DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, and 422

[CMS–4041–F]

RIN 0938–AK71

Medicare Program; Modifications to Managed Care Rules

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to comments that we received on a proposed rule that was published in the **Federal Register** on October 25, 2002. It implements certain provisions relating to the Medicare+Choice (M+C) program that were enacted in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection (BIPA) Act of 2000. It also addresses comments on, and makes revisions to, regulations that were discussed in the October 2002 proposed rule that were based on M+C program experience and feedback from M+C organizations.

EFFECTIVE DATES: This final rule is effective on September 22, 2003.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), added sections 1851 through 1859 to the Social Security Act (the Act) establishing a new Part C of the Medicare program, known as the Medicare+Choice (M+C) program. 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, could elect to receive benefits either through the original Medicare fee-for-service program or a M+C plan, if one was offered where he or she lived.

The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The BBA authorized a variety of private health plan options for beneficiaries, including both the traditional managed care plans (such as those offered by health maintenance organizations (HMOs)) that had been offered under section 1876 of the Act, and new options that were not previously authorized. Three types of M+C plans were authorized under the new Part C, as follows:

- 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 (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.

B. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) amended the M+C provisions of the Act. In a final rule that we published in the **Federal Register** on June 29, 2000 (65 FR 40170), we invited comments on many of the BBRA amendments. We noted in the October 25, 2002, proposed rule that we would respond to the comments relating to these BBRA provisions in this final rule.

We received comments from five organizations. Most of the comments were supportive of the changes brought about by the BBRA amendments and do not require our response. Most of the other comments addressed provisions other than the BBRA amendments. Rather they focused on the provisions of the final rules dealing with the BBA published on June 29, 2000. The following discussion responds to the comments made on BBRA.

Comment: Two major organizations commented on risk adjustment. One organization expressed concern that the collection of encounter data from physicians would be burdensome to physicians. A second organization indicated that they did not want to see a delay in implementation of the risk adjustment schedule as contained in BBRA.

Response: Legislation has determined the specifics of the schedules that CMS has implemented as to risk adjustment and the collection of encounter data. Section 511(a) of the BBRA amended section 1853(a) of the Act by providing for a risk adjustment transition schedule for calendar years (CY) 2000 and 2001 that differed from the one that we had provided as part of our risk adjustment methodology. The schedule was again modified in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Other BBRA provisions were also changed by the BIPA.

The final rule published on March 22, 2002 revised the regulations to reflect the changes to the BBRA provided in sections 502, 511, and 512 of the BIPA.

C. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (the BIPA) (Pub. L. 106–554), enacted December 21, 2000, further amended the M+C provisions of the Act. The final rule published on March 22, 2002 amended the regulations to reflect changes made by certain provisions of the BIPA, including those discussed in section I.B of this preamble, that amended provisions enacted in the BBRA. We published a proposed rule in the **Federal Register** on October 25, 2002 (67 FR 65672) that would revise M+C regulations to implement sections 605, 606, 611, 612, 615, 617, 620, 621, and 623 of the BIPA. In the October 2002 proposed rule, we also proposed modifying certain M+C regulatory provisions in response to program experience and feedback from M+C organizations.

D. Organization of the Preamble

The discussion of various policy issues in this final rule corresponds with the discussion of regulatory revisions that were presented in the October 2002 proposed rule. For the convenience of the reader, the analysis of comments and our responses are integrated with the discussion of each issue.

To accommodate the preamble's organization, we modified the numbering scheme accordingly. For example, roman numeral II is now Analysis of and Responses to Public Comments (instead of Provisions of this Proposed Rule), roman numeral III is Provisions of this Final Rule, and so forth.

We have also included a new section (II–A–10) discussing the fact that this final rule makes revisions to the regulations text to reflect changes to the statute made by section 616, which focuses on eliminating health disparities in the M+C program. We have provided a good cause statement for the inclusion of these revisions in this final rule to waive the requirement for notice and comment. As in the case of the revisions to the regulations made in the final rule published on March 22, 2002, notice and comment are not necessary since these revisions have no legal effect. Rather, they simply amend the text of the regulations to reflect statutory provisions whose applicability is

unaffected by these changes in regulation text. Although we are still sorting through implementation issues associated with this provision, we wanted to ensure that Congressional intent on this issue is reflected in M+C regulations.

In addition, we have made some minor revisions to Subpart O in an attempt to clarify information concerning our sanction authority. These changes do not add any new requirements, but serve to improve the regulatory language to more clearly affect the intent of the existing regulations (and statutory intent). We discuss these changes in the preamble and have modified the regulations accordingly.

II. Analysis of and Responses to Public Comments

In addition to the Response to Comments made above in reference to the BBRA, we received 10 letters containing over 100 specific comments. Comment letters were received from trade associations that represent providers and consumers, managed care organizations, and one individual. Below is a list of the areas that generated the most concern.

- Part 422 Subpart M—Grievances, Organization Determinations, and Appeals
- Part 422 Subpart C—Benefits and Beneficiary Protections
- Part 422 Subpart B—Eligibility, Election, and Enrollment
- Part 417 Subpart L—Medicare Contract Requirements.

A. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

1. Revision of Payment Rates for End-Stage Renal Disease (ESRD) Patients Enrolled in Medicare+Choice Plans

Section 605(a) of the BIPA amended section 1853(a)(1)(B) of the Act by requiring us to provide for appropriate adjustments to the M+C ESRD payment rates, effective January 1, 2002, to reflect the demonstration rate (including the risk adjustment methodology associated with the demonstration rate) of the social health maintenance organization ESRD capitation demonstration. This demonstration assessed whether it would be feasible to allow Medicare ESRD patients of all ages to enroll in M+C plans and to test risk-adjusted capitation payments for ESRD beneficiaries.

Before January 1, 2002, M+C ESRD capitation payments were based on State level base rates that were not risk-adjusted. The base payment rates were based on a base year (1997) amount that represented 95 percent of projected State average fee-for-service costs, as determined at that time.

Under section 605(c) of the BIPA, we were required to publish for public comment a description of the adjustments we proposed to make in accordance with section 605(a) of the BIPA. We published a proposed notice on May 1, 2001 (66 FR 21770) soliciting comments on the proposed adjustments. Section 605(c) of the BIPA further required us to publish these adjustments in final form so that the amendment made by section 605(a) of the BIPA would be implemented consistent with section 605(b) of the BIPA (which provided that the adjustments were to become effective with payments made for January 2002). We published this final notice in the **Federal Register** on October 1, 2001 (66 FR 49958). The foregoing process was separate from this rulemaking. In the October 2002 proposed rule, however, we proposed revisions to § 422.250(a)(2)(i)(B) to reflect our approach to implementing the requirements of section 605(a) of the BIPA.

The new ESRD payment methodology set forth in the final notice published on October 1, 2001—

- Increased the ESRD base payment rate for CY 2002 by 3 percent. We determined in the final notice that a 3 percent increase in the base rate was the most appropriate proxy for 100 percent of the estimated per capita fee-for-service expenditures for ESRD beneficiaries, and the most appropriate way to reflect the demonstration rates; and
- Adjusted State per capita rates by age and sex factors, in order to reflect differences in costs among ESRD patients.

These adjustment factors and rates for CY 2002 for enrollees with ESRD can be found on our Web site at *http:www.cms.gov/stats/hmorates/aapccpg.htm#2002rates.*

For the purpose of M+C payment, ESRD beneficiaries include all beneficiaries with ESRD, whether entitled to Medicare because of ESRD, disability, or age. Under the new M+C ESRD payment methodology published on October 1, 2001, rates would continue to include the costs of beneficiaries with Medicare as Secondary Payer (MSP) status. (Costs to Medicare of M+C ESRD enrollees with MSP status do not include payments made by other primary payers such as employer group health plans or other insurers.)

Several organizations commented on the revision of § 422.250(a)(2)(i).

Comment: Several commenters believe that the proposed revision to ESRD rates at § 422.250(a)(2)(i) should include payments made by primary payers other than Medicare, such as employer group health plans or other insurers. Since the M+C ESRD rates include the costs of beneficiaries with Medicare as Secondary Payer (MSP) status but exclude payments made by other primary payers such as employer group health plans or other insurers, the M+C ESRD rates are artificially low and do not reflect the actual health care costs. Two commenters also contended that the proposed payment methodology appears to be contrary to the provisions set forth in section 605(a) of the BIPA, which requires us to ''provide for appropriate adjustments to the M+C ESRD payment rates * * * to reflect the demonstration rate of the social health maintenance organization ESRD capitation demonstration.'' These commenters refer to a statement in the proposed Notice that the Demonstration rates were about 20 percent over rates paid outside the Demonstration because beneficiaries with MSP were not allowed to enroll in the Demonstration. The commenters conclude that the revisions to the ESRD payment methodology will significantly decrease the payment rates for M+C ESRD enrollees.

Response: As we stated in the October 1, 2001 final notice, we recognize that MSP for M+C ESRD enrollees is an issue. We noted that we would explore options within our payment system for addressing MSP status while proceeding to implement in CY 2002 the 3 percent base rate increase and the age and sex adjusters.

The ESRD Demonstration did not allow ESRD beneficiaries with MSP to enroll, and thus these beneficiaries were excluded from calculation of Demonstration payment rates. We are unable to exclude from the M+C program any beneficiaries with MSP who develop ESRD. Thus, we had to find a way to adapt the ESRD demonstration methodology to this different population. The provision for ''adjustments'' to ''reflect'' the demonstration rates and methodology does not mean that we must necessarily pay the same amount where the applicable circumstances, in this case the presence of beneficiaries with MSP, are different.

To assess whether the proposed M+C ESRD payment rates would increase or decrease payments to M+C organizations, the appropriate comparison would be M+C ESRD rates in effect prior to 2002, not the rates paid the ESRD Demonstration sites. The M+C

ESRD rates in effect prior to CY 2002 included the costs of beneficiaries with MSP, and we continued this approach. Two commenters are not correct in stating that the proposed M+C ESRD payment rates will significantly decrease payments to M+C organizations. In fact, the base rates were increased 3 percent under the method effective CY 2002. As we stated in the final notice, given current enrollment restrictions, we estimate that the age- and sex-adjusted average ESRD payment per beneficiary will result in a significant increase in payments to M+C organizations for their ESRD enrollees.

Accordingly, we are retaining the language we proposed which reflects the methodology we adopted through the 2001 notice process.

2. Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans

Section 606 of the BIPA amended section 1854(f)(1) of the Act to permit M+C organizations to elect to reduce or eliminate standard Part B premiums for their M+C Medicare enrollees, as an additional benefit, if the M+C organization has an adjusted excess amount, as defined in § 422.312(a)(2), for that plan in a contract year, beginning in CY 2003. Under section 606 of the BIPA, M+C organizations can elect to accept lower payments from us and apply 80 percent of the reduction to reduce the standard Part B premiums of M+C beneficiaries enrolled in that plan. The amount of the reduction in payments to the M+C organizations may not exceed 125 percent of the Medicare standard Part B premium rate set by us for that year, which is the amount that would result in eliminating the average enrollee's liability for the Part B premium entirely. The reduction must be applied uniformly to all similarly situated enrollees of the M+C plan.

In addition, section 606 of the BIPA required that the list of information made available to each enrollee electing an M+C plan must also include a description of any reduction in the Part B premiums. We proposed revising § 422.2, § 422.111(f), § 422.250(a)(1), and § 422.312 to reflect these provisions in the regulations. We received one comment in support of these regulations and are finalizing them as proposed.

3. Payment of Additional Amounts for New Benefits Covered During a Contract Term

Section 611 of the BIPA amended sections 1852(a)(5) and 1853(c)(7) of the Act with the intent of limiting the financial impact on M+C organizations of new coverage requirements adopted by the Congress. Before the enactment of the BIPA, section 1852(a)(5) provided that if a national coverage determination (NCD) of the Secretary which took effect after M+C payment rates were announced for a particular year, and that NCD would result in ''a significant change in the costs to a Medicare+Choice organization,'' M+C organizations were not required to cover them under their contracts, but the services were instead paid for on a fee-for-service basis through our fiscal intermediaries or carriers, until the next annual M+C payment announcement is made following the coverage change. Under the pre-BIPA version of section 1853(c)(7) of the Act, if an NCD resulted in ''significant'' costs, we were required to ''adjust appropriately'' capitation payments to reflect the new costs.

Section 611 of BIPA extended these provisions to changes in coverage resulting from legislation, in addition to those resulting from NCDs. We proposed revisions to § 422.109 to reflect these amendments. We received several comments on our proposed revised regulations.

Comment: Several commenters expressed concern that people enrolled in M+C organizations may not understand that new benefits or services available as a result of a national coverage determination (NCD) or legislative change in benefits may be paid in a different manner than other covered benefits when we determine that the costs of NCDs or legislative changes in benefits are ''significant.'' The commenters suggested that we publicize when new coverage is available, require M+C organizations to notify their members of the availability of the new benefits or services, and require M+C organizations to notify their members about the manner in which Medicare coverage and payment would take place. It was recommended that the notification should include a clear explanation of whether, and how much, the beneficiary might have to pay for the benefit or service until it is included in the M+C organization's capitation payment.

Response: We will continue to require M+C organizations to notify plan members when there is an NCD. If the NCD meets the ''significant cost'' threshold when the coverage is not included in the services, M+C organizations must cover the NCD under their contract in exchange for a monthly capitation payment. The M+C organization must notify plan members that original Medicare fee-for-service cost-sharing rules apply. M+C organizations are required to include an explanation of new NCDs in their next regularly scheduled beneficiary communication. If the new NCD or legislative change in benefits meets the ''significant cost'' threshold per § 422.109(a), the written explanation to beneficiaries about the new coverage will include the fact that the service will be paid in accordance with original Medicare payment rules and will include information on financial liability enrollees will have.

Comment: One commenter suggested that the final rule require M+C organizations to provide a statement in their *Summary of Benefits* that new Medicare benefits will be paid under traditional Medicare. It was also suggested that an explanation of the method by which enrollees in an M+C plan can access new benefits and services be included in the model *Evidence of Coverage.*

Response: It would be misleading to state that any new Medicare benefits would be paid under traditional Medicare rules. Unless new benefits meet the ''significant'' cost threshold, the M+C organization is required to cover them under its contract in exchange for its capitation payment. As stated above, M+C organizations are already held responsible for notifying enrollees of new coverage and of any cost sharing liability related to a new service, if the new service meets the ''significant cost'' threshold. Therefore, we do not believe it is feasible or even necessary to include the notification with respect to specific NCDs in the standardized *Summary of Benefits* or the annual *Evidence of Coverage,* because NCDs can be effective at any time during the year. We believe our current policy of having M+C organizations inform enrollees of NCDs when they occur both protects beneficiaries and prevents confusion.

Comment: One commenter suggested that we explain, in our program memoranda on new benefits, the procedures for direct reimbursement by the fiscal intermediary and the carrier in cases that meet the ''significant cost'' threshold and therefore are not covered by the M+C organization.

Response: We will make every effort to provide the suggested explanation in program memoranda on new benefits, if direct reimbursement by fiscal intermediaries and carriers is required because the new coverage meets the ''significant cost'' threshold. However, because program memoranda about new benefits are sometimes released independent of, and prior to, a determination that the new benefits meet the ''significant cost'' threshold described in § 422.109(a), it is not always possible to include such an

explanation in these program memoranda.

Comment: One commenter requested that we clarify that enrollees in an M+C plan are entitled to receive a new benefit if it is medically necessary, and that the M+C organization is responsible for ensuring access to, but not necessarily payment for, all new benefits.

Response: In accordance with section 1852 of the Act and regulations at § 422.101, M+C organizations must provide coverage of all Medicare-covered benefits that are available to beneficiaries residing in the plan's service area by furnishing, arranging for, or making payment for the services.

If an NCD or legislative change in benefits *does not* meet the ''significant cost'' threshold described in § 422.109(a), the M+C organization is required to provide coverage of the NCD or legislative change in benefits by furnishing, arranging for, or making payment for the services as of the effective date stated in the NCD or specified in the legislation. The M+C organization must also assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

If an NCD or legislative change in benefits *does* meet the ''significant cost'' threshold described in § 422.109(a), the M+C organization must provide coverage of the NCD or legislative change in benefits by furnishing or arranging for the NCD service or legislative change in benefits. However, the M+C organization is not required to pay or assume risk for the costs of that service or benefit until the contract year for which payments are adjusted to take into account the cost of the NCD service or legislative change in benefits. Medicare fee-for-service payment for the service is in addition to the capitation payment to the M+C organization and made directly by the fiscal intermediary and carrier to the M+C organization (or its designee, which may be the provider) in accordance with original Medicare payment rules, methods, and requirements.

Comment: One commenter recommended that we include the total costs resulting from all NCDs and legislative changes in benefits when making the ''significant cost'' determination. The commenter suggested that, if there is insufficient data for us to develop a reasonably reliable cost estimate for any NCD or legislatively mandated coverage, we should conclude that the costs for that new coverage have not been included in current M+C rates and that Medicare fee-for-service payment should be available for such coverage.

Response: We agree with the commenter's first point that several NCDs or legislative changes in benefits that do not individually trigger the existing regulatory definition of ''significant'' could potentially impose a greater burden than a single change that meets this definition. It would not be practical, however, to attempt to aggregate the costs of NCDs or statutory coverage changes during the ''transition'' year governed by section 1852(a)(5) of the Act, before capitation payments are ''adjust[ed] appropriately'' by us in the next payment announcement as required under section 1853(c)(7) of the Act. In part, this is because it would not be clear whether any aggregate test has been met until the last NCD or legislative change in benefits to be aggregated is issued. By that time, it would be too late to make any adjustment with respect to the M+C organization's obligation to cover earlier NCDs.

More importantly, the period prior to an adjustment in capitation rates is by definition ''temporary'' and limited to a period of less than 12 months. We believe that costs that may not be ''significant'' when the M+C organization knows they are being incurred for a temporary period of a few months would become ''significant'' if left unaccounted for in future payments indefinitely. Accordingly, we believe that it is reasonable to adopt a different interpretation of ''significant'' for purposes of deciding under section 1852(a)(5) of the Act whether to make temporary fee-for-service payments than for purposes of deciding whether, under section 1853(c)(7), to permanently ''adjust appropriately'' capitation payments. Given the temporary nature of partial year costs, we believe that the existing definition of significant costs in § 422.109(c) is appropriate for purposes of deciding whether to pay for services on a fee-for-service basis until an adjustment can be made to capitation payments. We believe that an M+C organization could bear the cost of any individual NCD or legislative change that does not meet this definition for the limited period of time involved prior to an appropriate adjustment being made to capitation rates.

However we believe that costs of NCDs and legislative changes that may not be significant when only in place for a few months could, when considered in the aggregate, be quite significant if left unaccounted for indefinitely in future capitation payments. Thus, in response to the commenters suggestion that the costs of NCDs and legislative changes be aggregated, we are providing for a different definition of ''significant'' costs to be used for purposes of the determination as to whether to make an adjustment under section 1853(c)(7) than applies for purposes of whether to pay on a fee-for-service basis under section 1852(a)(5) of the Act. We have revised the definition of significant cost (which was in § 422.109(c), but is now in § 422.109(a)) to provide that, for purposes of determining whether to make an adjustment under § 422.256, the tests in the definition of ''significant cost'' are applied to the aggregate costs of all NCDs and legislative changes in benefits made in the contract year. Under this test, the ''average cost'' of every NCD and legislative change in benefits would be added together. If the sum of all these average amounts exceeds the threshold under § 422.109(a)(1), then an adjustment to payment will be made under § 422.256 to reflect these costs. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceed the level set forth in § 422.109(a)(2), an adjustment to payment will be made under § 422.256.

We note that even when the ''significant cost'' threshold has been met under the existing definition, the current methodology for making the adjustment required under section 1853(c)(7) of the Act does not result in any adjustment in counties paid based on the minimum update rate (the so-called ''2 percent minimum update'' counties). The annual growth rate used to update M+C rates each year includes estimates of expenditures for new mid-year benefits. However, according to section 1853(c) of the Act, our Office of the Actuary uses the annual growth rate to update only the floor and blended rates, so the minimum 2 percent update rate does not reflect the costs of new benefits effective in the middle of the previous payment year. The impact is substantial because 64 percent of the 100 counties with the highest M+C enrollment in 2002 received the minimum update rate in the last three years, 2001 through 2003. The result is that M+C organizations have paid for almost all new benefits out of capitation payments that do not include payment for these new benefits.

We believe the Congress intended, in enacting section 1853(c)(7) of the Act, that payments to M+C organizations be adjusted to reflect the costs of new benefits when they are added through an NCD or legislative change. Since this does not occur under the current approach in the case of 2 percent counties, we are changing our method of making adjustments under section

1853(c)(7) of the Act. When the costs of NCDs and statutory coverage changes in a given year are determined to be ''significant'' under the new definition described above, these costs will be included in an ''NCD adjustment factor'' that will be added to the county rates in counties that will receive a 2 percent update. In other words, the 2 percent update will be applied to the newly adjusted rates. (The assumption is that the floor and blended rates are appropriately adjusted for new benefits because they are increased by the M+C growth rate that includes NCD and legislative changes in benefits estimates.) The ''NCD adjustment factor'' will be applied prospectively to the rate calculation for the year following the year after the NCDs and legislative benefit changes are effective. For example, NCDs and legislative changes determined to be significant in 2003 will be aggregated, and the ''NCD adjustment factor'' computed will be used to adjust payments for 2005. We have modified § 422.256(b) to codify in regulation this additional NCD adjustment factor adjustment to the M+C capitation rates.

Comment: One commenter supported the proposed rule and also asked whether the term ''significant'' would be defined as currently provided for in M+C regulations with a defined cost threshold.

Response: As discussed above, the proposed language at § 422.109(a) defining ''significant cost'' as it relates to the decision whether to make fee-for-service payment pursuant to section 1852(a)(5) of the Act is being retained.

As discussed above we are revising § 422.109 to provide that this definition will be applied to NCDs and legislative changes in benefits in the aggregate for purposes of the adjustments under § 422.256

4. Restriction on Implementation of Significant New Regulatory Requirements Midyear

Section 612 of the BIPA amended section 1856(b) of the Act to prohibit us from imposing significant new regulatory requirements on an M+C organization or plan, other than at the beginning of a calendar year. Comments on this issue and our responses follow.

Comment: One commenter asked that we use the term ''requirements'' instead of ''regulations'' in § 422.521. The commenter's reasoning for suggesting the use of ''requirements'' was that most documents from our agency that impose significant new cost or burdens are not in the form of regulations but are in the form of memoranda, guidance, manual chapters and the like.

Response: We agree with the commenter that requirements are often imposed through vehicles other than regulations. Therefore, in response to this comment, we are revising § 422.521 to extend the prohibition in section 612 of the BIPA to all requirements, not just those imposed in regulations. We note that we had previously made this commitment administratively.

Comment: One commenter requested that we define significant cost or burden as it is used in § 422.521. The commenter also suggested that we base the definition on cost or operational assessments conducted by us and by M+C organizations.

Response: We generally agree with the commenter and will explore methods to better define the meaning of ''cost and burden'' as those terms are used in § 422.521. However, we are leaving the text of § 422.521 unchanged.

5. Election of Uniform Local Coverage Policy for a Medicare+Choice Plan Covering Multiple Localities

Section 615 of the BIPA amended section 1852(a)(2) of the Act by adding a section that allows M+C organizations to achieve greater consistency of benefits for M+C plans covering multiple localities. In providing Medicare covered benefits to its enrollees, each M+C organization ordinarily must comply with, among other things, written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which the services are covered under the M+C plan. Some M+C organizations have plans that cover a large area, either a State or multiple counties in a State. Section 615 of the BIPA allows M+C organizations that offer a plan in a geographic area to which more than one local coverage policy applies, to uniformly apply the local coverage policy that is most advantageous to M+C enrollees in the plan. We will make the final determination as to which local coverage policy is most beneficial to M+C enrollees.

By electing to use this uniform coverage policy, M+C organizations can benefit from economies of scale when printing and distributing marketing materials and descriptions of benefits for their M+C plans. This policy will also enable M+C organizations to standardize coverage decisions and provider contracts across entire plans, rather than having different policies apply in different geographic areas of the same plan. We received three comments on our proposed revision.

Comment: Two commenters suggested that we apply the newly allowed uniform coverage policy rule across all M+C plans offered by an M+C organization and/or its subsidiaries. One commenter argued that such an expansion of the rule would serve both consistency and uniformity, as well as provide for significant cost-savings for multi-state M+C organizations.

Response: Section 615 of the BIPA is clear in restricting our authority to permit an M+C organization's election of a uniform local coverage policy to a specific plan offered by an M+C organization. The statute does not permit application of the uniform local coverage policy across different plans offered by a single M+C organization and/or its subsidiaries.

Comment: One commenter requested further guidance on the criteria that we will use to determine the local coverage policy that is most beneficial to M+C enrollees in a plan whose service area encompasses more than one local coverage policy area. The commenter also suggested allowing the M+C organization to identify the local coverage policy that it believes would be most beneficial to its enrollees. The M+C organization would notify us, providing justification for the local medical review policy selected as the most beneficial to its enrollees. If we did not disagree within 60 days of receipt of notice, the M+C organization's proposal would be deemed approved.

Response: We agree that clarification is needed for both the criteria that we will use in evaluating the local coverage policies that are most beneficial to M+C enrollees and the time frame within which that evaluation will occur. Since the benefits covered by a plan are essential to preparation of the adjusted community rate (ACR) proposal related to that plan (see § 422.306), an M+C organization proposing to adopt a uniform coverage policy for a plan must notify us 60 days prior to the date the ACR proposal for that plan is due. We believe that a 60-day window will permit us sufficient time to fully evaluate the proposed uniform coverage policy election related to a plan, and to notify the M+C organization of our decision, while still allowing sufficient time for the M+C organization to prepare and submit its ACR proposal in a timely manner. Therefore, we have added a new section § 422.101(b)(3)(i) which explains the time frame within which an M+C organization must notify us of its intent to adopt a uniform local coverage policy for a plan. In addition, we have added § 422.101(b)(3)(ii) which establishes the factors we will consider to evaluate the local coverage policy that is most beneficial to M+C enrollees. We, in turn, will notify the M+C

organization of our determination as to the most advantageous local coverage policy. The statute is clear in requiring us ''to identify'' the most advantageous local coverage policy; we therefore do not believe we could take the passive role of deeming approval through a non-response. Additionally, a positive response from us ensures that there can be no ambiguity as to which of the competing local coverage policies actually applies to all enrollees of the plan.

6. Medicare+Choice Program Compatibility With Employer or Union Group Health Plans

Section 617 of the BIPA amended section 1857 of the Act by adding a new subsection (i), which provides us broad authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of a fund established to furnish benefits to an entity's employees.

Previously, M+C organizations that contracted with an employer group or with a State Medicaid agency to provide benefits had to comply with all requirements of the regulations found in part 422. The authority in section 617 of the BIPA was first available for CY 2001. We informed M+C organizations that, in order to facilitate the offering of M+C plans under contracts with employers, labor organizations, or the trustees of a benefits trust fund, upon receiving a written request from an M+C organization, we have the option to waive or modify those requirements in part 422 of the regulations that would hinder the design of, the offering of, or the enrollment in an M+C plan. As indicated in the proposed rule, after we have approved a request for a waiver, the requesting M+C plan, and any other M+C organization, will be able to use the waiver in developing their ACR proposal. Any M+C plan using the waiver must include that information in the cover letter of its ACR proposal submission to us. The waiver or modification will take effect once the ACR proposal has been approved.

To date, we have approved the following three types of waivers under the authority granted us in section 617 of the BIPA:

- *Employer-Only Plans:* We are allowing M+C organizations to offer employer-only plans (that is, M+C plans not available to the individual market). M+C organizations are not required to market these plans to individuals. In addition, M+C organizations will not be required to submit the marketing materials for employer-only plans for our pre-review and approval.
- Actuarial Swaps: We are allowing M+C organizations to swap benefits not covered by Medicare of approximately equal value when an employer asks for a benefit package that differs from the package offered by the M+C organization to the individual market.
- Actuarial Equivalence: We are allowing M+C organizations to raise the co-payments for certain benefits but to provide a higher benefit level or a modification to the premium charged, as long as projected beneficiary liability was actuarially equivalent.

We received two substantive comments on the employer group waiver provisions.

Comment: A commenter asked that we confirm whether our waiver authority can be used in areas such as ACR proposals, and enrollment and disenrollment processes (for example, the use of electronic enrollment and disenrollment for employer group members). The commenter also suggested that we revise the regulation to ensure that it is flexible enough to accommodate such waivers, including clarification that requests to use approved waivers that are not related to benefit and rate proposals may be submitted at any time during the year.

Response: As noted above, Section 617 of the BIPA provides broad authority for us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in M+C plans under contracts between M+C organizations and employers or unions. Accordingly, under this authority, we have broad discretion to approve employer group waivers in all areas of the M+C program, including both enrollment and disenrollment and benefit and rate proposals. We do not believe that any change to the regulatory language implementing the waiver authority is necessary. The regulatory language implementing this waiver authority is consistent with the statutory language in section 1857(i) of the Act, which provides us wide latitude to approve appropriate waivers. In reviewing proposed waivers, we will balance the objective of promoting M+C enrollment by employer group members with the need to ensure that adequate protections are in place to ensure that employer group members enrolled in M+C plans have access to the Medicare covered benefits consistent with Medicare standards. Waiver requests by M+C organizations may be submitted at any time of the year.

Comment: Another commenter asked for clarification of § 422.106(a)(2) which states that employer group benefits that ''complement'' an M+C plan and the marketing materials associated with those benefits are not subject to our approval. The commenter was not clear as to what ''complement'' means in this context. The commenter further notes that paragraph (a)(2) continues, ''M+C plan benefits provided to enrollees of the employer * * * and the associated marketing materials, are subject to CMS review and approval.'' According to the commenter, these two sentences within paragraph (a)(2) are internally inconsistent and confusing, and the commenter suggested that the benefit package of an employer-only M+C plan was subject to our review and approval. The commenter also requested that we clarify that employer group benefits or marketing materials will not be subject to prior review as long as the M+C organization certifies, in its ACR, that an employer-only M+C plan benefit package contains all Medicare-covered items and services. The commenter also suggested that M+C organizations should not be required to send copies of employer group-marketing materials to us after printing.

Response: We agree that § 422.106 (a)(1) and (a)(2) need to be clarified. The purpose of § 422.106(a)(2) is to highlight the fact that the M+C regulations apply to those benefits that are included under our approved M+C benefit package and that the regulations do *not* apply to what are referred to in the regulation as ''complementary'' benefits. Complementary benefits are employer-sponsored benefits, which are outside of the ACR proposal and are independently arranged by an employer on behalf of its employer group members for the purpose of enhancing the M+C benefit package. Therefore, we have modified § 422.106(a)(2) to clarify that we do not regulate or approve employer-sponsored benefits.

Employer group plans are required to provide an ACR proposal that includes all Medicare Part A and Part B services. There are no additional ''prior review'' requirements for approving the M+C benefit package for employer group members. We have already approved a waiver related to prior review of marketing material of employer-only plans. However, all M+C organizations will continue to be required to send informational copies of the employer-only plan's marketing materials to our Regional Office that is the ''lead region.'' The employer group waivers are posted at our website at the following web address: *http://www.cms.hhs.gov/healthplans/employers/*.

7. Permitting End-Stage Renal Disease Beneficiaries To Enroll in Another Medicare+Choice Plan if the Plan in Which They Are Enrolled Is Terminated

Section 620 of the BIPA amended section 1851(a)(3)(B) of the Act to permit beneficiaries with end-stage renal disease (ESRD) to enroll in any other available M+C plan if the plan in which they are enrolled is terminated or the M+C organization discontinues the plan in the area in which the beneficiary lives. Before the BIPA, beneficiaries with ESRD who were affected by an M+C plan termination were only able to elect another plan offered by the same M+C organization or return to the original Medicare fee-for-service program.

Under this provision, if the beneficiary enrolls in another M+C plan, and that plan is subsequently terminated, he or she is able to elect another M+C plan (offered by the same M+C organization or a different organization) based upon that termination. This would be true for any subsequent M+C plan terminations or discontinuations that result in the enrollee's disenrollment. Thus, if the enrollee's plan is subsequently terminated or discontinued, the individual would have another opportunity to elect another M+C plan. The individual may use this election immediately, or may do so during a subsequent election period. Once the individual has made such an election, he or she may not join another M+C plan offered by another M+C organization unless his or her plan is terminated or discontinued. Thus, if the beneficiary exhausts his or her one election, and then later seeks to disenroll from the plan for reasons other than its termination, he or she may only enroll in another M+C plan offered by the same M+C organization, or return to original fee-for-service Medicare. If the beneficiary returns to original Medicare, he or she will not be able to later enroll in an M+C plan.

Comment: One commenter expressed concern that the preamble to the proposed rule could be misconstrued to mean that a beneficiary who is enrolled in an M+C plan and subsequently disenrolls from the plan for reasons other than the plan's termination or discontinuation can return to the original fee-for-service Medicare program and at some future date reenroll in a different plan offered by the same M+C organization.

Response: As explained above, we are clarifying that a beneficiary who elects another M+C plan as provided for under section 620 of the BIPA and later decides to disenroll from the plan for reasons other than its termination or discontinuation, may only elect another M+C plan offered by the same M+C organization at the time he or she is enrolled with that organization under some health plan it offers. In the commenters example, the beneficiary has spent time in original fee-for-service Medicare while not an enrollee with the organizations under any option. Under this circumstance, the enrollee would not be eligible to enroll in any M+C plan, including one offered by the M+C organization with which he or she was formerly enrolled.

Comment: Several commenters requested clarification as to whether or not the beneficiary had to elect a new M+C plan within a certain time frame. One commenter supported the establishment of a time limit, while others opposed any such time limit.

Response: In the preamble to the proposed rule, we indicated that we do not interpret section 1851(a)(3)(B) of the Act to require an enrollee to elect a new M+C plan immediately upon the termination or discontinuation of the M+C plan in which he or she is enrolled. This is based on section 620(b)(2) of the BIPA, which specifically extends this provision to individuals who had been enrolled in terminating or discontinued plans any time after December 31, 1998. In accordance with this section, and section 620(a) of the BIPA, these individuals are treated as M+C eligible individuals for purposes of electing to continue enrollment in another M+C plan. Because the statute clearly contemplates enrollment by individuals not currently enrolled in an M+C plan, we believe that the phrase ''continue enrollment'' in section 620(a) of the BIPA does not necessarily mean ''continue without interruption'' and, therefore, should not be time-limited. As stated above, the beneficiary may use his or her election immediately upon the plan's termination, or may use this election during a subsequent election period.

8. Providing Choice for Skilled Nursing Facility Services Under the Medicare+Choice Program

Section 621 of the BIPA amended section 1852 of the Act by adding a new subsection (l). This new subsection ensures that an M+C organization will give a Medicare beneficiary who is a resident of a skilled nursing facility (SNF) the option of returning to his or her ''home SNF'' for post-hospital extended care services upon discharge from a hospital when certain conditions are met.

The term ''home skilled nursing facility'' is defined as—

- The SNF in which the beneficiary resided at the time of admission to the hospital;
- A SNF providing post-hospital extended care services through a continuing care retirement community that provided residence to the beneficiary at the time of admission to the hospital; or
- The SNF in which the spouse of the beneficiary is residing at the time of discharge from the hospital.

In order for a home SNF to be offered under this section, the SNF to which the beneficiary will be returned must either have a contract with the M+C organization to provide post-hospital services or must agree to accept substantially similar payment under the same terms and conditions that apply to SNFs under contract with the M+C organization. The coverage provided must be no less favorable to the beneficiary than coverage of post-hospital services that are otherwise covered under the M+C plan.

The requirement to return the beneficiary to his or her home SNF would not apply if the applicable SNF is not qualified to provide benefits under Medicare Part A to beneficiaries not enrolled in an M+C plan. A SNF that is not contractually bound to do so could refuse to accept an M+C beneficiary or impose conditions on the acceptance of the beneficiary for post-hospital extended care services.

The requirements of this new subsection (l) first became applicable under contracts entered into or renewed on or after December 20, 2000.

We received one comment relating to this provision.

Comment: The commenter expressed concern regarding potential quality issues when a plan member uses the ''return home'' benefit to enter a non-plan SNF. In addition, the commenter believes that this provision ''binds'' the internal operations of an M+C organization and could set a precedent for other areas of care in the future.

Response: We agree that an M+C organization does not have the same ability to verify the quality of non-contract SNFs as it does contract SNFs. For this reason, we will allow an M+C organization to advise members who are obtaining services in a non-contract SNF under the ''return home'' benefit that the M+C plan cannot guarantee the quality of care that members will receive in the non-contract SNF. However, we also note that an M+C organization can only refer members to Medicare certified SNFs. The ''return home'' SNF benefit was established

legislatively and, thus, does not set a precedent for other benefits of this type unless the Congress extends the benefit to other benefits by similar legislation.

9. Increased Civil Money Penalty for Medicare+Choice Organizations That Terminate Contracts Mid-Year

Section 1857(g)(3) of the Act provides us with the authority to impose intermediate sanctions, including civil money penalties, on M+C organizations for the same reasons for which we can terminate an M+C organization's contract. Section 1857(c)(2) of the Act provides that we may, at any time, terminate an M+C organization's contract if we determine that the M+C organization—

- Failed substantially to carry out the contract;
- Is carrying out the contract in a manner inconsistent with the efficient and effective administration of the M+C program; or
- No longer substantially meets the applicable conditions of the M+C program.

Section 623 of the BIPA amended section 1857(g)(3) of the Act by providing us the authority to establish and levy separate and distinct civil money penalties when we determine that an M+C organization has failed to substantially carry out the terms of its contract based upon the M+C organization's termination of its contract with us in a manner other than that provided in the M+C contract and in § 422.512.

Under section 1857(g)(3)(D) of the Act, in such cases, we may impose a civil money penalty of ''$100,000 or such higher amount as the Secretary may establish by regulation.'' We believe that the Congress provided us with the authority to provide for a higher civil money penalty amount than $100,000 in recognition of the fact that the $100,000 specified in the Act may not provide an effective deterrent in some instances to discourage M+C organizations from terminating their contracts in a manner inconsistent with the procedures described in the regulations. In developing regulations providing for a potentially higher civil money penalty amount, it is appropriate for us to consider the number of Medicare beneficiaries who could be adversely affected by an M+C organization's decision to terminate its contract with us in a manner that violates M+C rules.

Thus, we proposed to establish the amount of this civil money penalty as either $250 per Medicare member enrolled in the terminated M+C plan or plans at the time the M+C organization terminated its contract with us, or $100,000, whichever is greater. We added the ''whichever is greater'' provision to discourage violations of the contract termination provisions by M+C organizations with lower M+C plan enrollment. In either instance, this new civil money penalty represents a substantial increase over the current civil money penalty of $25,000 for similar violations, and serves as an effective deterrent against M+C contract terminations violations that could potentially harm Medicare beneficiaries.

We received one comment on this change in civil money penalties.

Comment: The commenter seeks affirmation that we will not impose civil money penalties when the mid-year termination is caused by an event that is not within the control of the M+C organization (for example, substantial loss of network capability).

Response: We will not create an exception to waive the civil money penalties at § 422.758(b) because an M+C organization is experiencing network problems. If an M+C organization loses network capacity during the year, we expect that the M+C organization will establish new provider contracts or pay for services on a fee-for-service basis. There may be situations that require us to terminate a contract mid-year. For example, we have used our immediate termination authority at § 422.510(a)(5) to protect beneficiary access to health care when an M+C organization experiences financial difficulties so severe that access to health care is endangered. Section 623 of the BIPA was not written to permit us to levy a civil money penalty if we, not the M+C organization, take the termination action. The law was designed to prohibit M+C organizations from inappropriately ending their contractual commitments without our consent.

10. Eliminating Health Disparities in Medicare+Choice Program

Section 616 of the BIPA amended section 1852(e) of the Act by requiring that an M+C organization's Quality Assurance Program have a separate focus on racial and ethnic minorities. This provision was not included in the October 2002 proposed rule because we had not developed any policies to propose. Although we are still evaluating implementation issues, we are adding a new paragraph (4) to § 422.152(f) to reflect this BIPA provision. Prior notice and comment is not necessary in the case of this change, because merely adding the statutory requirements to the regulations text has no legal effect. We have included a good cause statement below for waiving prior notice and comment with respect to this change.

B. Skilled Nursing Facility Care Under Medicare+Choice

Under section 1814(a)(2)(B) of the Act, the Medicare extended care skilled nursing facility (SNF) benefit covers skilled nursing care or other skilled rehabilitation services that the beneficiary requires on a daily basis and that are only available in a SNF on an inpatient basis.

Generally, we will only cover this benefit following a hospital stay of not less than 3 days. Under section 1812(f) of the Act, however, we may authorize coverage of SNF care without a prior hospital stay if two conditions are met. First, the coverage of these services must not result in any increase in Medicare program payments, and second, the coverage must not alter the acute care nature of the benefit.

We have determined that these conditions are met in the case of SNF services furnished by an M+C organization that covers SNF services. Accordingly, we proposed changes in the regulations to reflect this determination, specifically, adding a new § 409.20(c)(4), revising § 409.30(b) and § 409.31(b), and adding a new § 422.101(c).

Several organizations, representing both providers and consumers, stated that they agreed with our proposed changes.

Comment: One commenter recommended that we clarify that after voluntarily disenrolling from the M+C program, the beneficiary may receive Part A SNF care if he or she meets the skilled level of care requirement.

Response: The commenter is correct that under this final rule, Part A SNF care would be covered for an individual who meets the skilled level of care requirement if he or she voluntarily disenrolls from a M+C program that was covering the care without a prior 3-day hospital stay. We believe that § 409.30(b)(2)(ii) makes this sufficiently clear that no further clarification is needed.

Comment: A major organization recommended that we clarify that when a beneficiary converts from a M+C stay in a SNF to a fee-for-service stay, a new 100 day period begins, unless the prior days under M+C were skilled care.

Response: We agree with this recommendation. If skilled care is provided to the beneficiary while he or she is enrolled in the M+C organization, then this time period counts towards the 100 days. If it is unknown whether or not skilled care is provided or the care

is unskilled, then the 100 days starts when the fee-for-service stay begins. We will clarify this provision in the Intermediary Manual.

Comment: Two commenters proposed that the waiver of the 3-day hospital requirement for SNF care also be applied to cost contractors (health maintenance organizations and competitive medical plans) under section 1876 of the Act. One commenter argued ''* * * that expanding the provision to cost contractors will result in a substantial reduction in Medicare costs for inpatient hospitalization. These savings will more than counterbalance any increases in SNF costs. We believe that inpatient admissions may occur when perhaps the more appropriate level of care is in a skilled nursing facility. We believe that allowing an exception to the three-day prior hospitalization requirement will result in net savings to the Medicare program.''

Another commenter noted that, ''Organizations participating in the Medicare program as cost plans are structured in the same manner as M+C organizations and have the same inherent incentives for the provision of quality care in the most appropriate setting. Since this structure promotes similar patterns of practice regardless of the type of Medicare contract, we believe that the criteria described above would be met if this policy were applied to cost plans.''

Response: M+C organizations are paid on a capitated basis, so they have an incentive to contain costs. However, cost contractors under section 1876 of the Act do not have such an incentive. We have no evidence to indicate that they would reduce hospital admissions if we were to waive the 3-day prior hospital stay requirement. Therefore, we have decided not to accept this recommendation at this time.

C. Disenrollment by the M+C Organization

Section 422.74(d)(4) provides that, except where continuation of enrollment under § 422.54 applies, an individual must be disenrolled from an M+C plan if he or she is out of the service area for over 6 months. The proposed rule included a revision to § 422.74(d)(4) creating an exception to this 6-month rule for ''visitor'' or ''traveler'' type programs. Under the proposed exception, M+C organizations could continue to offer extended ''visitor'' or ''traveler'' programs to members who have been out of the service area for up to 12 months, provided that the plan included the full range of services available to other members. M+C organizations offering these programs may limit their availability to certain areas and may impose restrictions on obtaining benefits, except for urgent, emergent, and post-stabilization care, and renal dialysis. These organizations do not have to disenroll members in these extended programs who remain out of the service area for up to 12 months. However, those M+C organizations without this program must continue to disenroll members once they have been out of the service area for more than 6 months. We received one comment supporting this change, and are adopting it as proposed.

D. Reporting Requirements for Physician Incentive Plans

Section 1852(j)(4)(A)(iii) of the Act requires M+C organizations to provide us with descriptive information regarding their physician incentive plans (PIP) sufficient to permit us to determine whether the plan is in compliance with the applicable requirements. The current regulations interpreted this provision to require that an M+C organization submit the CMS PIP Disclosure Form (OMB No. 0938–0700) to us with its contract application and annually thereafter. We are changing the reporting requirement to allow M+C organizations to maintain the required PIP information in their files and submit that information to us upon request. Several commenters agreed with this change.

Comment: A commenter requested that we provide clear guidance on what information managed care organizations should maintain in their files.

Response: Section 417.479(h)(3) and § 422.210(b) provide details on the information that should be maintained in either the contractor or subcontractor files for purposes of responding to inquiries from beneficiaries. Since there will no longer be routine reporting of PIP information to us, the cost-contracting health maintenance organizations/competitive medical plans and M+C organizations should simply maintain sufficient information ''...to permit CMS to determine whether the plan is in compliance with the applicable requirements,'' should we request it.

Comment: A commenter requested that, under the cost program, two types of entities, health maintenance organizations and competitive medical plans, are eligible for contracting. The proposal omits a reference to competitive medical plans.

Response: We will revise the regulation to cover competitive medical plans.

Comment: A commenter suggested that the instructions for amending § 417.479(h) appear incorrect. The disclosure to beneficiaries provision is in paragraph (h)(3), not (h)(2). Thus, we should replace paragraph (h)(1) and (h)(2) with the new (h)(1). Then paragraph (h)(3) would be designated (h)(2).

Response: The commenter is correct in noting an inconsistency in our proposed revision. Therefore, § 417.479(h)(1) will remain as written in the proposed regulation, with the addition of a reference to competitive medical plans, as noted above. Section 417.479(h)(2) will be revised to include only the rules on pooling of patients. Finally, § 417.479(h)(3), related to disclosure to Medicare beneficiaries, will remain as part of the regulation with a minor, editorial change.

E. M+C Appeals Process

1. Defining Who Can Request Organization Determinations

Currently, the M+C regulations at § 422.566(c) specify that any of the parties listed in § 422.574 can request an M+C organization determination. It has come to our attention that, in some cases, the use of this cross-reference has been misconstrued to mean that, in order to request an organization determination on behalf of an enrollee, an affiliated provider would need to be an authorized representative, and a non-affiliated provider would need to be an assignee. Although we discussed this issue in our June 29, 2000 final rule (65 FR 40282), some confusion has continued.

We have always intended for requests for organization determinations to be more inclusive than requests for appeals. To clarify this point, we have eliminated the existing cross-reference to § 422.574 and we are listing those who may request an M+C organization determination under § 422.566(c). Determination requests may be made by—

- The enrollee (including his or her authorized representative);
- Any provider that furnished, or intends to furnish, services to the enrollee; or
- The legal representative of a deceased enrollee's estate.

The fact that an individual or entity may request an organization determination does not necessarily entitle that individual or entity the right to request an appeal, unless the conditions for party status under § 422.574 are met.

Comment: We received two comments regarding who can request an

organization determination under § 422.566(c). One commenter supported the elimination of the cross-reference with the provision that only treating or attending providers involved with the enrollee's health care should be allowed to request organization determinations.

Another commenter believed that in an effort to discourage inappropriate use of the process, providers should only be allowed to make requests for organization determinations with the full knowledge and agreement of the enrollee. The commenter recommended that we establish this distinction in the preamble or regulation, and, if an enrollee indicates that a requested organization determination is inconsistent with his or her wishes, then the M+C organization should be able to cease action on the request.

Response: We believe that the text, ''any provider that furnishes, or intends to furnish, services to the enrollee,'' already addresses the commenter's concern that the provider requesting an organization determination be involved with the enrollee's health care. Because enrollees in some M+C plans are free to seek care from providers within or outside of the M+C organization's network and all enrollees may go out of network for emergency and certain other services, we believe it is appropriate to use the all-inclusive term ''any,'' instead of ''treating,'' to describe the providers furnishing, or intending to furnish, services to enrollees.

We agree with the second commenter that providers should request organization determinations only with the full knowledge and agreement of enrollees. This is particularly important for unaffiliated providers that might seek payment for services already furnished to enrollees. In addition, an M+C organization may cease action on a provider's request for an organization determination that is inconsistent with an enrollee's wishes.

2. Effectuation Times When M+C Organizations File Appeals

The current regulations at § 422.618 and § 422.619 establish effectuation times when an M+C organization's denial of coverage or payment is overturned, either through its own reconsideration process or by an independent outside entity. Effectuate means to authorize, pay for, or provide coverage. The M+C organization may not appeal the independent outside entity's decision. Section 422.618 also requires that, if the independent outside entity's determination is reversed (in whole or in part) by an administrative law judge (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 the M+C organization receives notice reversing the determination. In these situations, the M+C organization, like an enrollee, has 60 days to appeal.

The ambiguity in the current regulations, which require effectuation of a determination within 60 days, but also permit further appeal within the same time frame, results in confusion. To reconcile these two regulatory provisions, we proposed to revise the rules so that M+C organizations may await the outcome of a Departmental Appeals Board (the Board) review before effectuating a decision of an ALJ. This change would serve to balance the M+C organization's right to appeal with the need to ensure that an enrollee would not be faced with a potentially large debt in the event that the Board overturns the ALJ after the service has been furnished to the enrollee.

In § 422.618(c), we proposed to retain, as the general rule, the 60-day effectuation requirement for reversals by an ALJ or higher level of appeal. This is because we did not want to effectively negate the M+C organization's 60-day right to request an appeal to the Board or higher level. However, our expectation was that M+C organizations would not take the maximum 60 days to effectuate a decision they do not intend to appeal. We proposed to redesignate the current § 422.618(c), as § 422.618(c)(1) and provide that the 60-day deadline for effectuation was the ''general rule.'' We then proposed to add a new § 422.618(c)(2) which would allow for an exception to the 60-day standard if the M+C organization decided to request a Board review consistent with § 422.608. We proposed to allow the M+C organization to await the outcome of the Board review before it pays for, authorizes, or provides the service under dispute. Under the provision, we would require an M+C organization that files an appeal with the Board concurrently to send a copy of its request and any accompanying documents to the enrollee. Additionally, in the proposed rule, the M+C organization was required to notify the independent review entity of the requested appeal.

Consistent with this change, we also proposed to revise § 422.619(c) with regard to effectuating expedited reconsidered determinations. As in standard appeals, we proposed to allow an exception for the M+C organization to await the outcome of the Board's review before the M+C organization authorizes or provides the service under dispute. Additionally, an M+C organization that files an appeal with the Board would be required concurrently to send a copy of its request and any accompanying documents to the enrollee, as well as notifying the independent review entity of the requested appeal.

Comment: Some commenters believe that the 60-day time frame for an M+C organization to decide whether to appeal (and ultimately pay for or provide a service) is too long. One commenter suggested that the time frame to allow an M+C organization to appeal to the Departmental Appeals Board (DAB) should be reduced to 30 days. Another commenter believes that M+C organizations generally know well before 60 days whether they intend to appeal an administrative law judge's (ALJ's) decision. Instead, an M+C organization more likely would need a 60-day time frame to gather evidence in support of an appeal. The commenter argued that, since enrollees already wait a long time for ALJ decisions, enrollees should not be made to wait another 60 days to receive care.

Other commenters supported our attempt to reconcile the provisions that, on the one hand, allow an M+C organization the right to appeal an ALJ's decision, but, on the other hand, require the M+C organization to effectuate the decision before a final DAB decision. One commenter supported a 60-day, rather than a 72-hour, effectuation time frame for expedited reviews.

Response: Currently, § 422.618(c)(1) and § 422.619(c)(1) require an M+C organization to 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 that the M+C organization receives a decision reversing a determination. Section 422.608 also provides for an appeal by the M+C organization within the same 60-day time period that effectuation must occur. While we appreciate the commenters' concerns that 60 days seems like a long time for M+C organizations to appeal, we believe that we should allow M+C organizations the same 60-day time frame afforded to other parties when they file appeals. Thus, we will maintain the current 60-day standard at § 422.608 for all parties seeking review by the DAB.

We recognize that an enrollee may encounter a delay in obtaining a service if an M+C organization appeals; however, both the DAB and the ALJ hearing offices have procedures to screen cases and to give priority to pre-service denial cases, including immediate assignment and resolution of

cases involving imminent health risks. Thus, as proposed, we are adding § 422.618(c)(2) and § 422.619(c)(2) to allow for an exception to the 60-day effectuation standard when an M+C organization requests DAB review. An M+C organization may await the outcome of the DAB's review before it pays for, authorizes or provides the service under dispute.

Comment: One commenter was concerned with our statement that ''* * * the M+C organization would have to meet the medical exigency standard for providing or authorizing services as expeditiously as the enrollee's health condition requires regardless of the 60-day time frame.'' The commenter interpreted this statement to mean that a M+C organization that intends to appeal an ALJ decision would still have to apply the medical exigency standard, and provide services if warranted under this standard notwithstanding the filing of a DAB appeal. The commenter thought that this would undercut the exception to the effectuation time frames and undermine a M+C organization's right under both the appeals process and, though it is not clear to us why, the Administrative Procedure Act (APA). Instead, the commenter recommends that we permit the exception to the effectuation rule under all circumstances, and promulgate an expedited review process for the DAB to follow in medically exigent cases. Another commenter urged us to monitor whether M+C organizations take the maximum 60 days to implement a decision that they do not intend to appeal.

Response: The section of the proposed rule that the commenter references is a discussion about our reason for maintaining a 60-day effectuation requirement for expedited appeals, as opposed to 72 hours. We wanted to make clear that, despite our intention to maintain the 60-day requirement, M+C organizations still would be held to the medical exigency standard if they did not intend to pursue an appeal of an ALJ decision. In other words, just because we had retained the 60-day time-frame for appealing, this did not mean that an M+C organization could take 60 days to effectuate if it was not pursuing an appeal. Rather, in this instance, it must 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.

We agree with the commenter, however, that when a M+C organization is appealing the ALJ decision, it should not be required to effectuate the ALJ decision, and would not apply the medical exigency standard until it was time to effectuate a decision from the DAB. We also agree with the commenter that the DAB should expedite cases in which there is a medical exigency, and inform the commenter that the DAB has procedures in place to do so. Finally, with respect to monitoring, we agree that M+C organizations should be monitored to see whether they are delaying effectuation 60 days in cases in which they are not appealing the ALJ decision.

Comment: Some commenters were pleased with our proposal that M+C organizations notify enrollees and the independent review entity (IRE) in the event of an appeal to the DAB. They believed that such notification would enable enrollees to file evidence, arguments or legal memoranda to the DAB in support of an ALJ decision.

Response: We agree with the commenters and are retaining this proposal which requires a M+C organization to concurrently send a copy of its appeal request and the accompanying documents to the enrollee and the IRE at § 422.618(c)(2) and § 422.619(c)(2) in this final rule.

Comment: One commenter recommended that we apply an exception to the effectuation provision for cases in which the M+C organization intends to dispute determinations made by the IRE.

Response: The regulations only provide for appeals by M+C organizations at the ALJ level or higher. The only way for an M+C organization to ''challenge'' the IRE's decision is to request a reopening in accordance with § 422.616. A reopening is an administrative action outside of the realm of the appeals process and we do not believe that delaying effectuation under these circumstances is warranted.

F. Requiring Health Care Prepayment Plans (HCPPs) and Remaining Cost Plans To Follow the M+C Appeals Process

In the proposed rule, we solicited comments on whether HCPPs and the remaining cost plans should follow the M+C appeals and grievance processes under subpart M of part 422. We have not included these provisions in this final regulation, because we need more time to analyze the comments and evaluate implementation issues.

G. Technical Clarifications

1. Grace Period for Late Premium Payments

We are making a technical change to address concerns that M+C organizations have raised concerning the starting date for the 90-day grace period for late premium payments. Section 422.74(d)(1)(ii) provides that an M+C organization may disenroll a Medicare beneficiary when the organization has not received payment within 90 days after it has sent a written notice of nonpayment to the individual. Several M+C organizations requested that the 90-day grace period start on the day the premium payment was due, rather than the day the notice was sent. Since the notice has to be provided within 20 days of the premium due date, starting the grace period on the premium due date would ensure that the beneficiary has at least 70 days following receipt of the notice to pay the premium and avoid disenrollment. We believe that this constitutes an appropriate grace period and proposed to change the regulation accordingly. We received one comment supporting this change and are adopting it as proposed.

2. Payment for Hospice Care

In the proposed rule, we proposed to clarify information concerning changes in M+C payments when an individual has elected hospice care.

Specifically, we proposed to revise § 422.266(d) to make clear that when enrollees of M+C plans elect to receive hospice care under § 418.24, we will not make any payment for the hospice care to the M+C plan beginning with the next month's payment after the election, except for the portion of the payment applicable to additional benefits, as described in § 422.312. Currently, the regulation refers to capitation payments being reduced to this amount which produces the same result. However, this language was changed from the language that applies to health maintenance organizations and competitive medical plans, and we believe the latter language makes the policy clearer.

We received no comments on this change and have revised § 422.266(c) to reflect this clarification.

3. Clarification of Subpart O to Effectuate Statutory Intent

We are making minor changes to Subpart O in an attempt to clarify information regarding our sanction authority. These changes do not add any new requirements. They serve to improve the wording of certain areas to more clearly reflect statutory intent.

Section 1857(g)(1) of the Act contemplates violations that are generally considered ''fraud and abuse.'' This section further states, ''* * * the Secretary may provide, in addition to

any other remedies authorized by law, for any of the remedies described in paragraph (2) * * * .'' Because the OIG has the traditional authority to investigate fraud complaints, the regulation should ensure that it is understood that the OIG stands in the place of ''the Secretary'' when civil money penalties are imposed for such violations. We (CMS) would have authority for other intermediate sanctions under M+C. Currently, § 422.752(a) states, ''For the violations listed below, CMS may impose *any* of the sanctions specified in § 422.750 * * *.'' *Any* of the sanctions presupposes that we may freeze marketing, enrollment, payment *and impose civil money penalties.* This stands in contrast to the statutory intent and it clearly contrasts with § 422.756(f)(2) where, in discussing civil money penalties, the regulation currently reads, ''In the case of a violation described in § 422.752(a) * * * in accordance with 42 CFR parts 1003 and 1005, the OIG may impose CMPs on M+C organizations * * *'' We are changing § 422.752(a) to clarify when the OIG has the sole authority to impose civil money penalties.

Section 422.756(f)(3) references the OIG's regulations at parts 1003 and 1005. This cross-reference creates confusion without further clarification. The civil money penalty provisions included in the OIG's regulations at parts 1003 and 1005 implement section 1876 of the Act, not the M+C program under the BBA. We are proposing a regulatory change to eliminate any reference to part 1003 for information about which level of civil money penalty might apply.

Section 422.758 states that civil money penalties can be $25,000 or $10,000 per each determination. According to the statute at section 1857(g) of the Act, the actual amount could be lower. For example, section 1857(g)(3)(A) of the Act states that we may impose civil money penalties ''of not more than $25,000.'' The same applies to § 422.758(b), which references ''up to $10,000'' not ''$10,000.'' Section 422.750 states that the OIG can impose civil money penalties ranging from $10,000 to $100,000. Section 1128A of the Act continually uses the ''up to'' language. We are revising the regulatory language to clarify statutory intent.

4. Correcting a Cross-Reference in Subpart E (Relationships With Providers)

In § 422.202(a)(4), a change is needed to correct a cross-reference. Specifically, the text ''must conform to the rules in § 422.204(c)'' is being revised to read ''must conform to the rules in § 422.202(d).'' (§ 422.204(c) does not exist.)

III. Provisions of This Final Rule

The provisions of this final rule are as follows:

- In § 409.20, we added paragraph (c)(4) to define the term ''post-hospital SNF care'' to include SNF care that does not follow a hospital stay if the beneficiary is enrolled in an M+C plan.
- In § 409.30, we revised paragraph (b)(2) to add an exception to the preadmission requirements for enrollees of M+C organization plans.
- In § 409.31, we added paragraph (b)(2)(iii) to add a condition to the level of care requirements which states that, for an M+C enrollee, a physician has determined that a direct admission to a SNF without an inpatient hospital stay would be medically appropriate.
- In § 417.479, we revised paragraph (h) to modify the reporting requirements concerning physician incentive plans.
- In § 422.2, we revised the definition of additional benefits to include a reduction in the Medicare beneficiary's standard Part B premium.
- In § 422.50, we revised paragraph (a)(2) to include a new condition in the exception that a beneficiary with ESRD is not eligible to elect an M+C plan. An individual with ESRD whose enrollment in an M+C plan is discontinued because we or the M+C organization terminated the organization's contract for the plan, is now eligible to elect another M+C plan, if the original enrollment was terminated after December 31, 1998.
- In § 422.74, we revised paragraph (d)(1)(ii) to reflect that an M+C organization may only disenroll a Medicare enrollee when the organization has not received payment within 90 days after the date the premium payment was due.
- In § 422.74, we revised paragraph (d)(4) to allow M+C organizations to operate ''visitor'' or ''traveler'' programs that provide benefits beyond urgent and emergent care to their enrollees who are out of the service area for more than 6 months but less than 12 months.
- In § 422.101, we revised paragraph (b)(3) to reflect the provisions in section 1852(a)(2)(C) of the Act that permit M+C organizations with plans that cover large areas encompassing more than one local coverage policy area to elect to have the local coverage policy for the part of the area that is the most beneficial to the M+C enrollees apply to all M+C enrollees in the plan. his policy allows M+C organizations to standardize coverage decisions and provider contracts across the entire plan, rather than having different policies apply to different geographic areas of the same plan.
- In § 422.101, we added paragraph (c) to include in the requirements relating to Medicare covered benefits the option to provide for coverage as a Medicare benefit post-hospital SNF care in the absence of a prior hospital stay.
- In § 422.106, we added new paragraph (c) to reflect the provisions in section 1857(i) of the Act that permits us to grant a waiver or modification of requirements in part 422 that hinder the design of, the offering of, or the enrollment in, M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of benefits funds.
- In § 422.109, we revised the definition of ''significant cost'' (which was in § 422.109(c), but is now in § 422.109(a)) to provide that, for purposes of determining whether to make an adjustment under § 422.256, the tests in definition of ''significant cost'' are applied to the aggregate costs of all NCDs and legislative changes in benefits made in the contract year. Under this test, the ''average cost'' of every NCD and legislative change in benefits would be added together. If the sum of all these average amounts exceeds the threshold under § 422.109(a)(1), then an adjustment to payment will be made under § 422.256 to reflect these costs. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceed the level set forth in § 422.109(a)(2), an adjustment to payment will be made under § 422.526. We also added language to explain that an NCD or legislative change in benefits that does not meet the ''significant cost'' threshold must be provided, and paid for, by the M+C organization as of the effective date of the NCD or legislative change in benefits.
- In § 422.111, we added paragraph (f)(8)(iii) to add any reduction in Part B premiums to the list of information that must be disclosed to each enrollee electing an M+C plan.
- We added § 422.133 to contain the new requirement that M+C organizations return residents of SNFs to their home SNF for post-hospital extended care services after discharge from a hospital. This new section contains the definition of home SNF, the requirements for return to the home SNF, and the exceptions to the general rule.
- In § 422.152(f), we added section (4) to reflect the requirement that M+C organizations' Quality Assurance Programs have a separate focus on racial and ethnic minorities.

• In § 422.202(a)(4), we corrected a cross-reference.

• In § 422.210, we revised paragraph (a) to reflect changes to the reporting requirements concerning physician incentive plans.

• In § 422.250, we revised paragraph (a)(1) to reflect that, beginning with the initial payment for CY 2003, monthly payments to M+C organizations may be reduced by the amount described in new § 422.312(d) for the reduction of the beneficiary's standard Part B premium.

• In § 422.250, we also revised paragraph (a)(2) to redesignate paragraph (a)(2)(i)(B) as (a)(2)(i)(C) and to add new paragraph (a)(2)(i)(B) to reflect that, when we establish ESRD rates, we will apply appropriate adjustments, including risk adjustment factors.

• In § 422.256, we revised paragraph (b) to reflect that we will make appropriate payment adjustments for new benefits covered during a contract term due to NCDs and legislative changes in benefits that result in a significant increase in costs to M+C organizations, based on an analysis by our chief actuary. We also revised this section to reflect that we will apply a ''NCD adjustment factor'' in calculating rates for counties receiving the two percent minimum update. This factor will represent the percent of total Medicare cost attributed to the aggregate costs of all NCDs and legislative changes in benefits in the previous year.

• In § 422.266, we revised paragraph (c) to clarify that when enrollees of M+C plans elect to receive hospice care under § 418.24, we will not make any payment for the hospice care to the M+C plan beginning with the next month's payment after the election, except for the portion of the payment applicable to additional benefits, as described in § 422.312.

• In § 422.312, we redesignated paragraph (d) as paragraph (e) and added new paragraph (d) to reflect that an M+C organization may apply adjusted excess amounts to additional benefits and accept lower payments from us, which would allow a reduction of standard Part B premiums for its enrollees. The reduction in standard Part B premiums could not equal more than 80 percent of the reduction in payments to the M+C organization and the payment reduction could not exceed 125 percent of the standard Part B premium. In addition, the reduction in premium would have to be applied uniformly to all similarly situated enrollees.

• We added new § 422.521 to indicate that we will not implement, other than at the beginning of a calendar year, requirements that would impose new cost or burden on M+C organizations or plans, unless a different effective date is required by statute.

• In § 422.566, we revised paragraph (c) to delete the cross-reference to § 422.574 and to delineate who can request an organization determination.

• In § 422.618, we revised paragraph (c) to add an effectuation exception when the M+C organization files an appeal with the DAB in the case of a standard reconsidered determination.

• In § 422.619, we revised paragraph (c) to add an effectuation exception when the M+C organization files an appeal with the DAB in the case of an expedited reconsidered determination.

• In § 422.758, we revised paragraph (b) to include the new maximum amount of the civil money penalties that we would impose on M+C organizations that terminate their contracts in a manner other than that described in § 422.512. The new penalty amount will be $100,000 or $250 per Medicare enrollee from the terminated plan or plans, whichever is greater.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on revisions to regulations. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. We followed this procedure with respect to all but one of the regulatory revisions made in this final rule. As noted above, the proposed rule did not include the revision to § 422.152(f) that we are making in this final rule that adds a new paragraph (4) reflecting the provisions of section 616 of the BIPA. The requirement that we issue regulations in proposed form for public comment can be waived, however, if an agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, and it incorporates a statement of the finding and its reasons in the rule issued.

We find that publishing the new paragraph (4) in § 422.152(f) in proposed form is unnecessary, because this provision only revises the regulations text to reflect the provisions of section 616 of the BIPA, and has no legal effect. These provisions were enacted by the Congress, and took effect on the date mandated by the legislation without regard to whether they are reflected in conforming changes to the regulation text. In the new § 422.152(f)(4), we merely have revised the regulation text to reflect section 616. Therefore, we do not believe that publishing a notice of proposed rulemaking is necessary and we find good cause to waive the notice of proposed rulemaking and to issue this final rule.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (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.

Section *417.479(h)—Physician Incentive Plans.* In this final rule, we require HMOs to provide us, upon request, information concerning its physician incentive plans. HMOs are also required to provide this information to any Medicare beneficiary who requests it. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938–0700.

Section 422.50(a)(2)—In this final rule, this section states that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by an M+C organization is eligible to elect an M+C plan offered by that organization. Also, an individual with end-stage renal disease whose enrollment in an M+C plan is terminated or discontinued after December 31, 1998 because we or the M+C organization terminated the M+C organization's contract for the plan or discontinued the plan in the area in which the individual resides is eligible to elect another M+C plan. An individual who elects an M+C plan under paragraph (a)(2)(ii) of this section may elect another M+C plan if the plan elected under paragraph (a)(2)(ii) also is terminated or discontinued in the area in which the individual resides.

The burden associated with this requirement is the time and effort for the individual to submit a new election form. While this section is subject to the PRA, this burden is currently captured in approved collection 0938–0753.

Section 422.74(d)(4)(i)—In the final rule, this section states that 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 us, that the individual has permanently moved.

This section requires that the individual must prepare and provide a written statement to the M+C organization that he or she has permanently moved. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938–0753.

Section 422.106(c)(1)—M+C organizations may request, in writing, a waiver or modification of those requirements in part 422 that hinder the design of, the offering of, or the enrollment in, M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of benefits funds.

We believe that the burden associated with this requirement is minimal. We anticipate approximately 100 requests for waivers or modifications submitted on an annual basis and that it will take approximately 2 hours to prepare each request. The total annual burden associated with this requirement is estimated to be 200 hours.

Section 422.106(c)(2)—In this final rule, this section states that approved waivers or modifications under this paragraph may be used by any M+C organization on developing its ACR proposal. Any M+C organization using a waiver or modification must include that information in the cover letter of its ACR proposal submission.

The burden associated with this requirement is the time and effort for the M+C organization to include the information in the cover letter of its ACR proposal submission. Although this requirement is subject to the PRA, the burden is minimal; therefore, the burden is captured in the analysis for § 422.106(c)(1).

Section 422.111(f)(8)(iii)—In this final rule, this section has been revised to add any reduction in Part B premiums to the list of information that must be disclosed to each enrollee electing an M+C plan.

The burden associated with this requirement is the time and effort for the M+C organization to disclose information to each enrollee electing an M+C plan. Although this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938–0778.

Section 422.152(f)(4)—We have added this section to reflect the statutory provision of requiring M+C organizations' quality assurance programs to have a separate focus on racial and ethnic minorities. We estimate that it will take each M+C organization approximately 2 hours to add a separate focus on racial and ethnic minorities to its quality assurance program. Since there are approximately 150 M+C organizations, we estimate the annual burden associated with this requirement to be approximately 300 hours.

Section 422.210(a)(1)—In the final rule, this section states that each M+C organization must provide to us upon request, descriptive information about its physician incentive plan in sufficient detail to enable us to determine whether that plan complies with the requirements of § 422.208.

This section requires the M+C organization to prepare and submit, upon request, descriptive information to us. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938–0700.

Section 422.266(a)—In this final rule, an M+C organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity).

While this requirement is subject to the PRA, the burden associated with it is captured in approved collection 0938–0753.

In summary, the total burden hours for this proposed rule is calculated to be 500 hours. The breakdown is as follows:

§ 417.479(h)—burden captured in 0938–0700

§ 422.50(a)(2)—burden captured in 0938–0753

§ 422.74(d)(4)(i)—burden captured in 0938–0753

§ 422.106(c)(1)—200 hours

§ 422.106(c)(2)—burden captured in 422.106(c)(1)

§ 422.111(f)(8)(iii)—burden captured in 0938–0753

§ 422.152(f)(4)—300 hours

§ 422.210(a)(1)—burden captured in 0938–0700

§ 422.266(a)—burden captured in 0938–0753

0938–0700 is approved for 450 hours and expires on April 30, 2004 and 0938–0753 is approved for 2,120,006 hours and expires on October 31, 2005.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

This final rule, which changes M+C regulations in accordance with provisions set forth in the BIPA, is not a major rule with economically significant effects as defined in Title 5, U.S.C. section 804(2) and is not an economically significant rule under Executive Order 12866. This final rule will result in increases in total expenditures of less than $100 million per year.

The budgetary impact of section 605 of the BIPA, which mandated revised ESRD payments, was estimated to be $270 million over the 5 years between FY 2002 to FY 2006, based on the FY 2002 President's budget. These payments are in the current baseline and have no impact on the budget. In addition, these provisions have already been implemented through our 2002 annual payment notice. The additional cash expenditures for these M+C ESRD beneficiaries under this provision of the BIPA affected those M+C organizations that enrolled the approximately 18,000 ESRD beneficiaries in their plans. Additional expenditures for this provision have been incorporated into the M+C payment rates from CY 2002 forward.

This estimate assumed continuation of the current restrictions on enrollment in the M+C program for ESRD beneficiaries. This estimate also included the impact of adjusting for age and sex and the impact of raising the ESRD base rates by 3 percent. We estimate that the change in policy for

NCDs in this rule adds approximately $48 million per year to the Federal budget.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status, or by having revenues of between $6 million and $29 million or less annually. (For details, see the Small Business Administration publication that sets forth size standards for health care industries at 65 FR 69432.) Individuals and States are not included in the definition of small entities.

For purposes of the RFA, most managed care organizations are not considered to be small entities. We estimate that fewer than 5 out of 177 M+C organization contractors have annual revenues of $7.5 million or less. Approximately 35 percent of M+C organization contractors have tax-exempt status, and thus, for purposes of the RFA, are considered to be small entities. We have examined the economic impact of this final rule on M+C organizations, including those that are tax-exempt, and, therefore, small entities. We find that overall the economic impact is positive, due to the revised ESRD rates mandated by section 605 of the BIPA, which are generating an increase in payments; the increase in payments due to the revised policy on NCDs, and the reductions in regulatory burden due to the premium reductions in section 606, the waivers of M+C rules specified in section 606 for employers and related organizations, the waiver of the 3 day hospital stay for SNF admissions, and the reduction of the physician incentive reporting requirements. Therefore, we certify that this final rule will not have a significant impact on a substantial number of small businesses. The data available do not allow us to determine the distributional effects of this increase. We have not considered alternatives to lessen the economic impact or regulatory burden of this final rule because the regulatory burden is reduced and payment to the plans is increased by this rule. The major change between the proposed and final rule is the method for computing a significant national coverage determination. This change will have a net benefit to M+C organizations. We certify that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a final rule has a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds. Almost 2 percent of M+C enrollees reside in payment areas outside MSAs. Because information on the payment terms in contracts between M+C organizations and their providers is not available, data are not available on the level of this economic impact.

B. The Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1998 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined, and we certify that this final rule has no consequential effect on State, local, or tribal governments.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed or final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will impose no direct requirement costs on State and local government, will not preempt State law, or have any Federalism implications.

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

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 417

Administrative practice and procedure, Grants programs-health, Health care, 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, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Posthospital SNF Care

■ 2. In § 409.20, the following amendments are made as set forth below:

■ a. Paragraph (c)(3) is revised.

■ b. Paragraph (c)(4) is added.

§ 409.20 Coverage of services.

* * * * *

(c) * * *

(3) The term *swing-bed hospital* includes a CAH with swing-bed approval under subpart F of part 485 of this chapter.

(4) The term *post-hospital SNF care* includes SNF care that does not follow a hospital stay when the beneficiary is enrolled in a plan, as defined in § 422.4 of this chapter, offered by a Medicare+Choice (M+C) organization, that includes the benefits described in § 422.101(c) of this chapter.

Subpart D—Requirements for Coverage of Posthospital SNF Care

■ 3. In § 409.30, paragraph (b)(2) is revised to read as follows:

§ 409.30 Basic requirements.

* * * * *

(b) * * *

(2) The following exceptions apply—

(i) A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital or CAH, or a beneficiary enrolled in a Medicare+Choice (M+C) plan, may be admitted at the time it would be medically appropriate to begin an active course of treatment.

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M+C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.101(c) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

■ 4. In § 409.31 paragraph (b)(2)(ii) is revised, and a new paragraph (b)(2)(iii) is added to read as follows:

§ 409.31 Level of care requirement.

* * * * *

(b) * * *

(2) * * *

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital or inpatient CAH services; or

(iii) For which, for an M+C enrollee described in § 409.20(c)(4), a physician has determined that a direct admission to a SNF without an inpatient hospital or inpatient CAH stay would be medically appropriate.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 5. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart L—Medicare Contract Requirements

§ 417.479 [Amended]

■ 6. In § 417.479, the following amendments are made as follows:

■ a. In paragraph (g)(2)(ii), the reference in the second sentence to ''(h)(1)(v)'' is removed and ''(h)(2)'' is inserted in its place.

■ b. The heading for paragraph (h) is revised.

■ c. Paragraph (h)(1) is revised.

■ d. Paragraph (h)(2) is revised.

■ e. The introductory text to paragraph (h)(3) is revised.

§ 417.479 Requirements for physician incentive plans.

* * * * *

(h) *Disclosure and other requirements for organizations with physician incentive plans.* (1) Disclosure to CMS. Each health maintenance organization or competitive medical plan must provide to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

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

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

(iv) The distribution of payments to physicians from the risk pool is not calculated separately by patient category; and

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

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

* * * * *

PART 422—MEDICARE+CHOICE PROGRAM

■ 7. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

■ 8. In § 422.2, the introductory text is republished, and the definition of *Additional benefits* is revised to read as follows:

§ 422.2 Definitions.

As used in this part—

* * * * *

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

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 9. In § 422.50, paragraph (a)(2) is revised to read as follows:

§ 422.50 Eligibility to elect an M+C plan.

(a) * * *

(2) Has not been medically determined to have end-stage renal disease, except that—

(i) 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; and

(ii) An individual with end-stage renal disease whose enrollment in an M+C plan was terminated or discontinued after December 31, 1998, because CMS or the M+C organization terminated the M+C organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another M+C plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another M+C plan.

* * * * *

■ 10. In § 422.74, the following amendments are made as set forth below:

■ a. Paragraph (d)(1)(ii) is revised.

■ b. Paragraph (d)(4) is revised.

§ 422.74 Disenrollment by the M+C organization.

* * * * *

(d) * * *

(1) * * *

(ii) The M+C organization has not received payment within 90 days after the date the premium was due.

* * * * *

(d) * * *

(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 CMS, that the individual has permanently moved—

(A) Out of the M+C plan's service area; or

(B) From the residence in which the individual resided at the time of enrollment in the M+C plan to an area outside the M+C plan's service area, for those individuals who enrolled in the M+C plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule.* If the individual has not moved from the M+C plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the M+C organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(iii) *Exception.* If the M+C plan covers services other than emergent, urgent, maintenance and poststabilization, and renal dialysis services (as described in § 422.100(b)(1)(iv) and § 422.113) when the individual is out of the service area for a period of consecutive days longer than 6 months but less than 12 months, but within the United States (as defined in § 400.200 of this chapter), the M+C organization may elect to offer to the individual the option of remaining enrolled in the M+C plan if—

(A) The individual is disenrolled on the first day of the 13th month after the

individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the M+C plan on obtaining these services while absent from the M+C plan's service area for the extended period; and

(C) The M+C organization makes this option available to all Medicare enrollees who are absent for an extended period from the M+C plan's service area. However, M+C organizations may limit this option to enrollees who travel to certain areas, as defined by the M+C organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care.

(iv) *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.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 11. In § 422.101, the following amendments are made as follows:
■ a. Paragraph (b)(3) is revised.
■ b. Paragraph (c) is added.

§ 422.101 Requirements relating to basic benefits.

* * * * *

(b) * * *

(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 organization. If an M+C organization covers geographic areas encompassing more than one local coverage policy area, the M+C organization may elect to uniformly apply to plan enrollees in all areas the coverage policy that is the most beneficial to M+C enrollees. M+C organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to M+C enrollees as follows:

(i) An M+C organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in § 422.306(a), which is 60 days before the date adjusted community rate proposals are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to M+C enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the M+C organization of its approval or denial of the selected uniform local coverage policy or policies.

(c) M+C organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

■ 12. In § 422.106, the following amendments are made as follows:
■ a. The section heading is revised.
■ b. Paragraphs (a) introductory text, (a)(1), and (a)(2) are revised.
■ c. Paragraph (b) introductory text is revised.
■ d. A new paragraph (c) is added.

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an M+C organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover 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 employer, labor organization, fund trustees, 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 and benefits provided to enrollees eligible for benefits under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an M+C plan, which are not part of the M+C plan, are not subject to review or approval by CMS.

* * * * *

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

* * * * *

(c) *Waiver or modification.* (1) M+C organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph may be used by any M+C organization in developing its Adjusted Community Rate (ACR) proposal. Any M+C organization using a waiver or modification must include that information in the cover letter of its ACR proposal submission.

■ 13. Section 422.109 is revised to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) *Definitions.* The term *significant cost,* as it relates to a particular NCD or legislative change in benefits, means either of the following:

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

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

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

(2) The estimated cost of all Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national standardized annual capitation rate, as described in § 422.254(f), multiplied by the total number of Medicare beneficiaries for the applicable calendar year. For purposes of § 422.256 only, this test is applied to all NCDs or legislative changes in benefits, in the aggregate, for a given year. If the sum of the average cost of each NCD or legislative change in benefits exceeds the amount in paragraph (a)(1) of this section, or the aggregate costs of all NCDs and legislative changes for a year exceeds the percentage in paragraph (a)(2) of this section, the costs are considered ''significant.''

(b) *General rule.* If CMS determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost described

in paragraph (a) of this section, a M+C organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the ''significant cost'' threshold described in § 422.109(a), the M+C organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective.* Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the M+C organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the M+C organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

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

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

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are—

(i) Costs relating directly to the provision of services related to the NCD or legislative change in benefits that were noncovered services before the issuance of the NCD or legislative change in benefits; and

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

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective.* For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the M+C organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the M+C organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. M+C organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the M+C plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for M+C plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

■ 14. In § 422.111, a new paragraph (f)(8)(iii) is added to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(f) * * *

(8) * * *

(iii) The reduction in Part B premiums, if any.

* * * * *

■ 15. A new § 422.133 is added to subpart C to read as follows:

§ 422.133 Return to home skilled nursing facility.

(a) *General rule.* M+C plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the M+C organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the M+C organization.

(b) *Definitions.* In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the M+C plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(c) *Coverage no less favorable.* The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the M+C plan.

(d) *Exceptions.* The requirement to allow an M+C plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the M+C plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

Subpart D—Quality Assurance

■ 16. In § 422.152, a new paragraph (f)(4) is added to read as follows:

§ 422.152 Quality assessment and performance improvement program.

* * * * *

(f) * * *

(4) *Focus on racial and ethnic minorities.* The M+C organization's Quality Assurance program must include a separate focus on racial and ethnic minorities.

Subpart E—Relationships With Providers

■ 17. In § 422.202, paragraph (a)(4) is revised to read as follows:

§ 422.202 Participation procedures.

(a) * * *

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the

M+C organization, this process must conform to the rules in § 422.202(d).

■ 18. In § 422.210, paragraph (a) and the introductory text to paragraph (b) are revised to read as follows:

§ 422.210 Disclosure of physician incentive plans.

(a) *Disclosure to CMS.* Each M+C organization must provide to CMS information concerning its physician incentive plans as requested.

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

* * * * *

Subpart F—Payments to Medicare+Choice Organizations

■ 19. In § 422.250, the following amendments are made as follows:

■ a. Paragraph (a)(1) is revised.

■ b. Paragraph (a)(2)(i)(B) is redesignated as (a)(2)(i)(C).

■ c. A new paragraph (a)(2)(i)(B) is added.

§ 422.250 General provisions.

(a) *Monthly payments*—(1) *General rule.* (i) Except as provided in paragraphs (a)(2) or (f) of this section, CMS makes advance monthly payments equal to 1/12th of the annual M+C capitation rate for the payment area described in paragraph (c) of this section adjusted for such demographic risk factors as an individual's age, disability status, sex, institutional status, and other factors as it determines to be appropriate to ensure actuarial equivalence.

(ii) Effective January 1, 2000, CMS adjusts for health status as provided in § 422.256(c). When the new risk adjustment is implemented, 1/12th of the annual capitation rate for the payment area described in paragraph (c) of this section will be adjusted by the risk adjustment methodology under § 422.256(d).

(iii) Effective January 1, 2003, monthly payments may be reduced by the adjusted excess amount, as described in § 422.312(a)(2), and 80 percent of the reduction in monthly payments used to reduce the Medicare beneficiary's Part B premium, up to a total of 125 percent of Part B premium amount.

(2) * * *

(i) * * *

(B) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors. CMS also establishes annual changes in capitation rates using the methodology described in § 422.252. Effective 2002, a special adjustment is made to increase ESRD rates to 100 percent of estimated per capita fee-for-service expenditures and rates are adjusted for age and sex. In subsequent years, rates are adjusted for age, sex, and other factors, if appropriate.

* * * * *

■ 20. In § 422.256, paragraph (b) is revised to read as follows:

§ 422.256 Adjustments to capitation rates and aggregate payments.

* * * * *

(b) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the M+C organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b). The Office of the Actuary in CMS will apply a new NCD adjustment factor each year that reflects significant costs of NCDs and legislative changes in benefits for coverage effective in the second prior year. The new NCD adjustment factor will be applied to the 2 percent minimum update rate described in § 422.252(c).

* * * * *

■ 21. In § 422.266, the following amendments are made as follows:

■ a. Paragraph (a) introductory text is revised.

■ b. Paragraph (c) is revised.

§ 422.266 Special rules for hospice care.

(a) *Information.* An M+C organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity) if—

* * * * *

(c) *Payment.* (1) No payment is made to an M+C organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in § 422.312. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS's monthly capitation payment to the M+C organization is reduced to an amount equal to the adjusted excess amount determined under § 422.312. In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The M+C organization, provider, or supplier for other Medicare-covered services to the enrollee.

Subpart G—Premiums and Cost-Sharing

■ 22. In § 422.312, the following amendments are made as follows:

■ a. Paragraph (d) is redesignated as paragraph (e).

■ b. A new paragraph (d) is added.

§ 422.312 Requirement for additional benefits.

* * * * *

(d) *Reduction in payments.* As of January 1, 2003, as a part of providing additional benefits under paragraph (b) of this section, if there is an adjusted excess amount for the plan it offers, the M+C organization—

(1) May elect to receive a reduction (not to exceed 125 percent of the standard Part B premium amount) in its payments under § 422.250(a)(1), 80 percent of which will be applied to reduce the Part B premiums of its Medicare enrollees; and

(2) Must apply the reduction uniformly to all similarly situated enrollees of the M+C plan.

* * * * *

Subpart K—Contracts With Medicare+Choice Organizations

■ 23. A new § 422.521 is added as set forth below:

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on M+C organizations or plans, unless a different effective date is required by statute.

Subpart M—Grievances, Organization Determinations and Appeals

■ 24. In § 422.566, paragraph (c) is revised to read as set forth below:

§ 422.566 Organization determinations.

* * * * *

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her authorized representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) An enrollee (including his or her authorized representative); or

(ii) A physician (regardless of whether the physician is affiliated with the M+C organization).

■ 25. In § 422.618, paragraph (c) is revised to read as set forth below:

§ 422.618 How an M+C organization must effectuate standard reconsidered determinations or decisions.

* * * * *

(c) *Reversals other than by the M+C organization or the independent outside entity.*—(1) *General rule.* 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 or that it has appealed the decision.

(2) *Effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board.* If the M+C organization requests Departmental Appeals Board (the Board) review consistent with § 422.608, the M+C organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A M+C organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

■ 26. In § 422.619, paragraph (c) is revised to read as set forth below:

§ 422.619 How a M+C organization must effectuate expedited reconsidered determinations.

* * * * *

(c) *Reversals other than by the M+C organization or the independent outside entity.*—(1) *General rule.* If the independent outside 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.

(2) *Effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board.* If the M+C organization requests Departmental Appeals Board (the Board) review consistent with § 422.608, the M+C organization may await the outcome of the review before it authorizes or provides the service under dispute. A M+C organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

Subpart O—Intermediate Sanctions

■ 27. In § 422.756, the following amendments are made as set forth below:

■ a. Paragraph (f)(2) is revised.

■ b. Paragraph (f)(3) is revised.

§ 422.756 Procedures for imposing sanctions.

* * * * *

(f) * * *

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1005 of this title, the OIG may impose civil money penalties on the M+C organization in accordance with part 1005 of this title in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under paragraph (b) of § 422.752 other than a determination based upon a violation under § 422.510(a)(4), in accordance with the provisions of part 1005 of this title, CMS may impose civil money penalties on the M+C organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

■ 28. In § 422.758, the following amendments are made as set forth below:

■ a. The introductory text is designated as paragraph (a) introductory text.

■ b. Paragraph (a) is redesignated as paragraph (a)(1) and is revised.

■ c. Paragraph (b) is redesignated as paragraph (a)(2) and is revised.

■ d. A new paragraph (b) is added.

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

(a) * * *

(1) For the violations listed below, CMS may impose the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any M+C organization that has a contract in effect. The M+C organization may also be subject to other applicable remedies available under law.

(2) For each week that a deficiency remains uncorrected after the week in which the M+C organization receives CMS's notice of the determination—up to $10,000.

(b) If CMS makes a determination under § 422.752(b) and § 422.756(f)(3), based on a determination under § 422.510(a)(1) that an M+C organization has terminated its contract with CMS in a manner other than described under § 422.512—$250 per Medicare enrollee from the terminated M+C plan or plans at the time the M+C organization terminated its contract, or $100,000, whichever is greater.

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

Dated: April 3, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 3, 2003.

Tommy G. Thompson,

Secretary.

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