109(b)(5) to provide that M+C enrollees are responsible only for coinsurance amounts.
- We are revising § 422.111(e) to decouple the enrollee notice time frame from the ''issuance or receipt'' of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date.
- We are revising § 422.112(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.
- At new § 422.113(b) we are specifying that ''urgently needed services'' are not ''emergency services.''
- We are clarifying at § 422.113(b)(2)(ii) that prior authorization may not be required from the beneficiary in wallet card instructions or in other enrollee materials . We are also specifying that instructions on what to do in an emergency should include a statement

specifying that in the event of an immediate and serious threat to health, the enrollee may call 911.

• We are revising § 422.113(b)(2)(iii) to expressly set forth the requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson definition of emergency at § 422.2 regardless of final diagnosis.

• In order to clarify the distinction between a removal of deemed status by HCFA based on HCFA's own survey and a removal based on a determination by an accreditation organization based on its accreditation survey, we are revising § 422.156(a) to separate these two situations.

• We are revising § 422.157(a)(3) to relax the prohibition on the participation of managed care organization representatives in private accreditation organization activities.

• We are revising § 422.158(e) to provide that we will act within the same timeframes that apply to fee-for-service deeming.

• To help clarify that the appeals procedures apply only for adverse participation decisions, we are redesignating the provider appeals procedures from § 422.204(c) to new § 422.202(d).

• Section 422.204 has been re-titled ''Provider selection and credentialing'' and contains the general rule that an organization must have written policies and procedures for the selection and evaluation of providers.

• We are consolidating the regulations concerning antidiscrimination and choice of providers into new § 422.205. We reaffirm that M+C organizations are prohibited from discriminating against providers based solely on their licensure or certification, and specify that when an M+C organization declines to include a provider in its network, it must notify the provider of the reason for its decision.

• We have revised § 422.214 to clarify the rules concerning payments to noncontracting providers.

• We have revised § 422.216(f) to indicate that, for PFFS purposes, ''deemed contract'' providers are considered to be noncontracting providers when they furnish services in an emergency department of a hospital.

• We are revising § 422.257 to permit M+C organizations to require that their contractors provide them with complete and accurate encounter data.

• We are adding two terms—''first tier'' and ''downstream''—to the list of definitions at § 422.500 that we believe clarify the types of entities to which the M+C contracting requirements described at § 422.502(i) apply.

• We are revising the definition of ''clean claim'' in § 422.500 to require that claims include data for encounter data submission, and meet the original Medicare ''clean claim'' requirements in order to be considered a clean claim.

• In consultation with the Office of Inspector General, we are revising the compliance plan requirements under § 422.501 to eliminate mandatory self-reporting.

• In order to ensure that M+C enrollees are not put at financial risk in situations where provider groups or other entities ''downstream'' from an M+C organization become insolvent, we are revising § 422.502 to strengthen the protections for Medicare enrollees in situations where an M+C organization or its contractors encounter financial difficulties.

• Section 422.502(l), concerning certifications of the accuracy of payment data, has been modified to be consistent with the OIG's ''good faith'' standard, under which M+C organizations certify the accuracy of payment information to their ''best knowledge, information, and belief.'' We are also permitting the delegation of this responsibility to individuals other than the CEO or CFO of the M+C organization.

• We are revising § 422.506(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year.

• We are deleting § 422.506(b)(ii) in response to a concern that the standard for declining to renew an M+C contract was too vague to enforce.

• We are adding a new § 422.510(a)(12) that would specify that a substantial failure to comply with marketing guidelines is grounds for termination, non-renewal, or intermediate sanction.

• We are changing the language at section § 422.520(a)(3) to indicate that non-clean claims and the remaining 5 percent of clean claims not paid within 30 days must be either paid or denied within 60 calendar days from the date of the request.

• We are revising the definition of an organization determination under § 422.566 to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights.

• To further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both §§ 422.568(a) and 422.572(b) that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision.

• We are revising § 422.568(c) and (d) to modify the requirement concerning written notification of M+C enrollees when a service is denied in whole in or part.

• We have added new § 422.619 concerning effectuation of expedited reconsideration determinations.

• We have revised § 422.620 to eliminate the requirement that M+C organizations distribute to enrollees the notification of noncoverage of inpatient hospital care.

We have also made many minor technical and conforming changes to the M+C regulations to ensure that citation references are accurate, use more consistent terminology, and correct typographical errors in the current regulations.

IV. Collection of Information Requirements

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

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain information collection requirements.

Note: Unless otherwise noted below, all information collection requirements in this rule are currently approved under OMB approval #0938–0753, which currently expires August 31, 2000.

Section 422.60 Election Process

Paragraph (b) of this section states that M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by § 422.306(a)(1). The

burden associated with this reporting provision is captured under § 422.306.

Section 422.74 Disenrollment by the M+C Organization

Paragraph (c) of this section requires that if the disenrollment is for any reason other than death or loss of entitlement to Part A or Part B, the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures. This requirement is currently approved under 0938–0763, which expires March 31, 2003.

Section 422.111 Disclosure Requirements

Paragraph (e) requires the M+C organization to make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days (revised from 15 days) before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The burden associated with this requirement has not changed.

Section 422.113 Special Rules for Ambulance Services, Emergency and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services

Paragraph (b)(2) of this section requires that enrollees be informed of their right to call 911.

The burden associated with this disclosure provision is the time it takes an M+C organization to inform each beneficiary of his or her right. In addition, instructions to seek prior authorization for emergency services and/or before the enrollee has been stabilized may not be included in any materials furnished to the enrollee. We anticipate that these requirements will be provided as part of standard enrollment disclosures. Therefore, the burden associated with this requirement is contained in section 422.64.

Section 422.152 Quality Assessment and Performance Improvement Program

Paragraph (e) of this section requires that an organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan to measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this reporting provision is the time it takes an M+C organization to gather and submit the information. ''All Medicare+Choice organizations and an organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan will be required to measure performance under their plans, using standard measures required by HCFA, and report their performance to HCFA. Reporting will be required annually. Currently the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB #0938–0701. The currently approved annual per plan burden is estimated to be 400.53 hours. Therefore, the total burden associated with this requirement is 180,239 hours (400.53 hours × 450 plans (100 new/350 current)).

Section 422.202 Participation Procedures

Paragraph (d) of this section requires that an M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees give the affected individual written notice as required by this section.

This section also requires that an M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

The burden associated with these reporting provisions is the time it takes an M+C organization to write the notice and give it to the practitioner and the appropriate licensing, or disciplinary bodies or to other appropriate authorities. We estimate that it will take 450 plans, 10 hours to produce and disclose 10 notices on an annual basis, for a national annual burden of 4,500 hours.

In addition this paragraph requires that 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.

The burden associated with this reporting provision is the time it takes an M+C organization and provider to write the notice and furnish it to the other party. We estimate that 450 entities will be required to write 10 notices, at 1 hour per notice, for a national annual burden of 4,500 hours.

Section 422.205 Provider Antidiscrimination Rules

The reporting requirement of this section requires that, if an M+C organization declines to include a given provider or group of providers in its network, it furnish written notice to the affected provider(s) of the reason for the decision.

The burden associated with this reporting provision is the time it takes an M+C organization to write and provide the required notice. We estimate that it will take 450 plans, 30 minutes to produce and disclose 20 notices on an annual basis, for a national annual burden of 4,500 hours.

Section 422.206 Interference With Health Care Professionals' Advice to Enrollees Prohibited

The reporting requirement in paragraph (b)(2) requires that, through appropriate written means, an M+C organization make available information on any conscience protected policies to HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111. With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice within 90 days after adopting the policy at issue.

The revision to the information collection provisions requires the M+C organization to make available policy changes. We estimate that it will take 30 minutes for each of the 450 M+C organizations to comply, for a total of 2,225 hours nationally on an annual basis.

Section 422.257 Encounter Data

Paragraph (d)(1) of this section requires that M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service, when appropriate, and to all relevant national standards. M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services. In addition, M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of

complete and accurate encounter data as required by HCFA.

The burden associated with this paragraph is currently approved under OMB approval #0938–0753.

Section 422.568 Standard Timeframes and Notice Requirements for Organization Determinations

Under paragraph (a) of this section, when a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee. When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

The revision to this provision is that requiring the M+C organization to notify the beneficiary of its reasons for delay and of the right to file a grievance.

We estimate that this requirement will add 40 hours for each of the 450 M+C organizations to the burden currently captured under 0938–0753, for an annual addition of 18,000 hours.

Under paragraph (c), at each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed notice from the M+C organization regarding the enrollee's services. The practitioner must provide the enrollee with complete information, using approved notice language in a readable and understandable form, necessary to contact the M+C organization.

The burden associated with this reporting provision is the time it takes a practitioner to notify the beneficiary. We estimate that there will be 160 encounters per entity (450) and that each notification will take an average of 15 minutes to do so, for a national annual burden of 4,500 hours.

Under paragraph (d), if an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

In addition to the currently approved burden under 0938–0753, the burden associated with this reporting provision is the time it takes to write the detailed decision and provide it to the beneficiary. We estimate that there will be 160 occasions per entity (450) for which a detailed decision must be provided and that each notification will take an average of 15 minutes for a national annual burden of 4,500 hours.

Under paragraph (e), the notice of any denial under paragraph (d) of this section must, in addition to currently approved requirements, (1) for service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and (2) for payment denials, describe the standard reconsideration process and the rest of the appeal process.

The burden associated with this reporting provision is the time it takes an M+C organization to add the required information to a notice. We estimate that it will take 450 plans 1 hour to produce and disclose the necessary language on an annual basis, for a national annual burden of 450 hours.

Section 422.570 Expediting Certain Organization Determinations

The information collection requirement in this section ((d)(2)(iii)) that is not currently approved under 0938–0753 requires that, if an M+C organization denies a request for expedited determination, it must take give the enrollee prompt oral notice of the denial and subsequently deliver, within 2 calendar days (proposed as 2 working days), a written letter that informs the enrollee of the right to resubmit a request for an expedited determination with a physician's support. The currently approved burden, associated with this requirement has not changed.

Section 422.572 Timeframes and Notice Requirements for Expedited Organization Determinations

The information collection requirement change to paragraph (b) requires that, when the M+C organization extends the deadline, it notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension.

The additional burden associated with this requirements set forth in this section is the time it takes an M+C organization to notify the beneficiary of the delay and the reasons for it. We estimate that 450 plans will provide extension notices to approximately 100 of their M+C enrollees on an annual basis and it will take an average of 5 minutes per notification. Therefore, the annual national burden is estimated to be 3,750 hours.

Section 422.584 Expediting Certain Reconsiderations

The information collection change to this section requires that, if an M+C organization denies a request for expedited reconsideration, it must give the enrollee prompt oral notice, and subsequently deliver, within 2 calendar days, a written letter that (in addition to currently approved disclosure requirements) informs the enrollee of the right to resubmit a request for an expedited reconsideration with a physician's support.

The one time burden associated with this disclosure requirement is the time it takes an M+C organization to add the requisite language to the letter it furnishes to the beneficiary. We estimate that it will take each M+C organization (450) an average of 30 minutes to add the language to its current letter for notifying beneficiaries, for a national annual burden of 2,250 hours.

Section 422.620 How Enrollees of M+C Organizations Must Be Notified of Noncoverage of Inpatient Hospital Care.

The information collection change to this section the clarification that in *all* cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, the hospital (as provided under paragraph (d) of this section) or M+C organization must provide written notice to the enrollee that includes the elements described in this section. The burden associated with this requirement is currently approved and captured under 422.622.

We have submitted a copy of this final rule to OMB for its review of the revised information collection requirements in §§ 422.60, 422.74, 422.111, 422.113, 422.152, 422.205, 422.206, 422.257, 422.568, 422.570, 422.572, 422.584, and 422.620. 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 N2–14–26, 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 Heron Eydt, HCFA Desk Officer.

V. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Section 1102(b) of the 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

As a result of changes to the M+C regulations to reflect provisions of the BBRA, this rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). We consider a major rule to be one with economic effects of $100 million or more in a given year, and as noted below in section V.B.8 of this regulatory impact analysis, the effects of the BBRA changes reach this threshold. Generally, a major rule takes effect 60 days after the date the rule is published in the **Federal Register**. In this case, however, as discussed in detail above in section I.C of this preamble, the BBRA included specific effective dates for its various M+C provisions. For the most part, the statutory changes are self-explanatory, and have already taken effect. Thus, except as provided under the BBRA, the provisions of this final rule with comment period take effect 30 days after publication in the **Federal Register**.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more. This final rule with comment period will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below these thresholds as well.

1. Summary of the Final Rule

As discussed in detail above, this rule implements only limited changes in the M+C regulations published June 26, 1998 (and further amended February 17, 1999). While we do not expect the changes contained in this final rule to have a significant economic impact, we believe that we have a responsibility to keep the public informed of the impact of inherent features of the M+C program, such as payment changes and the implementation of risk-adjusted payments. We attempted to describe the impacts of these payment changes in the interim final rule. However, after a year of experience administering the program, we now have a better understanding of the impact of the payment changes. This impact analysis will examine payment effects associated with these two items, and respond to public comments concerning the economic impact of M+C policies.

2. Summary of Comments on Impact of M+C Program

Although commenters on the interim final rule generally recognized that the payment methodology and rates associated with the M+C program were implemented as directed by the BBA, several commenters still expressed concern that resulting payments to M+C organizations were insufficient to keep pace with the costs of providing medical care. These commenters suggested that the new payment methodology, particularly when combined with the implementation of a risk adjustment mechanism in 2000, could have the unintended consequence of limiting, rather than expanding, the health plan choices available to Medicare beneficiaries. M+C organizations have withdrawn from some areas, and many beneficiaries have experienced growing premium increases or benefit reductions. Commenters also asserted that the M+C regulations contained discretionary provisions that added unnecessarily to the administrative burden on M+C organizations. In particular, commenters identified quality standards, provider participation requirements, and attestation procedures as examples of what they considered overly proscriptive rules that had the potential to raise health plan costs. In general, commenters urged us to evaluate more carefully the cumulative impact of the changes introduced by the M+C program.

We noted in our February 17, 1999 limited M+C final rule that we needed a statistically-based model to evaluate the total impact of payment changes for M+C organizations. We have subsequently developed a model that estimates the impact of risk-adjusted payments on M+C organizations. This impact analysis focuses on results from this model. When possible, we provide detail on impacts by geographic area and by organization size.

We then discuss some of the concerns raised by commenters about likely withdrawals from the M+C program. Finally, our analysis examines available information concerning the administrative burden associated with selected M+C requirements.

B. Payment Changes

1. Background

Prior to the BBA, Medicare's capitation rates for managed care plans had been set at 95 percent of expected costs based on actual fee-for-service costs. Because of the variation in fee-for-service expenditures for different counties due to different utilization patterns and cost structures, the Medicare managed care rates for different counties were also quite divergent. In addition, there was significant evidence that Medicare had paid more for enrollees in the Medicare managed care programs than it would have paid in the fee-for-service program. This was due primarily to the favorable selection that these plans have experienced.

The BBA made a number of changes in Medicare payments to managed care plans including:

- Increasing payments in counties that historically had the lowest payment rates (and generally have not had risk-based Medicare managed care plans) through the use of a payment floor and by introducing a blended payment rate.

• Reducing the rate increases in counties that historically had higher payment rates.

• Reducing M+C capitation rates by phasing in the removal of direct and indirect medical education payments from M+C capitation rates beginning in 1998 (and phasing in direct payment of these ''carved out'' amounts to the institutions providing care to M+C enrollees).

Payment increases from year to year after 1997 are based on an update factor that is the rate of increase in projected Medicare expenditures each year, less a statutorily specified reduction (reducing the rate to .8 percent less in 1998 and .5 percent less each year thereafter through 2002). However, all counties are guaranteed a minimum payment increase of 2 percent over the preceding year's base rates.

The BBA also mandated the introduction, by the year 2000, of risk-adjusted payments in the M+C program. Risk adjustment will have the effect of reducing payments to plans because, as a number of studies have shown, relatively healthier Medicare beneficiaries enroll in M+C plans. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations can do better under risk adjustment than they would if case mix stayed the same.

These M+C payment changes were intended to promote the three objectives which we discuss below in V.B.2, 3 and 4.

2. Promote the Availability of M+C Plans in Lower Payment Areas

The introduction of a ''floor'' on the payment rates for M+C organizations was intended to make the program financially viable in areas where the AAPCC appeared to be too low for any organization to recoup its costs. Beginning in 1998, the floor was set at $367 and was adjusted annually by the rate of growth of the overall Medicare program. By providing this floor payment level, M+C organizations are paid more than would otherwise be spent on the same beneficiaries in original Medicare.

Some county payment rates are raised through implementation of blended payments. These rates are calculated as a blend of national average rates adjusted for local input prices and area-specific rates. Area-specific rates are 1997 payment rates, adjusted for spending for graduate medical education, and updated using the national M+C update factor.

By raising the M+C payment levels higher than the spending amounts in original Medicare, it was hoped that M+C organizations would be attracted to these lower payment areas. In the chart below, we have compared the M+C county payment rates for 2001 to the area-specific rate in each county. In 2001, 3,020 counties will receive a payment rate higher than their area-specific rate. The payment rate for Arthur, Nebraska, will be 77 percent or $175 higher, the greatest improvement for any county.

The payment floor and the phased in blended payments were also designed to raise the payment level for more than just the lowest payment counties. Raising payments above the levels determined by the pre-BBA methodology was intended to give organizations that have operated in lower payment counties the opportunity to enhance their benefit packages, thereby increasing enrollment.

The largest improvements in payments are for areas with relatively small numbers of beneficiaries, and are largely achieved in most cases by applying the payment floor. Many more beneficiaries live in counties where the improvements are more modest (up to a 5 percent difference). These counties were primarily those paid under the blend mechanism in 2000, whose payment improvements were safeguarded by the minimum increase component of the formula for 2001.

Following is a breakout of the 3,147 U.S. counties by percentage improvement over their area specific rate:

TABLE 1.—PERCENT DIFFERENCE BETWEEN M+C PAYMENT RATES AND AREA-SPECIFIC PAYMENT RATES, 2001

Percentage difference	Number of counties	Number of beneficiaries (000s)	Payment is floor	Payment is blend	Payment is minimum increase
Negative	127	1,318	0	0	127
0 to 5	1,000	15,741	0	0	1,000
5 to 10	946	9,848	62	0	884
10 to 20	572	4,133	401	0	171
20 to 30	264	888	264	0	0
30 to 40	131	408	131	0	0
40 to 50	68	142	68	0	0
50 to 60	26	52	26	0	0
60 to 70	9	18	9	0	0
70 to 80	4	5	4	0	0
Total	3,147	32,554	965	0	2,182

Source: HCFA, CHPP.

Counties where M+C payment rates are lower than their area-specific payment rate tend to be those that have received the minimum increase for each of the four years that the M+C payment formula has been in place, and also had relatively little medical education spending. The cumulative four-year increase of the national update was approximately 9.3 percent, only a percentage point higher than the cumulative four-year increase of 8.2 percent for those counties receiving the minimum update each year. The area-specific payment rate in 2001 reflects a reduction to the 1997 rate of 80 percent of spending attributable to medical education. Thus, a county with relatively high medical education spending will have a higher M+C payment rate than area-specific payment rate even if it also had received the minimum update each year.

3. Reduce the Wide Disparities in Payments Between High and Low Payment Areas

By changing how payment rates are calculated, the BBA also sought to even out the wide disparity in Medicare managed care payment rates across

counties, an issue that had been a concern for lower-payment areas. Table 2 shows the percentage of counties that received the floor, a blended rate, or the minimum 2 percent increase for each year calculated using the BBA methodology.

TABLE 2.—PERCENT OF COUNTIES RECEIVING FLOOR, BLEND, OR 2 PERCENT INCREASE

Year	Floor counties (percent)	Blend counties (percent)	2 percent counties (percent)
1998	33.8	00.0	66.2
1999	39.7	00.0	60.3
2000	29.1	63.1	7.8
2001	30.7	00.0	69.3

Source: HCFA, CHPP.

There were only limited payment increases for 1998 and 1999, with counties receiving either the floor payment or the minimum 2 percent update. This was due primarily to the combined effects of the amount of the national update and the budget neutrality provision affecting calculation of the blended rate. In 2000, however, well over half the counties are receiving the blended rate. The enrollment-weighted average increases in M+C payments nationwide in the year 2000 over 1999 is slightly more than 5 percent. For 2001, all counties will receive the floor payment or the minimum 2 percent update, again because of the budget neutrality provision and a national update that reflects the extremely low rate of spending in original Medicare in 1999. Although most counties will receive the minimum increase in 2001, many of these had enjoyed relatively large increases due to the blended rates in 2000, which the minimum increase essentially will preserve.

As illustrated in the graph below (1997 Medicare+Choice Payment Rates Compared with 2001 Payment Rates), the new payment formulas have changed the distribution of payment rates across counties, although perhaps not as quickly as the Congress envisioned because of the unusually low national increases in spending. In 1997, county payment rates for aged beneficiaries ranged from $221 to $767. Through the implementation of the payment floor, blended payment rates, and minimum update, payments have increased substantially at the low end of the distribution, and increases at the high end have slowed. The range of payment rates in 2001 is only somewhat smaller: between $415 and $831, but the 2001 payment curve is straighter than the 1997 curve, indicating a narrower distribution.

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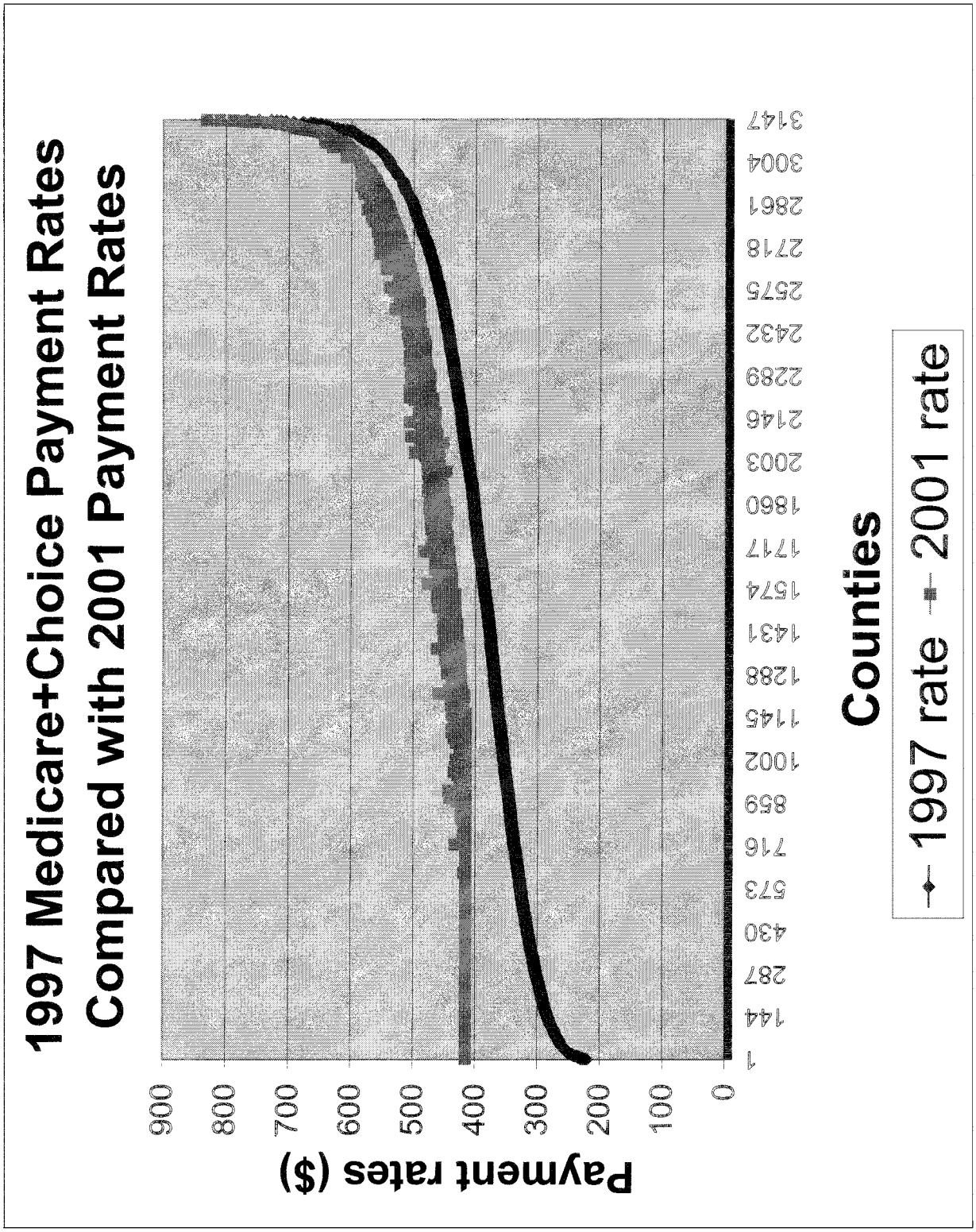

Source: HCFA, CHPP

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While national numbers show the overall pattern, the impact is highlighted when examining the effect of the BBA on the payment rates at the State level. Table 3 shows the effect of the payment changes in two States: Oregon and Florida. Both States have significant M+C enrollment penetration, but Oregon's rates are low, and Florida's are high.

The BBA payment changes have narrowed the regional difference. In 1997, prior to the BBA payment changes, Florida's weighted average payment rates were 149 percent higher than those of Oregon. (Florida's statewide average payments were at 114 percent of the national average, while Oregon's were at 76 percent.) In 2001, Florida's rates will be 136 percent of Oregon's, because many Oregon counties had benefited from blended payment rates in 2000, while many large Florida counties received the minimum update that year.

Lower-paid States such as Oregon receive relatively higher rates of payment increases than higher-paid States such as Florida. These differential payment increases will bring both States' average payments closer to the national average payment rate.

TABLE 3.—COMPARISON OF MEDICARE+CHOICE PAYMENT RATES IN OREGON AND FLORIDA

State	Weighted average payment rate 2001	Weighted average payment increase 97–01 (percent)	Payment rate as a percent of national 1997 (percent)	Payment rate as a percent of national 2001 (percent)
Oregon	$435.25	22.5	76	83
Florida	581.15	9.6	114	111
National	523.85	12.4	100	100

Despite the BBA changes, the levels of benefits and premiums between higher and lower payment counties continue to vary in 2000. In Oregon, for example, premiums range from $35 to $83 for benefit packages that do not include outpatient drug coverage, and between $81 and $123 for packages including drug coverage. In Florida the enrollment-weighted average monthly premium is $84 per month, and all enrollees in Florida M+C plans have drug coverage in their basic package. Over time, the BBA payment changes may narrow this difference.

4. Establish a Fairer Payment System

The BBA mandated that we ''implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment [to M+C organizations] starting no later than January 1, 2000.'' The BBA also gives us the authority to collect inpatient hospital data for discharges occurring on or after July 1, 1997, and allows us to require additional data from M+C organizations for services occurring on or after July 1, 1998.

a. Description of the Inpatient Risk Adjustment Model. In implementing the BBA mandate, we selected the Principal Inpatient Diagnostic Cost Group (PIP–DCG) model as the risk adjustment method to implement in 2000. Under the PIP–DCG model, individuals are assigned to a single PIP–DCG group based on the principal inpatient diagnosis they were assigned during an inpatient stay, that has the greatest future cost implications. The model is prospectively based; in other words, base year inpatient diagnoses are used in the model to predict payment year health expenditures. The model also uses age, sex, original reason for Medicare entitlement (such as age or disability), and entitlement to state payments for Medicaid to derive a predicted expenditure level. This predicted expenditure amount is then converted to beneficiary relative risk factors by dividing an individual's predicted expenditures by the national mean. Because this model was developed and calibrated using a year of inpatient diagnoses, a full year of data is essential for assigning beneficiary risk factors. Beneficiaries ''new'' to Medicare (for whom no prior diagnosis information exists) have their payments based on the average expenditures for their age group. To determine risk adjusted monthly payment amounts for each M+C enrollee, individual risk factors will be multiplied by the appropriate payment rate for their county of enrollment.

We decided to include a transition period as a component of our risk adjustment methodology, initially using a blend of payment amounts under the current demographic system and the PIP–DCG risk adjustment methodology. Under a blend, payment amounts for each enrollee will be separately determined using the demographic and risk methodologies (that is, taking the separate demographic and risk rate books and applying the demographic and risk adjustments, respectively). These payment amounts would then be blended according to the percentages for the transition year. This transition to full risk adjusted payment will be phased in over 5 years. Following is the transition schedule to comprehensive risk adjusted payment as mandated by the BBRA:

Calendar year	Demographic method (percent)	PIP–DCG method (percent)
2000	90	10
2001	90	10
2002	80	20

b. Impact of Risk Adjustment. The impact analysis presented here employs a ''point in time'' approach. To estimate the payment impact of the risk adjustment change, we compared actual demographic-based payments to estimated risk adjusted payments for the exact same enrollees for September 1998. Aggregated to the M+C organization level, the difference in these amounts represents a reasonable estimate of change in payment due to risk adjustment. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations can do better under risk adjustment than they would if case mix stayed the same.

This analysis uses the best data available at this time. The data to be used for actual payments (beginning January 1, 2000) will be based on hospital discharge data for the calendar year beginning on July 1, 1998 and ending June 30, 1999. The actual impact of the risk adjustment system relative to the current demographic system at the time of implementation may differ, due primarily to potential changes in M+C organization enrollment profiles and possible improvement in the quality and completeness of M+C organization data.

The impacts presented here show estimated figures for both the full effects of the PIP–DCG based payment system (that is, with no transition period), and for the first implementation year during which a 10 percent phase-in was included as part of the methodology. To estimate impacts under phase-in years, full impact results can be multiplied by the appropriate proportion of the risk adjustment payments. For example, the first year risk adjusted payment phase-in level is 10 percent. Therefore, to estimate the impact under a 10 percent risk adjusted phase-in, the impacts can be multiplied by .10.

If our methodology did not include a transition period, payments to M+C organizations would decrease by approximately 5.7 percent. This is a revision over preliminary estimates of 7.6 percent, which were prepared using an earlier, more limited data set. The majority of M+C organizations would face payment decreases of between five and eight percent.

The table below presents the simulated impacts aggregated to our administrative regions. None of our regions will experience increased payments under the proposed system. The variation between regions is not considerable. Organizations in the Atlanta region will see an average .7 percent reduction, and organizations in the Seattle region will see less than a .4 percent reduction.

TABLE 4.—PAYMENT SUMMARY FOR SELECTED M+C ORGANIZATIONS BY HCFA REGION

Region	Enrollees	Percent difference (phase-in)	Percent difference (full impact)
Boston	359,819	−0.55	−5.50
New York	564,252	−0.35	−3.47
Philadelphia	583,740	−0.66	−6.61
Atlanta	895,021	−0.70	−7.00
Chicago	530,558	−0.50	−4.97
Dallas	472,627	−0.69	−6.93
Kansas City	154,223	−0.61	−6.14
Denver	128,069	−0.62	−6.25
San Francisco	1,710,117	−0.57	−5.69
Seattle	282,765	−0.35	−3.45
Total	5,681,191	−0.57	−5.74

In addition, we simulated impacts by M+C organization enrollment size. Table 5 reveals that the variation in impact between the small M+C organizations and the large M+C organizations does not appear to be systematic. M+C organizations of all sizes are very close to the national average, although smaller organizations will experience a slightly higher reduction.

TABLE 5.—PAYMENT SUMMARY FOR SELECTED M+C ORGANIZATIONS BY SIZE OF ENROLLMENT

Enrollment size	Enrollees	Percent difference (phase-in)	Percent difference (full impact)
Less than 500	5,115	−0.71	−7.10
500–2,999	88,594	−0.81	−8.10
3,000–4,999	993,829	−0.69	−6.87
5,000–9,999	354,271	−0.62	−6.22
10,000–24,999	1,177,118	−0.58	−5.79
25,000–49,999	1,029,859	−0.54	−5.41
50,000–99,999	1,471,009	−0.52	−5.23
100,000 or more	1,455,843	−0.61	−6.09
Total	5,681,843	−0.57	−5.74

5. M+C Organization Withdrawals

At the end of 1998, approximately 100 organizations dropped Medicare managed care contracts or reduced the number of counties in which a plan was offered. The result of these withdrawals was that nearly 50,000 beneficiaries were left with no remaining M+C plan in their county. Likewise, the analysis of 1999 health plan departures shows that approximately 79,000 additional M+C beneficiaries were forced to leave the program because there was no plan offered in their area.

Table 6 below shows the decline in beneficiaries' access to a M+C plan in their area (declining about 2 percentage points from the 1999 level of almost 70 percent).

TABLE 6.—PERCENT OF BENEFICIARIES WITH ACCESS TO M+C PLANS

1999			2000		
Urban	Rural	Total	Urban	Rural	Total
84.2	22.5	69.7	82.0	20.8	67.7

Of the 71 counties that had an M+C plan in 1999 but will no longer have an M+C option in 2000, 11 were considered high payment counties. In fact, the average increase in 2000 for these 71 counties is 6.2 percent. The county in this situation with the greatest increase was Clallum County, in Washington State, which received a blended rate increase of 12.8 percent over their 1999 rate.

Plan decisions to withdraw from M+C do not appear to be caused only by changes in payment amounts. Payment is rising in all counties this coming year by an average of 5 percent, and will rise by as much as 18 percent in some areas. BBA payment reforms were designed to increase payment in counties that had the lowest rates, and therefore the fewest number of plans. Yet counties receiving the largest increases under the BBA payment system are experiencing the most disruption. Plan withdrawals are affecting 11.1 percent of enrollees in counties where rates are rising by 10 percent, but affecting only 2.3 percent of enrollees where rates are rising by just 2 percent.

Table 7 shows the States with the largest percentage decrease since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

TABLE 7.—STATES WITH LARGEST PERCENT DECREASE IN ACCESS TO M+C OPTION IN 2000 FROM 1997

State	Total Medicare population	Decrease in beneficiaries	Percent decrease in beneficiaries
Utah	207,838	183,541	88
Louisiana	621,826	175,645	28
Virginia	894,573	246,274	28
New Hampshire	172,069	45,627	27
South Carolina	575,890	130,118	23
Maryland	652,599	119,392	18

While several States have experienced a significant loss of access to M+C plans, other States have seen access to M+C organizations increase. In addition, the M+C program continues to grow despite challenges that parallel those in the larger managed care market in the United States. As of January 2000, there were 6.2 million M+C enrollees representing over 16 percent of the more than 39 million seniors and disabled Americans in Medicare. Total Medicare managed care enrollment has more than doubled in the past four years from 3.1 million enrollees at the end of 1995 to 6.9 million enrollees as of April 1, 2000. (Total managed care enrollees consist of M+C enrollees and enrollees in Medicare Managed Care Cost Plans, Health Care Prepayment Plans, and managed care demonstrations.) However, the rate of growth has dropped significantly from earlier periods, and has grown by only 1 percent per month the last several months.

Table 8 below shows the States with the largest percentage increase since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

TABLE 8.—STATES WITH LARGEST PERCENT INCREASE IN ACCESS TO M+C OPTION IN 2000 FROM 1997

State	Total Medicare population	Increase in beneficiaries	Percent increase in beneficiaries
Maine	219,944	138,067	63
Iowa	488,180	171,017	62
South Dakota	122,220	118,493	29
Oklahoma	519,239	114,185	24
West Virginia	345,587	65,794	20
North Carolina	1,149,374	54,040	18

6. Premium Increases

In our Impact Analysis that accompanied the Interim Final Rule we stated that ''Reductions in capitated payment amounts in what are now relatively higher payment areas may result in reduced benefits for beneficiaries.'' While higher premiums and reduced benefits were not intended effects of the BBA, they are also not surprising given the reduced payment increases in higher cost areas. While benefits, premiums, and cost sharing remained relatively stable in 1999, year 2000 has been different.

Analysis of the Adjusted Community Rate proposals submitted in July show that premiums for 2000 have increased, especially in rural areas. For example, in 1999, the enrollment-weighted average premium for a basic plan was $5.35. For 2000, this amount will almost triple to $15.84.

Table 9 shows the percent of M+C beneficiaries living in the designated areas that have access to a plan with the associated premium. While the percent of beneficiaries with access to zero dollar premium plans is expected to be reduced by more than 3 percentage points, the percent of beneficiaries that must pay a $40–$100 premium has more than doubled. In 1999, only 50,000 Medicare beneficiaries lived in an area where the minimum premium is in the $80 to $100 range; however, in 2000, the number will rise to 207,000. The majority of these individuals (60 percent) are residents of rural counties.

TABLE 9.—PERCENT OF BENEFICIARIES LIVING IN DESIGNATED AREAS HAVING ACCESS TO AN M+C PLAN WITH ASSOCIATED PREMIUM 1999

Premium amount	1999			2000			Total percent change
	Urban (percent)	Rural (percent)	Total (percent)	Urban (percent)	Rural (percent)	Total (percent)	
$0	79	63	78	78	40	75	−3
$0.01–$19.99	1	2	2	3	11	4	2
$20.00–$39.99	5	14	5	9	18	9	4
$40.00–$59.99	4	11	5	6	17	6	2
$60.00–$79.99	1	8	2	1	7	2	0
$80.00–$99.99	0	0	0	0	0	1	1

In addition, access to a zero premium plan for rural beneficiaries will be reduced by almost 50 percent. In 1999, 1.3 million rural beneficiaries (63 percent of those with any plan available) live in an area with at least one zero premium plan; in 2000, only 784,000 rural beneficiaries, (40 percent of those with any plan available), will have such an option. One-half million fewer rural beneficiaries will have access to a zero premium plan.

7. Premiums in Areas With Only One Plan

Medicare beneficiaries who live in areas with only one plan will be particularly affected by premium increases. Approximately 8 percent of M+C beneficiaries (just over three million) live in areas with only one plan. Note also in Table 10 that of the 207,000 beneficiaries who live in areas where the minimum monthly premium available is over $80, 94 percent (over 195,000) live in areas with only one plan available. There will be a nearly six-fold increase from 1.6 percent to 9.3 percent in the percentage of beneficiaries who live in an area where the sole M+C plan available has a monthly premium in the $80 to $100 range.

TABLE 10.—MEDICARE BENEFICIARY POPULATION (TOTAL), ACCESS TO ONLY ONE PLAN

Minimum premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	803,162	31.6	599,553	28.4
$0.01–$19.99	17,614	0.7	0	0.0
$20.00–$39.99	467,284	18.4	410,662	19.5
$40.00–$59.99	716,662	28.2	683,029	32.4
$60.00–$79.99	499,095	19.6	220,237	10.4
$80.00–$99.99	39,742	1.6	195,432	9.3
Total	2,543,559	100	2,108,913	100

Premium increases in areas with only one plan will have the most pronounced impact in rural areas. From 1999 to 2000, roughly the same percentage of beneficiaries who live in rural areas will have only one plan available—28.4 percent and 29.6 percent in each year, respectively. However, Table 11 shows that zero premium plans are becoming less widely available in rural areas. It also shows that there will be a significant increase in the number of rural Medicare beneficiaries whose only M+C option is a relatively high cost plan.

TABLE 11.—MEDICARE BENEFICIARY POPULATION (RURAL ONLY) ACCESS TO ONLY ONE PLAN

Minimum premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	271,833	37.7	174,956	28.1
$0.01–$19.99	17,614	2.4		0.0
$20.00–$39.99	96,131	13.3	104,796	16.8
$40.00–$59.99	135,440	18.8	146,425	23.5
$60.00–$79.99	160,647	22.3	81,774	13.1
$80.00–$99.99	39,742	5.5	115,669	18.5
Total	721,407	100	623,620	100

8. Impact of BBRA

The Balanced Budget Refinement Act (BBRA) made two changes to the payment methodology established by the BBA. First, Section 512 of the BBRA introduced bonus payments for M+C organizations that enter previously unserved counties. These organizations will receive an additional 5 percent payment for the first 12 months and an additional 3 percent for the subsequent 12 months. The second change in section 517 of the BBRA was to lower the reduction in the National per Capita Medicare +Choice Growth percentage

from a 5 percent reduction to a 3 percent reduction in calculating the 2002 payment rates.

The Congressional Budget Office (CBO) estimated that the bonus payments would amount to additional payments of $.1 billion over three years. Our experience to date suggests that this figure may be high, as currently there are only five M+C organizations receiving bonus payments and very few pending applications from prospective M+C organizations that would be eligible for the bonus. However, there is an application on file from a prospective M+C organization that envisions expanding into a large number of previously unserved counties. If this organization is extremely successful in enrolling beneficiaries, the CBO estimate could in fact be a low estimate.

We estimate that lowering the reduction of the National per Capita Medicare+Choice Growth percentage in the year 2002 will provide an additional $80 million in payments to plans in 2002, and an additional $560 million over 5 years. Payments to plans in all subsequent years will be higher because of the effect of lowering the reduction on the baseline.

C. Response to Comments on Interim Final Rule

Since the publication of our June 26, 1998 interim final rule, we have implemented several significant changes aimed at alleviating unnecessary administrative burdens. Examples of these changes include the less expansive provider participation requirements adopted in our February 17, 1999 rule, our December 1998 revisions to the QISMC standards as discussed below, and clarification of the attestation requirements through this final rule. Clearly the cumulative effect of these changes will be to reduce the administrative costs associated with these requirements. Although we continue to solicit quantifiable data that can help us to assess the costs of complying with particular provisions, we have not received any data in this regard. We remain particularly interested in detailed estimates of the administrative costs associated with the QISMC and HEDIS standards. Research of available literature/studies related to these administrative costs is presented below.

1. Quality Standards

The BBA codified many existing quality assurance requirements that had been established through operational policy letters and other guidance issued under the Medicare risk and cost contracting programs.

On September 28, 1998, we issued interim Quality Improvement Systems for Managed Care (QISMC) standards and guidance. QISMC is a system for ensuring that managed care organizations contracting with Medicare and Medicaid protect and improve the health and satisfaction of enrolled beneficiaries. It consists of a set of standards and guidelines developed around four domains—quality assessment and performance improvement, enrollee rights, health services management, and delegation.

QISMC was developed in conjunction with federal and state officials, beneficiary advocates and the managed care industry to develop a coordinated quality oversight system to reduce duplicative or conflicting efforts, emphasize demonstrable and measurable improvement, and avoid reinventing the wheel. QISMC standards represent the evolution of existing quality standards being used by commercial, Medicare and Medicaid health plans or managed care organizations. We believe QISMC incorporates the currently accepted quality assurance elements and provides safeguards for vulnerable Medicare and Medicaid populations enrolled in managed care.

We reviewed NCQA accreditation 1999 standards for their consistency with QISMC standards. This is an appropriate comparison because the National Committee for Quality Assurance has been recognized as a forerunner in assuring quality assurance in health plans through its accreditation processes, and development and implementation of HEDIS performance data reporting. Also, many Medicare+Choice organizations are NCQA accredited.

Our findings are provided in the table below, which was reviewed by NCQA representatives in order to assure the highest level of technical accuracy. In general, almost two-thirds of NCQA accreditation 1999 standards were determined to be either consistent with variation or highly consistent or identical to QISMC standards.

TABLE 12

[In percent]

NCQA 1999	Overall	Domain 1	Domain 2	Domain 3	Domain 4
		Quality assessment and performance improvement	Enrollee rights	Health services management	Delegation
Substantially Greater Than QISMC	12	4	11	17	.....
Consistent with QISMC	62	65	68	53	100
Substantially Fewer Requirements	26	30	21	29	.....

Beneficiaries will benefit significantly from information available to them about the performance of their health plans as well as through improvements in the delivery of care and services that evolve out of on-going quality improvement projects under QISMC. Beneficiaries already have access to health plan performance and consumer satisfaction measures about the M+C organizations available in their area through our beneficiary education campaign and individual plan marketing.

We expect that as consumers become increasingly familiar with health plan performance and consumer satisfaction information, it will become an integral part of their decision-making process, in addition to cost and benefits, for selecting their M+C organization. It is our intent that as consumers become better informed and decide not to select plans of lower quality, such plans will be motivated to initiate improvements in the quality of care they provide.

At the same time, we expect that plan's focus on one national and one plan-specific quality assessment and performance improvement project each year will improve the delivery of services to Medicare beneficiaries, especially beneficiaries suffering from chronic conditions. M+C organizations will need to be proactive in identifying and treating beneficiaries who suffer

from medical conditions which are the focus of their quality assessment and performance improvement projects in addition to their HEDIS measures. This will ultimately lead to improved care and services for Medicare beneficiaries through the institutionalization of these practices.

a. QISMC Compliance. Purchaser demands have driven many managed care organizations to become NCQA accredited, implement quality measurement and performance improvement strategies, and report performance and satisfaction data. This has resulted in many managed care organizations becoming NCQA accredited, especially on the east and west coasts. We estimate that the cost of becoming NCQA accredited ranges between $300,000–$500,000.

We do not believe that QISMC will present significant additional fixed costs for M+C organizations that have already received accreditation from the National Committee for Quality Assurance. While QISMC presents some subtle and significant differences from NCQA accreditation, we do not expect that organizations that have prepared for NCQA accreditation will incur significant additional costs to comply with QISMC. We recognize that there will be incremental costs associated with QISMC, such as costs associated with additional quality assessment and performance improvement projects, internal staff training expenses, and oversight and compliance.

In addition, we expect that some M+C organizations that are not NCQA accredited may incur higher costs to comply with QISMC than organizations in other parts of the country.

b. HEDIS Reporting. Since 1997, we have required M+C organizations to report HEDIS and consumer satisfaction data. Beginning in 1998, we required M+C organizations to begin reporting audited HEDIS data as a result of inconsistencies in HEDIS reporting.

We do not expect that requirements for reporting HEDIS and consumer satisfaction measures are inconsistent with expectations that private purchasers have access to health plan performance data (GAO, June 1998). As a result, we do not expect that organizations will incur significant new fixed costs as a result of requirements to report performance measurement and consumer satisfaction data, since we expect that M+C organizations will use audited HEDIS data. However, we do recognize that there may be incremental costs to reporting audited HEDIS data in terms of additional processes, audit fees, etc.

In addition, requirements for M+C organizations to report audit HEDIS data will likely yield improved processes for collecting and reporting complete, accurate and timely data as a result of an independent third party review of their data collection, warehousing and production/reporting processes.

c. Quality Assessment and Performance Improvement Projects. We recognize that a significant difference between QISMC and NCQA accreditation 1999 is that QISMC is much more prescriptive in defining the type, scope and measurement of quality assessment and performance improvement projects. In response to industry concerns, we have reduced the number and delayed the timeframe for implementing quality assessment and performance improvement projects.

At the same time, specifying beginning and ending dates for QAPIs will ensure that plans do not become mired in projects that do not end. We expect that plans will focus their efforts on achieving results and institutionalizing improvements in the delivery of care, data collection and reporting and information system improvements gained from successful QAPI projects. Even in instances where demonstrable improvements were not obtained, we expect that, in many cases, some improvement will result.

In addition, plans will have added incentives to initiate performance improvement projects that will lead to more cost-effective delivery of health care services, such as influenza immunization. For example, one national managed care organization increased the percentage of Medicare enrollees receiving flu shots from 27 percent to 55 percent in one year. The organization reported a reduction of about 30 percent in hospital admissions for pneumonia, savings of about $700,000, and fewer lives lost. (GAO, May 1996) We expect that investments in QAPI activities will lead to cost-savings over and above the initial investment.

We recognize that some high-performing managed care organizations will have less ability to achieve additional improvements in some areas. Some organizations will respond to incentives to select projects where results may be more easily obtainable. We continue to believe, however, that there are significant gains that remain to be made in the delivery of quality services.

We concur with industry comments that small plans may have difficulty in complying, since they may not have a statistically credible population for producing reliable and/or comparable measures. For example, a small plan with a healthier population than average may not have sufficient instances of myocardial infarction for which beta-blocker treatment would be appropriate. We will work with these organizations to address these and other unique issues that may arise.

We believe that requiring plans to participate in at least one national and one plan-specific QAPI project annually and to demonstrate a 10 percent improvement in their QAPI is in the best interest of beneficiaries. These requirements will improve the quality of care and services delivered to Medicare and other populations served by the M+C organization, as performance improvement practices become routine.

d. Deeming. To avoid duplication of effort and unnecessary administrative burdens with respect to internal quality assurance requirements, we are recognizing accrediting by national, private accrediting organizations that we determine to be consistent with our QA requirements. We believe that this will significantly benefit a significant portion of M+C organizations that are already accredited, reducing costs, capitalizing on efficiencies, and avoiding duplicative processes.

2. Provider Procedures

Much less information is available about other requirements cited by some commenters as entailing significant administrative burdens. For example, we received many public comments regarding provider participation requirements. We responded to many of those comments in our February 17, 1999, final rule (64 FR 7968), under which we narrowed many of the requirements set forth in our June 26, 1998 interim final rule (63 FR 34968). Modifications to the interim final rule included:

- Applying the applicable notice and appeal rights and consultation requirements only to physicians, as defined under section 1861 of the Act;
- Adopting a narrower interpretation of what constitute ''rules regarding participation'' to focus on whether a physician can participate under a given M+C plan;
- Clarifying that an M+C organization need only have reasonable procedures for notifying potential participating physicians of participation rules, which may include providing the information upon request;
- Clarifying that an M+C organization is not required to release information that an organization considers proprietary information;
- Clarifying that in the 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;

- Clarifying that there is no requirement that an organization obtain signatures acknowledging receipt of a notice of changes;
- Limiting the applicability of the appeals process to appealing adverse participation decisions;
- 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; and
- Clarifying that the information to be included in a notification of a decision to suspend or terminate an agreement with a physician is limited to information relevant to the decision.

Since publication of our February 17, 1999 final rule, we have subsequently communicated with several M+C organizations about the costs and benefits associated with the requirements included in this final rule. We believe that the steps taken in our February 17, 1999 final rule significantly reduced the burden on M+C organizations and also ensured that providers and beneficiaries receive the protections intended by Congress under the Act. For example, by narrowing the scope of the requirement for advance notice of changes in participation rules, an M+C organization need not prepare an advance notice for administrative and other changes that do not affect whether a physician can participate in a plan. Notification of most changes made by a M+C organization can be made via usual communication methods, such as regular newsletters, rather than through the preparation of special mailings or other more burdensome methods.

In addition, the M+C organization must consult with the physicians who have agreed to provide services under the 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. We understand that these requirements are consistent with current operational practices by M+C organizations and pose little additional burden, and that the costs associated with incremental changes would be marginal.

We also understand that our requirements concerning credentialing processes and prohibitions on discrimination reflect current practices and similar requirements from other entities (for example, accrediting bodies) and do not impose additional burden.

3. Attestation Requirements

Similarly, commenters objected to attestation requirements as discussed in detail above (See Subpart K). To receive a monthly payment under subpart F, the chief executive officer (CEO) or chief financial officer (CFO) of a M+C organization must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of relevant data that we request. Such data include specified enrollment information, encounter data, and other information that we may specify. The CEO or CFO must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization, and the information relied upon by us in determining payment is accurate. The CEO or CFO must certify that the encounter data it submits under § 422.257 are accurate, complete, and truthful. If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data. In addition, the M+C organization must certify that the information in its ACR submission is accurate and fully conforms to the requirements in § 422.310 in order to retain payment amounts below the amount of its ACR.

We understand that the collection and dissemination of this information by M+C organizations is undertaken in a manner that reflects an M+C organization's best efforts to ensure its accuracy, completeness, and truthfulness. Accordingly, we do not believe that this requirement imposes significant new burdens on an M+C organization that operates in good faith to comply with requirements under the M+C program. We realize that mistakes and errors may occur even under an organization's best efforts, and these attestation requirements are not intended to penalize an M+C organization that operates in good faith. We believe these requirements are important to safeguard the integrity of the M+C program against those few M+C organizations that do not utilize the kind of business and operational practices of most M+C organizations. We also believe the requirements will provide an important tool for seeking out the few bad actors that could harm the M+C program, beneficiaries, providers, and other M+C organizations. As suggested by many commenters, we have revised the requirements to establish a ''good faith'' compliance standard as opposed to requiring an attestation of 100 percent accuracy for encounters and enrollment (payment related) data. We believe this change should alleviate commenters concerns over the undue financial burdens associated with attestation requirements.

VI. Other Required Information

A. Federalism Summary Impact Statement

On August 4, 1999, the president signed Executive Order 13132 (effective November 2, 1999) establishing certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have federalism implications. Any such regulations must include a federalism summary impact statement that describes the agency's consultation with State and local officials and summarizes the nature of their concerns, the extent to which these concerns have been met, and the agency's position supporting the need to issue the regulation.

In this final rule, we are not promulgating any changes to the existing M+C regulations that meet any of the criteria mentioned above that would require the inclusion of a federalism impact statement under Executive Order 13132. However, the M+C interim final rule published on June 26, 1998 (63 FR 34968) did contain provisions that have a federalism impact, and we respond to comments on these provisions from States and other interested parties in this rule. Thus, in keeping with the intent of the Executive Order that we closely examine any policies that have federalism implications or would limit the policy making discretion of the States, we have prepared the following voluntary federalism impact statement.

In establishing the M+C program, the BBA included two provisions that have significant implications for States. First, under section 1855(a)(1) of the Act, an organization that wishes to participate in the M+C program generally is required to be organized and licensed under State law as a risk-bearing entity eligible to offer health benefits coverage in each State in which it offers an M+C plan. This statutory requirement is codified at § 422.400(a) and § 422.501(b)(1) of the M+C regulations, and we do not believe it interferes with State functions or limits their policy making discretion. The requirement does not imposes any significant

additional burdens on States, who for are already carrying out this licensing function. We received no comments from States on this provision.

The other aspect of the M+C statute and regulations that has significant federalism implications involves the Federal preemption provisions set forth under section 1856(b) of the Act and § 422.402. Section 1856(b)(3)(A) provides for Federal preemption of State laws, regulations, and standards affecting any M+C standard if the state provisions are inconsistent with Federal standards. As discussed in the preamble to the interim final rule (63 FR 35012), and in section II.I of this preamble, we are applying this ''general preemption'' in much the same way that we previously applied Executive Order 12612 on Federalism. That is, State laws or standards that are more strict than the M+C standards would not be preempted unless they prevented compliance with the M+C requirements.

In addition to this general preemption, the Congress also provided (under section 1856(b)(3)(B) for a ''specific preemption'' whereby M+C standards supersede any State laws and standards in the following three areas:

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

During the development of the June 26, 1998 interim final rule, we consulted with the National Association of Insurance Commissioners (NAIC) regarding the proper interpretation of these provisions. (The NAIC is the organization of the chief insurance regulators from the 50 states, the District of Columbia, and four U.S. territories.) The interim final rule contained an extensive discussion of this subject, including providing examples both of State laws that would be preempted under the M+C statue (such as ''any willing provider laws'' that would mandate the inclusion of specific types of providers or practitioners) and of State requirements that would continue to apply (such as a requirement that all providers and practitioners be licensed by the State and comply with scope of practice laws). We asserted our intention to adopt a narrow interpretation of the applicability of the three areas of specific preemption in order to ensure that any regulatory preemption of State law would be restricted to the minimum level necessary consistent with the BBA. State and local officials then had an opportunity to participate in the rulemaking process through their public comments on the M+C interim final rule.

For the most part, commenters representing State governments supported HCFA's narrow interpretation of the BBA's specific preemption provisions. (See section II.I of this final rule for a full discussion of comments on these provisions.) The most notable exception to this general support was the contention by one State that its mandatory drug benefit laws should not be preempted by the M+C benefit provisions; but we continue to believe that the specific preemption of ''benefit requirements'' under section 1856(b)(3)(B) of the Act clearly contradicts the State's contention. Moreover, we believe that our general approach is fully consistent with the ''Special Requirements for Preemption'' set forth in section 4 of Executive Order 13132. This section directs that an agency take action to preempt State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under Federal law or there is other clear evidence (such as an express statutory preemption provision) to conclude that Congress intended the agency to have the authority to preempt State law. It also provides that any regulatory preemption of State law be restricted to the minimum level necessary to achieve the objectives of the relevant statute. In conclusion, we believe that the concerns of State and local officials have been met to the greatest possible extent, consistent with the BBA's preemption provisions.

B. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to afford a period for public comments before issuing a regulation in final form. However, we may waive that procedure if we find good cause that prior notice and comment are impractical, unnecessary, or contrary to the public interest. In addition, section 1871(b)(2)(B) of the Act provides that a notice of proposed rulemaking is not required if a statute establishes a specific deadline for implementation of a provision that is less than 150 days after the enactment of the statute in which the deadline is contained. Finally, Congress provides in certain cases by statute for the publication of a final rule without prior notice and comment.

For the most part, the changes to the M+C regulations set forth in this final rule with comment period result from our review of the public comments on the June 26, 1998 interim final rule that established the M+C program. Congress expressly authorized the publication of that final rule without prior notice and comment in section 1856(b)(1) of the Act. To the extent the provisions of this final rule respond to comments on that rule, they will have been subjected to prior notice and comment. However, as discussed in detail in section I.C of this preamble, this rule also makes conforming revisions to the regulations that are necessary to reflect changes to the M+C statute resulting from the BBRA (Pub. L. 106–113) which was enacted on November 29, 1999. These changes in requirements and new requirements or provisions were enacted by Congress, and would be in effect without regard to whether they are reflected in conforming changes to the regulations text, since a statute controls over a regulation. In this final rule, we merely have revised the regulations text to reflect these new statutory provisions, as we interpret them. In most cases, the BBRA provisions have merely been incorporated virtually verbatim, with no interpretation necessary. Examples of such provisions include: the earlier availability of alternative Medicare enrollment options and the elimination of the lock-in rules for institutionalized individuals under section 501 of the BBRA, changes in the effective date of elections under section 502, the extension of Medicare cost contracts under section 503, the modification of the 5-year re-entry rule after contract terminations under section 513, flexibility to tailor benefits under an M+C plan under section 515, the delay until July 1 in the deadline for ACR submissions under section 516, the reduction in the adjustment in the national per capita M+C growth percentage under section 517, the new deeming provisions in section 518, the revised quality assurance requirements for PPOs under section 520, and the user fee provisions in section 522. For these types of provisions, we do not believe that publishing a notice a proposed rulemaking is necessary, nor would it be practical given that a number of the provisions have already taken effect consistent with effective dates established under the BBRA. (For example, the changes in the effective date of elections and the new quality assurance requirements for PPOs took effect on January 1, 2000, and several other provisions were effective upon enactment of the BBRA.) In addition, we believe that it would be contrary to the public interest to delay implementation of these provisions until the process of publishing both a proposed and a final

rule could be completed. Finally, we note that the BBRA was enacted on November 29, 1999; thus publication of a notice of proposed rulemaking is not required under section 1871(b) of the Act before implementing any new statutory provisions that took effect upon enactment or on January 1, 2000. Thus, we find good cause to waive proposed rulemaking for these provisions. We are, however, providing a 60-day period for public comment on those provisions.

In the case of two BBRA provisions, we have reflected our interpretation of the provisions in the regulations text. This interpretation is already in effect, and has been applied, as the provisions in question are already in effect. These provisions are section 501(c) of the BBRA, which permits an M+C organization that has reduced a plan service area to offer continued enrollment to current enrollees in all or a portion of the reduced areas, and section 512 that introduces ''bonus payments'' to encourage organizations to offer M+C plans in areas without such plans. Both of these provisions are discussed in detail in section I.C of this preamble, and both required a limited amount of interpretation of the statute in order to implement the provisions on a timely basis. For example, with regard to the continuation of enrollment option (which was effective upon enactment of the BBRA), we have clarified that an M+C organization may offer enrollment in any plan it offers in the affected area, rather than solely the plan in which an individual was previously enrolled. This clarification results in greater flexibility for M+C enrollees and is consistent with our interpretation of a similar statutory provision affecting individuals with ESRD. Similarly, with regard to the bonus payment provisions (which took effect as of January 1, 2000), we have indicated that if an M+C organization or organizations offers two or more new plans simultaneously in a given area, the organization could receive the bonus payments for each new plan. We believe this interpretation of the statute clearly is consistent with legislative intent to promote the availability of more M+C alternatives for Medicare beneficiaries.

Policy clarifications of this limited nature were essential to implement these BBRA provisions in a clear and timely manner. Again, it would have been impractical and contrary to the public interest to proceed with proposed rulemaking before implementing the interpretive policies linked with these provisions, nor is such rulemaking required under section 1871(b) of the Act. Thus, we believe that the ''good cause'' exemption to notice and comment rulemaking is equally applicable for these BBRA provisions as for the others discussed above, and the same 60-day period for public comment applies.

C. Responses to Comments

As discussed above, a limited number of the provisions set forth in this final rule are subject to a 60-day comment period. Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble and, if we proceed with subsequent rulemaking, we will respond to the comments in that document.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare+Choice, Penalties, Privacy, Provider-sponsored organizations (PSO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (2 U.S.C. 300e, 300e–5, 300e–9), and 31 U.S.C. 9701.

2. Revise § 417.402(b) to read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(b) The changes made to section 1876 of the Act by section 4002 of the Balanced Budget Act (BBA) of 1997 are incorporated in section 422 except for 1876 cost contracts. Upon enactment of the BBA (August 5, 1997) no new cost contracts or service area expansions are accepted by HCFA except for current Health Care Prepayment Plans that may convert to 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2004.

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. Section 422.2 is amended by:

A. Revising the definitions of ''Basic benefits,'' ''Benefits,'' ''M+C plan,'' ''Mandatory supplemental benefits,'' ''Optional supplemental benefits,'' ''Religious and fraternal (RFB) society,'' ''RFB plan,'' and ''Service area.''

B. Adding the definition of ''National coverage determination.''

C. Removing the definitions of ''Emergency medical condition,'' ''Emergency services,'' and ''Urgently needed services.''

§ 422.2 Definitions.

* * * * *

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

Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the M+C organization incurs a cost or liability under an M+C plan (not solely an administrative processing cost). Benefits are submitted and approved through the ACR process.

* * * * *

M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan (or in individual segments of a service area, under § 422.304(b)(2)).

* * * * *

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

* * * * *

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that HCFA makes under section 1862(a)(1) of the

Act, and publishes as a **Federal Register** notice or HCFA ruling. (The term does not include coverage changes mandated by statute.)

* * * * *

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

* * * * *

Religious and fraternal benefit (RFB) society means an organization that—

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

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

RFB plan means an M+C plan that is offered by an RFB society.

Service area means a geographic area approved by HCFA within which an M+C-eligible individual may enroll in a particular M+C plan offered by an M+C organization. Each M+C plan must be available to all M+C-eligible individuals within the plan's service area. In deciding whether to approve an M+C plan's proposed service area, HCFA considers the following criteria:

(1) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties. However, HCFA may approve a service area that includes a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, HCFA must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, HCFA may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

3. In § 422.4, revise paragraph (a)(1)(iii) and add a new paragraph (a)(1)(iv), to read as follows:

§ 422.4 Types of M+C plans.

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs) as specified in paragraph (a)(1)(iv) of this section, RFBs, and other network plans (except network MSA plans).

(iv) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

4. Revise § 422.8 to read as follows:

§ 422.8 Evaluation and determination procedures.

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

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

(3) After evaluating all relevant information, HCFA determines whether the contract applicant's application meets the applicable requirements of § 422.6.

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

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

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

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

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

(f) *Denial of application.* If HCFA denies the application, it gives written notice to the contract applicant indicating—

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

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

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

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

5. Revise § 422.10 to read as follows:

§ 422.10 Cost-sharing in enrollment-related costs (M+C user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that HCFA follows to determine the aggregate annual ''user fee'' to be contributed by M+C organizations and to assess the required user fees for M+C plans offered by M+C organizations.

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

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

(d) *Collection of fees.* (1) *Timing of collection.* HCFA collects the fees over 9 consecutive months beginning with January of each fiscal year.

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

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

(ii) For fiscal year 2000, $100 million and for fiscal year 2001 and each succeeding year, the M+C portion (as defined in paragraph (e) of this section) of $100 million.

(e) *M+C portion.* In this section, the term ''M+C portion'' means, for a fiscal year, the ratio, as estimated by the Secretary of the average number of individuals enrolled in M+C plans during the fiscal year to the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(f) *Assessment methodology.* (1) The amount of the M+C portion of the user fee each M+C organization must pay is assessed as a percentage of the total Medicare payments to each organization. HCFA determines this percentage rate using the following formula:

A times B divided by C where—

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

B is the 9-month (January through September) assessment period; and

C is the total fiscal year M+C user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) HCFA determines each organization's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. HCFA calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in HCFA's payment system on the first day of the month.

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

(4) If assessments reach the amount authorized for the year before the end of September, HCFA discontinues assessment.

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

6. Revise § 422.50(a) to read as follows:

§ 422.50 Eligibility to elect an M+C plan.

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

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

(2) Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization is eligible to elect an M+C plan offered by that organization;

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the M+C plan.

(ii) Resides outside of the service area of the M+C plan and is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements of § 422.112 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected M+C plan, even if the individual lives outside of the M+C plan service area, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements at § 422.12 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

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

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

* * * * *

7. In § 422.54, the heading of paragraph (b) and paragraphs (c)(2), (d)(1), and (d)(3) are revised to read as follows:

§ 422.54 Continuation of enrollment.

* * * * *

(b) *Basic rule.* * * *

(c) * * *

(2) An enrollee who moves out of the service area into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the plan. The enrollee must make the choice of continuing enrollment in a manner specified by HCFA. If no choice is made, the enrollee must be disenrolled from the plan.

* * * * *

(d) * * *

(1) *Continuation of enrollment benefits.* The M+C organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

* * * * *

(3) *Reasonable cost-sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

* * * * *

8. Section § 422.60 is amended by:

A. Revising paragraph (b)(1).

B. Adding paragraph (b)(3).

C. Revising paragraphs (e)(6), (f)(1), and (f)(3).

§ 422.60 Election process.

* * * * *

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

* * * * *

(3) HCFA considers enrollment limit requests for an M+C plan service area, other than those submitted with the adjusted community rate proposal, or for a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

* * * * *

(e) * * *

(6) Upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization transmits, within the timeframes

specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

(f) * * *

(1) In cases in which an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members, who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election form from the employer, the M+C organization must submit the enrollment within timeframes specified by HCFA.

9. Section 422.62 is amended by:

A. Removing, in paragraph (a)(3), the phrase ''as provide under'' and adding in its place the phrase ''as provided under''.

B. Revising paragraphs (a)(4)(i) and (a)(5)(i).

C. Adding new paragraph (a)(6).

D. Revising paragraph (b)(1).

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

(a) * * *

(4) * * *

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

* * * * *

(5) * * *

(i) For 2003 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan may elect an M+C plan, change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 3 months of the year.

* * * * *

(6) *Open enrollment period for institutionalized individuals.* After 2001, an individual who is eligible to elect an M+C plan and who is institutionalized, as defined by HCFA, is not limited (except as provided for in paragraph (d) of this section for M+C MSA plans) in the number of elections or changes he or she may make. Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an M+C eligible institutionalized individual may at any time elect an M+C plan or change his or her election from an M+C plan to original Medicare, to a different M+C plan, or from original Medicare to an M+C plan.

(b) * * *

(1) HCFA or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

* * * * *

10. Section 422.64 is revised to read as follows:

§ 422.64 Information about the M+C program.

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

11. Section § 422.66 is amended by:

A. Republishing the heading of paragraph (b) and the introductory text for paragraph (b)(3).

B. Revising paragraphs (b)(3)(i), (d)(1), (d)(3), the introductory text for paragraph (e), and paragraphs (e)(2), and (f).

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

* * * * *

(b) *Disenrollment*—

* * * * *

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

(i) Submit a disenrollment notice to HCFA within timeframes specified by HCFA;

* * * * *

(d) * * *

(1) *Basic rule.* An M+C plan offered by an M+C organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

* * * * *

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the M+C organization as an M+C enrollee, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

* * * * *

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

* * * * *

(2) The elected M+C plan is discontinued or no longer serves the area in which the individual resides, the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided under either § 422.54 or § 422.74(b)(3)(ii).

(f) *Exception for employer group health plans.* (1) In cases when an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election form from the employer, the M+C organization must submit a disenrollment notice to HCFA within timeframes specified by HCFA.

12. Revise § 422.68(c) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made, except that, if the election or change in election is made after the 10th day of any calendar month, then the election shall not take effect until the first day of the second calendar month following the date on which the election is made.

* * * * *

13. Section 422.74 is amended by revising paragraphs (b)(2)(i), (b)(3), (c),

(d)(1), the heading of paragraph (d)(3), (d)(4), and (d)(7) to read as follows:

§ 422.74 Disenrollment by the M+C organization.

* * * * *

(b) * * *

(2) * * *

(i) The individual no longer resides in the M+C plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

* * * * *

(3) *Plan termination or reduction of area where plan is available.* (i) *General rule.* An M+C organization that has its contract for an M+C plan terminated, that terminates an M+C plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an M+C organization discontinues offering an M+C plan in a portion of its service area, the M+C organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an M+C plan offered by the organization, provided that there is no other M+C plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

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

(1) Be mailed to the individual before submission of the disenrollment notice to HCFA; and

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

(d) * * *

(1) *Monthly basic and supplementary premiums are not paid timely.* An M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums under the following circumstances:

(i) The M+C organization makes a reasonable effort to collect unpaid premium amounts by sending a written notice of nonpayment to the enrollee within 20 days after the date the delinquent charges were due—

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

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

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

(ii) The M+C organization only disenrolls a Medicare enrollee when the organization has not received payment within 90 days after the date it has sent the notice of nonpayment to the enrollee.

(iii) The M+C organization gives the individual a written notice of disenrollment that meets the requirement set forth in paragraph (c) of this section.

(iv) If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and any mandatory supplemental premium, the M+C organization has the option to discontinue the optional supplemental benefits and retain the individual as an M+C enrollee.

* * * * *

(3) *Individual commits fraud or permits abuse of enrollment card.* * * *

* * * * *

(4) *Individual no longer resides in the M+C plan's service area.* (i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the M+C organization must disenroll an individual if the M+C organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved out of a plan's service area. If the individual has not moved from the M+C plan's service area, but has left the plan's service area for more than 6 months, the M+C organization must disenroll the individual.

(ii) *Special rule.* The M+C organization must disenroll an individual who is enrolled in the M+C plan, under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4), if the organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, to an area outside the M+C plan service area (unless continuation of enrollment is elected under § 422.54). If the individual has not permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, but has left the residence for over 6 months, the M+C organization must disenroll the individual.

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

* * * * *

(7) *Plan termination or area reduction.* (i) When an M+C organization has its contract for an M+C plan terminated, terminates an M+C plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the M+C organization must give each affected M+C plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

* * * * *

14. Section 422.80 is amended by:

A. Republishing the introductory text in paragraph (b)(5).

B. Revising paragraph (b)(5)(v).

C. Republishing the introductory text in paragraph (c).

D. Revising paragraph (c)(4).

E. Adding new paragraphs (e)(1)(vi), (e)(1)(vii), and (e)(1)(viii).

F. Revising paragraph (f).

§ 422.80 Approval of marketing materials and election forms.

* * * * *

(b) * * *

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

* * * * *

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

* * * * *

(c) *Guidelines for HCFA review.* In reviewing marketing material or election

forms under paragraph (a) of this section, HCFA determines that the marketing materials:

* * * * *

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

* * * * *

(e) * * *

(1) * * *

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all M+C organizations involved and have received prior approval by HCFA. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ M+C plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to M+C plan names in effect on July 31, 2000.

* * * * *

(f) *Employer group retiree marketing.* M+C organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, HCFA will not review portions of these materials that relate to employer group benefits.

15. Revise § 422.100 to read as follows:

§ 422.100 General requirements.

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

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

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

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

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

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

(c) *Types of benefits.* An M+C plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services, and additional benefits as defined in § 422.2 and meeting all requirements in § 422.312.

(2) Supplemental benefits, which consist of—

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

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

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

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

(2) At a uniform premium, with uniform benefits and cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.304(b)(2).

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

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

(g) *HCFA review and approval of M+C benefits.* HCFA reviews and approves M+C benefits using written policy guidelines and requirements in this part, operational policy letters, and other HCFA instructions to ensure that—

(1) Medicare-covered services meet HCFA fee-for-service guidelines;

(2) M+C organizations are not designing benefits to discriminate against beneficiaries; and

(3) Benefit design meets other M+C program requirements.

(h) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of M+C organizations may directly access (through self-referral) screening mammography and influenza vaccine.

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

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

(j) *Provider networks.* The M+C plans offered by an M+C organization may share a provider network as long as each M+C plan independently meets the access and availability standards described at § 422.112, as determined by HCFA.

16. Revise § 422.101 to read as follows:

§ 422.101 Requirements relating to basic benefits.

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

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's

service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) HCFA's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part; and

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

17. Revise § 422.102 to read as follows:

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to HCFA's approval, an M+C organization may require Medicare enrollees of an M+C plan other than an MSA plan to accept and pay for services in addition to Medicare-covered services described in § 422.101 and additional benefits described in § 422.312.

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

(3) HCFA approves mandatory supplemental benefits if the benefits are designed in accordance with HCFA's guidelines and requirements as stated in this part and instructions and operational policy letters.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each M+C organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the M+C plan.

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

(d) *Marketing of supplemental benefits.* M+C organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

18. Section 422.105 is amended by:

A. Revising the introductory text for paragraph (a).

B. Revising paragraph (f).

§ 422.105 Special rules for point of service option.

(a) *General rule.* A POS benefit is an option that an M+C organization may offer in an M+C coordinated care plan or network M+C MSA plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

* * * * *

(f) *POS-related data.* An M+C organization that offers a POS benefit through an M+C plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by HCFA.

19. Revise § 422.106 to read as follows:

§ 422.106 Coordination of benefits with employer group health plans and Medicaid.

(a) *General rule.* If an M+C organization contracts with an employer group health plan (EGHP) that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits supplementing the M+C plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the M+C program apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract.

(2) Employer benefits that complement an M+C plan, and the marketing materials associated with the benefits, are not subject to review or approval by HCFA. M+C plan benefits provided to members of the EGHP, and the associated marketing materials, are subject to HCFA review and approval.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate HCFA review under the Medicaid program. M+C plan benefits provided to individuals entitled to Medicaid benefits provided by the M+C organization under a contract with the State Medicaid agency are subject to M+C rules and requirements.

(b) *Examples.* Employer/Medicaid benefits, permissible EGHP or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the M+C basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the M+C plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

20. Section 422.108 is amended by:

A. Republishing the introductory text for paragraph (b).

B. Revising paragraphs (b)(2), (c), the introductory text in paragraph (d), and paragraph (e).

C. Adding a new paragraph (f).

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

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

* * * * *

(2) Identify the amounts payable by those payers; and * * * * *

* * * * *

(c) *Collecting from other entities.* The M+C organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

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

* * * * *

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

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C plans only to the extent that those State laws are inconsistent with the standards established under this part. A State cannot take away an M+C organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to

bill, for services for which Medicare is not the primary payer. Section 1852(a)(4) of the Social Security Act does not prohibit a State from limiting the amount of the recovery; thus, State law could modify, but not negate, an M+C organization's rights in this regard.

21. In 422.109, the introductory text for paragraph (b) and paragraph (b)(5) are revised to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs).

* * * * *

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

* * * * *

(5) Beneficiaries are liable for any applicable coinsurance amounts, but are not responsible for the Part A deductible.

* * * * *

22. Revise § 422.110(c) to read as follows:

§ 422.110 Discrimination against beneficiaries prohibited.

* * * * *

(c) *Additional requirements.* An M+C organization is 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)).

23. Section 422.111 is amended by:

A. Revising the introductory text in paragraph (a).

B. Revising paragraphs (b)(2)(i), (b)(4), and (b)(5)(i).

C. Republishing the introductory text in paragraph (c) and revising paragraph (c)(1).

D. Revising paragraph (e).

E. Adding new paragraph (f).

§ 422.111 Disclosure requirements.

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

* * * * *

(b) * * *

(2) * * *

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

* * * * *

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) * * *

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

* * * * *

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

(1) The information required paragraph (f) of this section.

* * * * *

(e) *Changes to provider network.* The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contracted is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

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

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

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

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

(5) *Potential for contract termination.* The fact that an M+C organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's M+C plan.

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

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

(ii) Any beneficiary cost-sharing.

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

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

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

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

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

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

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

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

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

(10) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to HCFA guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

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

(vi) Other performance indicators.

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

24. Section 422.112 is amended by:

A. Republishing the introductory text to paragraph (a).

B. Revising paragraphs (a)(2), (a)(3) and (a)(9).

C. Adding new paragraph (a)(10).

D. Removing paragraph (c).

§ 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:

* * * * *

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(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). The M+C organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

* * * * *

(9) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(10) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

* * * * *

25. Add new § 422.113 to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The M+C organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services.* (1) *Definitions.*

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

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

(B) Serious impairment to bodily functions; or

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

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

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

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

(2) *M+C organization financial responsibility.* The M+C organization is financially responsible for emergency and urgently needed services—

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

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

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

(v) With a limit on charges to enrollees for emergency services of $50 or what it would charge the enrollee if he or she obtained the services through the M+C organization, whichever is less.

(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.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as ''post-stabilization care services'').

(1) *Definition. Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *M+C organization financial responsibility.* The M+C organization—

(i) Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the M+C organization that are pre-approved by a plan provider or other M+C organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C

organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

(3) *End of M+C organization's financial responsibility.* The M+C organization's financial responsibility for post-stabilization care services it has not pre-approved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

26. Revise § 422.118 to read as follows:

§ 422.118 Confidentiality and accuracy of enrollee records.

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

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The M+C organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

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

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

27. Section 422.152 is amended by:

A. Revising the heading and introductory text for paragraph (b).

B. Revising the heading and introductory text for paragraph (e).

C. Revising paragraph (e)(1).

D. Republishing the heading of paragraph (f).

E. Adding new paragraph (f)(3).

§ 422.152 Quality assessment and performance improvement program.

* * * * *

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

* * * * *

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

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

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

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

* * * * *

(f) *Requirements for all types of plans*—

* * * * *

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

28. In § 422.154, the introductory text for paragraph (b) is republished, and paragraph (b)(2) is revised to read as follows:

§ 422.154 External review.

* * * * *

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

* * * * *

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

* * * * *

29. Revise paragraphs (a) and (b) in § 422.156 to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by HCFA; and

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

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality assurance.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

* * * * *

30. Section 422.157 is amended by republishing the introductory text for paragraph (a) and revising paragraphs (a)(3) and (b)(1) to read as follows:

§ 422.157 Accreditation organizations.

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

* * * * *

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

* * * * *

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

(i) Announces HCFA's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria HCFA will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

* * * * *

31. Revise the introductory text of § 422.158(e) to read as follows:

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

* * * * *

(e) *Notice of determination.* HCFA gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

* * * * *

32. Section 422.202 is amended by:

A. Revising the introductory text of paragraph (b).

B. Adding a heading to paragraph (c).

C. Adding a new paragraph (d)

§ 422.202 Participation procedures.

* * * * *

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

* * * * *

(c) *Subcontracted groups.* * * *

* * * * *

(d) *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.

33. Revise § 422.204 to read as follows:

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An M+C organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

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

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

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

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

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

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

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

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with HCFA permitting them to provide services under original Medicare.

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

34. Add § 422.205 to read as follows:

§ 422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available to M+C plan enrollees, an M+C organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an M+C organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an M+C organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

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

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

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and

control costs consistent with its responsibilities.

35. In § 422.206, the heading for paragraph (b) is republished and paragraph (b)(2) is revised to read as follows:

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

* * * * *

(b) *Conscience protection.* * * *

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

(i) To HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

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

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

* * * * *

36. Section 422.208 is amended by:

A. Republishing the introductory text for paragraph (c).

B. Revising paragraph (c)(2).

C. Adding a heading to paragraph (e).

§ 422.208 Physician incentive plans: requirements and limitations.

* * * * *

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

* * * * *

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

* * * * *

(e) *Prohibition for private M+C fee-for-service plans.* * * *

* * * * *

37. In § 422.214, the heading for paragraph (a) is republished and paragraphs (a)(1) and (b) are revised to read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

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

* * * * *

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.86(d)) of this chapter that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct graduate medical education costs.)

38. In § 422.216, paragraphs (a)(4), (b)(2), (c)(2), and the introductory text for paragraph (f) are revised to read as follows:

§ 422.216 Special rules for M+C private fee-for-service plans.

(a) * * *

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment mounts for services furnished to a beneficiary enrolled in an M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) * * *

(2) Noncontract providers. A noncontract provider may not collect from an enrollee more than the cost-sharing established by the M+C private fee-for-service plan as specified in § 422.308(b), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) * * *

(2) *Noncontract providers.* An M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA.

* * * * *

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to § 489.24 of this chapter, to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

* * * * *

39. Section 422.250 is amended by:

A. In paragraph (a)(1), removing the phrase ''in paragraph (a)(2)'' and adding in its place the phrase ''in paragraphs (a)(2) or (f)''.

B. Revising paragraph (a)(2)(i)(B).

C. Adding new paragraph (g).

§ 422.250 General provisions.

(a) * * *

(2) * * *

(i) * * *

(B) HCFA reduces the payment rate for each renal dialysis treatment by the same amount that the Secretary is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

* * * * *

(g) *Bonus payments.* (1) HCFA provides bonus payments to the M+C organization(s) that first offers a plan in a previously unserved county on or after January 1, 2000 and no later than December 31, 2001. The bonus payment amounts equal—

(i) For the first 12 months after a plan is offered in a previously unserved county, 5 percent of the monthly capitation rate otherwise payable under this section; and

(ii) For the subsequent 12 months, 3 percent of the monthly capitation rate otherwise payable under this section.

(2) A previously unserved county is defined as—

(i) A county in which no M+C plan has been offered; or

(ii) A county in which an M+C plan or plans has been offered, but where any M+C organization offering an M+C plan notified HCFA by October 13, 1999, that it will no longer offer plans in the county as of January 1, 2000.

(3) A plan is considered to be offered when—

(i) The M+C organization sponsoring the plan has a contract in effect to serve beneficiaries in the previously unserved area; and

(ii) The M+C plan is open for enrollment.

40. Revise § 422.254(b)(2) to read as follows:

§ 422.254 Calculation and adjustment factors.

* * * * *

(b) * * *

(2) The percentage points that HCFA uses to reduce its estimates are as follows:

(i) For 1998, 0.8 percentage points.

(ii) For years 1999 through 2001, 0.5 percentage points.

(iii) For 2002, 0.3 percentage points.

(iv) For years after 2002, 0 percentage points.

* * * * *

41. In § 422.257, revise paragraph (d) and add paragraph (g) to read as follows:

§ 422.257 Encounter data.

* * * * *

(d) *Other data requirements.* (1) M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards.

(2) The data must be submitted electronically to the appropriate HCFA contractor.

(3) M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services.

(4) M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate encounter data as required by HCFA. These provisions may include financial penalties for failure to submit complete data, or for failure to submit data that conform to the requirements for equivalent data for Medicare fee-for-service.

* * * * *

(g) *Deadlines for submission of encounter data.* Risk adjustment factors for each payment year are based on encounter data submitted for services furnished during the 12 month period ending 6 months before to the payment year (for example, risk adjustment factors for CY 2000 are based on data for services furnished during the period July 1, 1998 through June 30, 1999).

(1) The annual deadline for encounter data submission is September 10 for encounter data reflecting services furnished during the 12 month period ending the prior June 30 (for example, the deadline for submission of data for the period July 1, 1998 through June 30, 1999 is September 10, 1999).

(2) HCFA allows a reconciliation process to account for late data submissions. HCFA continues to accept encounter data submitted after the September 10 deadline until June 30 of the payment year (for example, until June 30, 2000 for data from the period July 1, 1998 through June 30, 1999). After the payment year is completed, HCFA recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

42. Revise § 422.300(b)(2) to read as follows:

§ 422.300 Basis and scope.

* * * * *

(b) * * *

(2) For contracts beginning on a date other than January 1 (according to § 422.504(d)), M+C organizations may submit ACRs on a date other than July 1 approved by HCFA.

43. Revise § 422.304(b) to read as follows:

§ 422.304 Rules governing premiums and cost-sharing.

* * * * *

(b) *Uniformity.* (1) *General rule.* The M+C monthly basic beneficiary premium, the M+C monthly supplemental beneficiary premiums, and the M+C monthly MSA premium of an M+C organization may not vary among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section). In addition, the M+C organization may not vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any), among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section).

(2) *Segmented service area option.* An M+C organization may apply the uniformity requirements in paragraph (b)(1) of this section to segments of an M+C plan service area (rather than to the entire service area) as long as any such segment is composed of one or more M+C payment areas, and the information specified under § 422.306 is submitted separately, as provided in that section, for each such segment.

* * * * *

44. Revise the introductory text in § 422.306(a)(1) to read as follows:

§ 422.306 Submission of proposed premiums and related information.

(a) *General rule.* (1) Not later than July 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to HCFA, in the manner and form prescribed by HCFA, for each M+C plan (or service area segment, under § 422.304(b)(2)) it intends to offer in the following year—

* * * * *

45. Section 422.310 is amended by:

A. In the introductory text for paragraph (d), removing the phrase ''paragraphs (a)(1) and (a)(2) of this section'' and adding in its place the phrase ''paragraphs (d)(1) and (d)(2) of this section''.

B. Revising paragraph (c)(3).

§ 422.310 Adjusted community rate (ACR) approval process.

* * * * *

(c) * * *

(3) *Additional revenues.* The relative cost ratio for total revenues for an M+C plan is determined by comparing the total revenues charged on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees (including payments from HCFA without any needed offsets or reductions, such as, those required by § 422.250(a)(2)(i)(B) for ESRD enrollees) that elected the M+C plan to the total revenues charged for non-Medicare enrollees over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation. When the relative cost ratio for total revenues is applied to the total initial rate, the value of additional revenues is the remaining value after removing the value of direct medical costs (as adjusted by paragraph (c)(1) of this section) and the value of Administration (as adjusted by paragraph (c)(2) of this section).

46. In § 422.312, the introductory text for paragraph (b) is republished and paragraph (b)(1) is revised to read as follows:

§ 422.312 Requirement for additional benefits.

* * * * *

(b) *Requirement for additional benefits.* If there is an adjusted excess amount for the plan it offers, the M+C organization must—

(1) Provide additional benefits with an actuarial value (less the actuarial value of any cost-sharing associated with the benefit) which HCFA determines is at least equal to the adjusted excess amount; and

* * * * *

47–50. In § 422.352, the introductory text for paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of an M+C contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

* * * * *

51. Section 422.500 is amended by:

A. Revising the definition of ''clean claim.''

B. Adding definitions for ''downstream entity'' and ''first tier entity.''

§ 422.500 Definitions.

* * * * *

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.257(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

* * * * *

52. Section 422.501 is amended by:

A. Republishing the introductory text in paragraphs (b), (b)(3), and (b)(3)(vi).

B. Revising paragraphs (b)(3)(vi)(G) and (b)(5).

C. Removing paragraph (b)(3)(vi)(H).

D. Republishing the introductory text in (d)(2) and (d)(2)(iii).

E. Revising paragraph (d)(2)(iii)(A).

§ 422.501 General provisions.

* * * * *

(b) *Conditions necessary to contract as an M+C organization.* Any entity seeking to contract as an M+C organization must:

* * * * *

(3) Have administrative and management arrangements satisfactory to HCFA, as demonstrated by at least the following:

* * * * *

(vi) A compliance plan that consists of the following:

* * * * *

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

* * * * *

(5) The M+C organization's contract must not have been terminated by HCFA under § 422.510 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified HCFA of the intention to terminate the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue; or

(ii) HCFA has otherwise determined that circumstances warrant special consideration.

* * * * *

(d) * * *

(2) Each contract under this section must provide that HCFA, or any person or organization designated by HCFA has the right to:

* * * * *

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

* * * * *

53. Section 422.502 is amended by:

A. In paragraph (a)(12), removing the phrase ''To comply will all requirements'' and adding in its place the phrase ''To comply with all requirements''.

B. Republishing the introductory text for paragraph (g).

C. Revising the introductory text for paragraph (g)(1) and the introductory text for paragraph (g)(3).

D. Revising paragraph (i)(3).

E. Revising paragraph (l).

§ 422.502 Contract provisions.

* * * * *

(g) *Beneficiary financial protections.* The M+C organization agrees to comply with the following requirements:

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

* * * * *

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the M+C organization may use—

* * * * *

(i) * * *

(3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C organization.

(ii) Accountability provisions that indicate that—

(A) The M+C organization oversees and is accountable to HCFA for any functions or responsibilities that are described in these standards; and

(B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the M+C organization's contractual obligations.

* * * * *

(1) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy,

completeness, and truthfulness of relevant data that HCFA requests. Such data include specified enrollment information, encounter data, and other information that HCFA may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization and the information relied upon by HCFA in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the encounter data it submits under § 422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its ACR submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.310.

54. In § 422.504, revise paragraph (b) and remove paragraph (d) to read as follows:

§ 422.504 Effective date and term of contract.

* * * * *

(b) *Term of contract.* Each contract is for a period of at least 12 months.

* * * * *

55. Section 422.506 is amended by:

A. Republishing the introductory text of paragraph (a)(2).

B. Revising paragraph (a)(2)(i) and the introductory text of paragraph (a)(3).

C. Removing paragraph (b)(1)(ii).

D. Redesignating paragraphs (b)(1)(iii) and (b)(1)(iv) as (b)(1)(ii) and (b)(1)(iii), respectively.

§ 422.506 Nonrenewal of contract.

(a) * * *

(2) If an M+C organization does not intend to renew its contract, it must notify—

(i) HCFA in writing, by July 1 of the year in which the contract would end;

* * * * *

(3) HCFA may accept a nonrenewal notice submitted after July 1 if—

* * * * *

56. Section 422.510 is amended by adding paragraph (a)(12) and revising paragraph (c)(1) to read as follows:

§ 422.510 Termination of contract by HCFA.

(a) * * *

(12) The M+C organization substantially fails to comply with the marketing requirements in § 422.80.

* * * * *

(c) * * *

(1) *General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, HCFA provides the M+C organization with reasonable opportunity to develop and receive HCFA approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

57. Revise § 422.514(b)(1) to read as follows:

§ 422.514 Minimum enrollment requirements.

* * * * *

(b) * * *

(1) For a contract applicant or M+C organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of the contract, HCFA may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or M+C organization must demonstrate to HCFA's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that HCFA takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or M+C organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or M+C organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, HCFA considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to HCFA; and

(iii) The contract applicant or M+C organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

* * * * *

58. Revise § 422.520(a)(3) to read as follows:

§ 422.520 Prompt payment by M+C organization.

* * * * *

(a) * * *

(3) All other claims must be paid or denied within 60 calendar days from the date of the request.

* * * * *

§ 422.550 [Amended]

59. In § 422.550(a)(2), the heading ''Unincorporated sole proprietor'' is removed and the heading ''Asset Sale'' is added in its place.

60. In § 422.561, the introductory text is republished and the definitions of ''Appeal'' and ''Authorized representative'' are revised to read as follows:

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in this subpart.

* * * * *

61. Section 422.562 is amended by republishing the introductory text for paragraphs (a) and (a)(1) and revising paragraph (a)(1)(ii).

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

* * * * *

(ii) A procedure for making timely organization determinations;

* * * * *

62. Revise § 422.566(b) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the M+C organization.

(4) Discontinuation of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the M+C organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

* * * * *

63. Section 422.568 is revised to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(c) *Written notification by practitioners.* At each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the M+C organization regarding the enrollee's services, consistent with paragraph (d) of this section. The practitioner's notification must—

(1) Provide the enrollee with the information necessary to contact the M+C organization; and

(2) Comply with any other requirements specified by HCFA.

(d) *Written notice for M+C organization denials.* If an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(e) *Form and content of the M+C organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by HCFA.

(f) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

64. Section 422.570 is amended by:

A. Revising paragraph (a).

B. Republishing the introductory text for paragraph (d).

C. Revising the introductory text to paragraph (d)(2) and revising paragraph (d)(2)(iii).

D. Adding a new paragraph (d)(2)(iv).

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

* * * * *

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

65. In § 422.572, revise paragraphs (b), (c), and (d) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and

inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements of this section.

* * * * *

66. Section 422.584 is amended by:

A. Revising paragraph (a).

B. Republishing the introductory text to paragraph (d).

C. Revising paragraph (d)(2).

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

67. Section 422.590 is amended by:

A. Republishing the heading for paragraph (a) and revising paragraph (a)(1).

B. Republishing the heading for paragraph (d) and revising paragraphs (d)(2), (d)(3), and (d)(4).

C. Republishing the heading for paragraph (g) and revising paragraph (g)(2).

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

(d) *Expedited reconsideration*—* * *

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements.

* * * * *

(g) *Who must reconsider an adverse organization determination.* * * *

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

68. In § 422.594, the introductory text for paragraph (b) is republished, and paragraph (b)(1) is revised to read as follows:

§ 422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

* * * * *

69. Revise § 422.596 to read as follows:

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the M+C organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

70. Revise § 422.612(b) to read as follows:

§ 422.612 Judicial review.

* * * * *

(b) *Review of Board decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the Board decision if it is the final decision of HCFA and the amount in controversy is $ 1,000 or more.

* * * * *

71. Section 422.618 is amended by:

A. Revising the section heading.

B. Redesignating paragraph (b) as paragraph (c).

C. Adding a new paragraph (b).

D. Revising newly designated paragraph (c).

§ 422.618 How an M+C organization must effectuate standard reconsidered determinations or decisions.

* * * * *

(b) *Reversals by the independent outside entity.* (1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

72. Add new § 422.619 to read as follows:

§ 422.619 How an M+C organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the M+C organization.* If on reconsideration of an expedited request for service, the M+C organization completely reverses its organization determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent review entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

73. Section 422.620 is revised to read as follows:

§ 422.620 How enrollees of M+C organizations must be notified of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), written notice of noncoverage under paragraph (c) of this section must be provided to each enrollee. An enrollee is entitled to coverage until at least noon the day after such notice is provided. If PRO review is requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before notice of noncoverage is provided as described in paragraph (c) of this section, the entity that makes the noncoverage/discharge determination (that is, the hospital by delegation or the M+C organization) must obtain the concurrence of the physician who is responsible for the enrollee's hospital care.

(c) *Notice to the enrollee.* In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, written notice must be provided to the enrollee that includes the following elements:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date and time of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Additional information specified by HCFA.

74. Revise § 422.648(b) to read as follows:

§ 422.648 Reconsideration: Applicability.

* * * * *

(b) HCFA reconsiders the specified determinations if the contract applicant or the M+C organization files a written request in accordance with § 422.650.

75. In § 422.650, paragraphs (c) and (d) are revised to read as follows:

§ 422.650 Request for reconsideration.

* * * * *

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or M+C organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The M+C organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for

withdrawal must be in writing and filed with HCFA.

76. Revise § 422.652 to read as follows:

§ 422.652 Opportunity to submit evidence.

HCFA provides the M+C organization or contract applicant and the HCFA official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an M+C organization could choose to request a hearing as described at § 422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

77. Revise § 422.656 to read as follows:

§ 422.656 Notice of reconsidered determination.

(a) HCFA gives the M+C organization or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the contract applicant's qualifications to enter into, or the M+C organization's qualifications to remain under, a contract with HCFA under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the M+C organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

78. In § 422.660, the introductory text is republished and paragraph (a) is revised to read as follows:

§ 422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with HCFA under Part C of title XVIII of the Act.

* * * * *

79. In § 422.662, paragraphs (a) and (b) are revised to read as follows:

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

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

Dated: June 15, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: June 16, 2000.

Donna E. Shalala,

Secretary.

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