DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, and 422

[CMS–4041–P]

RIN 0938–AK71

Medicare Program; Modifications to Managed Care Rules

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement certain provisions of the Social Security Act (the Act) relating to the Medicare+Choice (M+C) program that were enacted in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).

It also proposes other changes to the M+C regulations based on program experience and feedback from M+C organizations.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 24, 2002.

ADDRESSES: In commenting, please refer to file code CMS–4041–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4041–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 445–G, Washington, DC 20201 or Centers for Medicare & Medicaid Services, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Tom Hutchinson, (410) 786–8953.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

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 Medicare fee-for-service program or an 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. Many of these amendments were reflected in a final rule with comment period published in the **Federal Register** on June 29, 2000 (65 FR 40170). We received five comments in response to that final rule, which will be addressed in the final rule responding to comments concerning this proposed rule.

Certain amendments to the new Part C made by the BBRA are relevant to the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), since the BIPA made changes to the BBRA amendments. For example, section 502 of the BBRA amended section 1851(f)(2) of the Act by providing that if an election or change in election to an M+C plan was made after the 10th day of a calendar month, the election would be effective the first day of the second calendar month following the date the election or change in election was made, not the first calendar month, as had been the case under the original M+C statute. As discussed in a final rule published on March 22, 2002 (67 FR 13278), the BIPA reversed this amendment and restored the original effective date.

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 BIPA further revised this transition schedule.

Section 512 of the BBRA amended section 1853 of the Act by adding a new paragraph (i) to provide for new entry bonus payments to encourage M+C organizations to offer plans where there were no M+C plans serving the area as of January 1, 2000. This BBRA provision was amended by the BIPA to permit M+C organizations entering counties that had been abandoned in 2001 to receive bonuses.

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 (BIPA), 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. In this proposed rule, we propose to revise the regulations to implement sections 605, 606, 611, 612, 615, 617, 620, 621, and 623 of the BIPA.

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 the 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) would be implemented consistent with 605(b) (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 new ESRD payment methodology set forth in the final notice published on October 1, 2001—

- Increased the ESRD base payment rate for 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.)

We propose to revise § 422.250(a)(2)(i) to reflect these changes to the payment methodology for ESRD enrollees set forth in the October 1, 2001 final notice.

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

Section 606 of the BIPA amended section 1854(f)(1) of the Act by allowing M+C organizations to reduce the standard Part B premiums for their M+C Medicare enrollees, as an additional benefit, if the M+C organization experiences 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 could now 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 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 would revise §§ 422.2, 422.111(f), 422.250(a)(1), and 422.312 to reflect these changes.

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

Section 611 of the BIPA amended section 1853(c)(7) of the Act by limiting the financial impact on M+C organizations of new coverage requirements adopted by the Congress. If we project that these new coverage requirements would result in a significant increase in costs to M+C organizations, M+C organizations would not be required to cover them under their contracts, but the services would be 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. After that, appropriate adjustments would be made to the payments made to M+C organizations to reflect the additional costs. Before the payment rate adjustments become effective, the change in benefits would not be part of the M+C organizations' contracts with us and would not be covered under the M+C plans. After the payment adjustments become effective, the change in benefits would become part of the M+C organizations' contracts with us and would be covered by the M+C plans.

We would revise §§ 422.109 and 422.256(b) accordingly.

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. We propose in a new § 422.521 to define significant regulatory requirements as those which impose a new cost or burden on M+C organizations, and for which a mid-year effective date is not required by statute.

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 would allow 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 would allow those M+C organizations that offer a plan in an area large enough that more than one local coverage policy is applied in the service area, to elect to have the local coverage policy for that part of the area that is the most beneficial to the M+C enrollees apply to all M+C enrollees in the plan. The Secretary will make the final determination as to which local coverage policy is most beneficial to the M+C enrollees.

By electing to use this uniform coverage policy, M+C organizations could use economies of scale when printing and distributing marketing materials and descriptions of benefits for their M+C plans. This policy would also enable the M+C organizations to standardize coverage decisions and provider contracts across entire plans, rather than having different policies apply to different geographic areas of the same plan.

We propose to revise § 422.101(b)(3) to reflect the new option allowed by section 615 of the BIPA.

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

Section 617 of the BIPA amended section 1857 of the Act by allowing 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, 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 at part 422.

The authority in section 617 of the BIPA was first available for calendar year 2001. We accordingly 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, under this proposed rule we would, upon written request from an M+C organization, 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. We indicated that after we have approved a request for a waiver, the requesting M+C plan, and any other M+C organization, would be able to use the waiver in developing its Adjusted Community Rate Proposal (ACRP). Any M+C plan using the waiver must include that information in the cover letter of its ACRP submission to us. The waiver or modification would take effect once the ACRP has been approved.

We informed M+C organizations that, at least initially, we would approve the following three types of waivers under the authority in section 617 of the BIPA:

- Employer-Only Plans: We would allow M+C organizations to offer employer-only plans (M+C plans not available to the individual market). M+C organizations would not be required to market these plans to individuals. In addition, M+C organizations would not be required to have the marketing materials for employer-only plans reviewed and approved by us.
- Actuarial Swaps: We would allow 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 would allow M+C organizations to raise the co-payments for certain benefits but provide a higher benefit level or a modification to the premium charged, as long as projected beneficiary liability was actuarially equivalent.

We also indicated that we would continue to review additional areas for waiver or modification and would issue further guidance once we have completed our review. We solicit comments on these categories, and whether we should provide for additional categories.

We propose to amend § 422.106 by adding a new paragraph (c) to reflect the authority in section 617 of the BIPA.

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 another M+C plan if the plan in which they are enrolled terminates its contract with us or 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 had no Medicare options other than another plan offered by the same M+C organization or the original Medicare fee-for-service program.

Section 620 of the BIPA allows ESRD beneficiaries to elect to enroll in another M+C plan if their plan terminates its contract with us or discontinues the plan in their area. However, this provision only authorizes the beneficiaries to make one election based on that termination. If the new M+C plan in which the ESRD beneficiary enrolls pursuant to section 620 of the BIPA terminates, the ESRD beneficiary may enroll in another M+C plan. This is true for any subsequent M+C plan terminations or discontinuations that result in the beneficiary's disenrollment. However, if the ESRD beneficiary enrolls in another M+C plan after his or her plan terminates its contract or discontinues the plan in the area in which he or she lives, then disenrolls from the new plan for a reason other than that the plan is terminating or discontinuing the plan in his or her area, he or she may not enroll in another new M+C plan unless the new plan is offered by the same M+C organization offering the M+C plan in which he or she was enrolled. If there is no plan meeting this criterion available, the beneficiary must instead return to the original Medicare fee-for-service program.

While this provision refers to ESRD beneficiaries electing to continue enrollment in another M+C plan, we do not interpret this to mean that the enrollee must make the election immediately upon the termination of the M+C plan in which he or she is enrolled. This is because, under section 620(b)(2) of the BIPA, an individual whose plan was terminated or discontinued any time after December 31, 1998 is eligible for enrollment under this provision, and is to be treated as if the plan terminated as of the date of enactment of the BIPA. Since the BIPA was enacted in the middle of a month, and a beneficiary could not be expected to be informed of its provisions in time to enroll effective the first of the next month, we believe that the Congress contemplated that the opportunity to enroll in another plan provided in section 620 of the BIPA does not necessarily have to be exercised immediately upon termination of an M+C plan. In other words, we do not interpret ''continue enrollment'' necessarily to mean ''continue without interruption''.

We propose to revise § 422.50(a)(2) to reflect the provisions in section 620 of the BIPA.

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 would ensure that an M+C organization would 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 posthospital extended care services upon discharge from a hospital.

The term ''home skilled nursing facility'' would mean—

- The SNF in which the beneficiary resided at the time of admission to the hospital;
- A SNF providing posthospital 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 would be returned must either have a contract with the M+C organization to provide posthospital services or 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 posthospital 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 posthospital extended care services.

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

This proposed rule would add a new § 422.133 to reflect the requirements of section 621 of the BIPA.

In addition to the requirements concerning returning beneficiaries to their home SNFs, this section also required that the Medicare Payment Advisory Commission (MEDPAC) conduct a study to analyze the effects of the new requirements. The study must examine the effects of the new requirements on the following:

- The scope of additional benefits provided under the M+C program.
- The administrative and other costs incurred by M+C organizations.
- The contractual relationships between M+C organizations and SNFs.

MEDPAC must submit a report on this study to the Congress no later than December 20, 2002.

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

Section 1857(g)(3) of the Act, authorizes us to impose intermediate sanctions, including civil money penalties, on M+C organizations for the same reasons that 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.

In §§ 422.510(a)(1) through (a)(12), we identified specific M+C organization behaviors that we have determined meet one of the grounds for termination described in section 1857(c)(2) of the Act. Further, in §§ 422.752(b) and 422.756(f)(3), we described the basis and procedures for imposing the intermediate sanctions that originate from M+C contract violations that are grounds for M+C contract termination by us.

Section 623 of the BIPA amended section 1857(g)(3) of the Act by providing us with enhanced civil money penalty authority, which we would implement in proposed § 422.758. Under section 623 of the BIPA, the Congress gave us the authority to establish and levy separate and distinct civil money penalties when our determination that an M+C organization has failed to substantially carry out the terms of its contract is based upon the M+C organization's termination of its contract with us in a manner other than that provided for in the M+C contract and in § 422.512. The new civil money penalty would apply to terminations occurring after December 21, 2000. The amount of this civil money penalty may not exceed $100,000, unless we establish a higher amount through further regulations.

We believe that the Congress extended the flexibility to establish a potentially higher civil money penalty in recognition of the fact that the $100,000 specified in the Act may, in some instances, not provide an effective deterrent to discourage M+C organizations from terminating their contracts in a manner inconsistent with the procedures described in the regulations. In developing this 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.

We propose 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 have 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 would represent a substantial increase over the current civil money penalty of $25,000 for similar violations and would serve as an effective deterrent against M+C contract terminations violations that could potentially harm Medicare beneficiaries.

This provision of the BIPA would create a separate category of civil money penalty, with a dollar amount unique to the violation, that we can impose on M+C organizations that fail to substantially carry out the terms of their contracts with us by violating the contract termination provisions described in § 422.512. Accordingly, we would revise § 422.758 and add a new paragraph (b) that describes this civil money penalty.

D. 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 are needed on a daily basis and only available in a SNF on an inpatient basis.

Generally, this benefit is only covered 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. We are proposing to revise the regulations to reflect this determination, so that a SNF stay without a prior 3-day hospital stay can be covered by Medicare if the admission to the SNF occurred while the beneficiary was

enrolled in a M+C plan that covers SNF services.

Under section 1852(a) of the Act, organizations contracting with us under the M+C program must provide to their Medicare enrollees at least those items and services for which benefits are available under the original Medicare fee-for-service program. These M+C organizations may also furnish additional coverage, including cost-sharing for Medicare benefits and benefits not covered under the original Medicare fee-for-service program. One additional benefit that many M+C organizations have chosen to furnish is care in a SNF that does not follow a 3-day hospital stay.

Because these SNF services were not Medicare covered services, the cost of the services were included either as an additional benefit funded out of the adjusted excess calculated in the Adjusted Community Rate (ACR), or as a supplemental benefit for which a premium was charged. An enrollee receiving SNF services under these circumstances would remain entitled to the SNF Medicare benefit, which required a prior 3-day hospital stay. Moreover, an enrollee in a SNF for services covered as an additional or supplemental benefit without a prior 3-day hospital stay would no longer have the SNF services covered if he or she disenrolled from the M+C plan (or the plan terminated) in the middle of the SNF stay. By exercising our authority under section 1812(f) and allowing Medicare coverage of SNF services without the prior 3-day hospital stay by an M+C organization that covered them as an additional or supplemental benefit, the entire SNF stay would then be considered a Medicare covered benefit.

Our determination that SNF services furnished by M+C organizations meet the two tests in section 1812(f) is based on the fact that M+C organizations are paid a monthly per-Medicare enrollee payment to provide all contracted services. Thus, Medicare costs would not be affected by permitting SNF services to be covered by Medicare without the prior 3-day hospital stay. The savings from the 3-day hospital stay would be applied to the SNF care for those same 3 days. This would also provide incentives for the M+C organizations to provide care more cost effectively. Some evidence indicates that M+C organizations, particularly coordinated care plans, can shorten hospital stays and shift patients to post acute or subacute settings, such as SNFs, more quickly than under the original Medicare program. If SNF care is the appropriate level of care, M+C organizations may use SNF care rather than more expensive hospital care for similar patients requiring post hospital care. For some patients and diagnoses, the M+C organization may bypass the hospital stay and admit the beneficiary directly to a SNF.

We make a capitation payment for each enrollee using a formula set in section 1853 of the Act. Allowing an M+C organization to provide a SNF benefit that does not require a 3-day hospital stay as part of its basic Medicare benefit package would not affect any payments to M+C organizations. Since we are already paying for the transition from M+C organizations to the original Medicare program during a SNF stay, there would be no additional program costs. If those M+C enrollees had been in the original Medicare program, they would have had a 3-day hospital stay. M+C organizations that take advantage of this new benefit would furnish it the same way it has been used in the past, to shift care to the SNF setting that otherwise would have occurred in the hospital when the beneficiary's physician determines that a SNF stay would meet the level of care requirement.

We would add a § 409.20(c)(4), revise §§ 409.30(b) and 409.31(b), and add a new § 422.101(c) to reflect these changes.

E. Disenrollment by the M+C Organization

The interim final rule published in the **Federal Register** on June 26, 1998 (63 FR 35067) provided that an M+C plan enrollee who remained out of the M+C plan's the service area for more than 12 months was considered to have moved out of the service area, and must be disenrolled by the M+C organization offering the plan. There were several comments in response to this interim final rule concerning this issue. Commenters were concerned about beneficiaries being out of the service area of a plan, but still enrolled in the plan, in which case they could only receive urgent and emergent care. They believed that an enrollee who was out of the service area for more than 6 months should join another M+C plan that could provide all healthcare benefits, not just urgent and emergent care. As a result of these comments, in the final rule with comment period published in the **Federal Register** on June 29, 2000 (65 FR 40270, we shortened the time in which an enrollee could be out of the service area and still remain enrolled in the M+C plan from 12 months to 6 months.

However, this change had the consequence of limiting the ''visitor'' or ''traveler'' type programs that many M+C plans have for their enrollees who leave the service area for extended periods of time, exceeding 6 months. These programs allow enrollees to remain enrolled in the M+C plan and to receive more than just urgent and emergent care when out of the service area. For example, enrollees may temporarily stay with a relative while recuperating from an illness, or may temporarily travel to a more temperate climate during colder weather, or may just travel for an extended period of time. The M+C organizations have expressed concerns about the impact of the current 6-month rule on these programs. In response to these concerns, we propose to create an exception to the 6-month rule that would allow the plans to continue to offer these programs that extend the out-of-service-area benefits from 6 to 12 months. The M+C organizations offering these programs would be allowed to impose restrictions on obtaining benefits, except for urgent, emergent, and post stabilization care, and renal dialysis. Enrollees in these programs would not be disenrolled if they are out of the service area for up to 12 months, but enrollees in M+C plans without this program would continue to be disenrolled if they are out of the service area for 6 months or more. We propose to revise § 422.74(d)(4) to reflect this change.

F. Reporting Requirements for Physician Incentive Plans

Section 1852(j)(4)(B)(iii) of the Act required 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. In this proposed rule, we would change the reporting requirement to allow M+C organizations to maintain the required PIP information in their files (or their subcontractors' files) and submit it to us upon request (such as during a site visit). Furthermore, we propose to delete the specific requirements concerning the type of information that would have to be maintained.

We would retain all other requirements pertaining to physician incentive plans, such as the stop-loss provisions and the requirement that M+C organizations provide information to beneficiaries upon request. This change would also apply to HMOs

contracting with us who are also required to submit the same information concerning their physician incentive plans.

When the physician incentive plan requirements were enacted, the Congress expressed concern that financial incentives could lead to physicians hesitating to provide needed referral services. Because this proposed rule would modify the reporting requirements, there may be concern that this could lead to a reduction in the quality of care provided to beneficiaries. However, we have taken a number of steps to improve the quality of care provided by M+C organizations, such as the collection of Health Plan Employer Data Information Sets (HEDIS) and the Consumer Assessment of Health Plans Survey (CAHPS), and we have implemented a number of other quality improvement projects. These improved quality assessments provide direct measures of quality and access that we believe make it less necessary to receive annual reports on PIP arrangements. In addition, this proposed approach would be consistent with the reporting requirements of private accrediting organizations, such as the National Committee for Quality Assurance (NCQA), which only reviews incentive plans when investigating quality problems.

We propose to revise §§ 417.479(h)(2) and 422.210(a) to reflect these changes.

G. 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 40,282), some confusion has continued.

The intent of the regulation has always been for the provisions governing requests for organization determinations to be more inclusive than the provisions governing requests for appeals. To clarify this point, we are proposing to eliminate the existing cross-reference to § 422.574 and list 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 furnishes, 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.

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. The M+C organization may not appeal the overturning of its denial of coverage or payment in either of these situations. 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 are proposing that M+C organizations may await the outcome of a Departmental Appeals Board (the Board) review before effectuating a decision of an ALJ. This proposal would serve to balance the M+C organizations' 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 had been rendered to the enrollee. The Board's practice is to screen all of its cases upon arrival to identify and give priority to pre-service denial cases, including immediate assignment and resolution of cases involving imminent health risks.

In § 422.618(c), we would retain the 60-day effectuation requirement for reversals by an ALJ or higher level of appeal because we do not want to negate the M+C organizations' 60-day right to request an appeal to the Board or higher level. However, our expectation is that M+C organizations would not take the maximum 60 days to effectuate a decision they do not intend to appeal. We are proposing to redesignate the current § 422.618(c) as § 422.618(c)(1) and add a new § 422.618(c)(2) to allow for an exception to the 60-day standard if the M+C organization decides to request a board review consistent with § 422.608. We would 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 proposed 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, the M+C organization would be required to notify the independent review entity of the requested appeal.

Consistent with this proposed change, we would also revise § 422.619(c) with regard to effectuating expedited reconsidered determinations. As in standard appeals, we would 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 notify the independent review entity of the requested appeal.

We considered reducing the time frame in § 422.619(c) from 60 days to 72 hours for the M+C organization to authorize or provide the service under dispute. This would have been consistent with our reasoning for other effectuation guidelines because if the M+C organization originally had rendered a decision favorable to the enrollee, it would have been required to do so within the maximum organization determination time frame. However, we decided to maintain the 60-day effectuation time frame, so that we do not limit the M+C organizations' 60-day window in which to appeal. If we had required M+C organizations to effectuate a decision within 72 hours, we would have forced them to decide whether to appeal within that same 72 hours. Thus, we would have had to require notice to the enrollee regarding effectuation. Moreover, the M+C organization would have to send a second notice to the enrollee when the M+C organization filed its appeal. To eliminate confusion for enrollees and a

cumbersome process for M+C organizations, we would maintain the requirement that when an expedited determination is reversed, in whole or in part, by an ALJ or at a higher level of appeal, the M+C organization must effectuate the decision within 60 days. We would emphasize, however, 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.

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

We are soliciting comments on whether HCPPs and the remaining cost plans should follow the M+C appeals and grievance processes under subpart M of part 422. Currently, HCPPs and the remaining cost plans adhere to the provisions under subpart Q of part 417, which implemented the former managed care program for risk contracts under section 1876 of the Act. We believe that the M+C appeals process provides enhanced enrollee protections, such as faster processing times and streamlined notice procedures. We recognize that the remaining cost plans are expected to be phased out by 2004, therefore we solicit comments concerning whether the burdens associated with complying with subpart M of part 422 outweigh the protections afforded to beneficiaries. Moreover, unlike cost plans, HCPPs do not provide in-patient hospital services, thus, we are not proposing that HCPPs follow §§ 422.620 through 422.622, which provide for immediate Peer Review Organization review for in-patient hospital discharges.

I. Technical Clarifications

1. Grace Period for Late Premium Payments

We are proposing a technical change in this proposed rule to address concerns M+C organizations have raised concerning when the 90-day grace period for premium payments begins running. The regulation currently provides, at § 422.74(d)(1)(ii), that an M+C organization may only disenroll a Medicare enrollee when the organization has not received payment within 90 days after the date it has sent a written notice of nonpayment to the enrollee. Several M+C organizations have asked that the 90-day grace period begin to run on the day the premium payment was due, not the day the notice was sent. We believe that as long as the beneficiary receives notice under § 422.74(d)(1)(i)(C) that he or she would be disenrolled if payment is not made by the end of the grace period, a 90-day grace period beginning at the payment due date is sufficient. Because the notice has to be provided within 20 days after the payment was due, this would ensure the enrollee of 70 days following the notice within which to make payment, and avoid disenrollment.

We are accordingly proposing to revise § 422.74(d)(1)(ii) to provide that the M+C organization may only disenroll a Medicare enrollee when the organization has not received payment within 90 days after the date the premium was due.

2. Payment for Hospice Care

We are proposing a clarification in this proposed rule to provide information concerning changes in M+C payments when an individual has elected hospice care.

We would revise § 422.266(d) to make clear that when enrollees of M+C plans elect to receive hospice care under § 418.24, we would 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. This clarification makes the language of the rules regarding hospice care for M+C enrollees the same as the rules for HMOs and CMPs.

We propose to revise § 422.266(c) to reflect this clarification.

II. Provisions of This Proposed Rule

The provisions of this proposed rule are as follows:

- In § 409.20, we would add a paragraph (c)(4) to add a definition of the term ''posthospital 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 would revise paragraph (b)(2) to add an exception to the preadmission requirements for enrollees of M+C organization plans.
- In § 409.31, we would add a new paragraph (b)(2)(iii) to add a condition to the level of care requirements 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 would revise paragraph (h) to modify the reporting requirements concerning physician incentive plans.
- In § 422.2, we would revise the definition of additional benefits to include a reduction in the Medicare beneficiary's standard Part B premium.
- In § 422.50, we would revise paragraph (a)(2) to include in the exception to the general rule that a beneficiary with end-stage-renal-disease (ESRD) is not eligible to elect an M+C plan, that 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 eligible to elect another M+C plan, if the original enrollment was terminated after December 31, 1998.
- In § 422.74, we would revise 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 would revise 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 would revise paragraph (b)(3) to reflect the provisions in section 1852(a)(2)(C) of the Act permitting 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. This 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 would add a paragraph (c) to include in the requirements relating to Medicare covered benefits the option to provide for coverage as a Medicare benefit of posthospital SNF care in the absence of a prior hospital stay.
- In § 422.106, we would add a new paragraph (c) to reflect the provisions in section 1857(i) of the Act permitting 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 would revise the definition of ''significant cost'' to include legislative changes in benefits

and detail that if we project that the legislative changes in benefits would result in significant costs to M+C organizations, we would pay (through our fiscal intermediaries and carriers) the additional costs outside the contract until the next payment update. Subsequently, an adjustment would be made to payments under the contract to reflect the new costs.

- In § 422.111, we would add a new 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 would add a new § 422.133 to contain the new requirement that M+C organizations return residents of SNFs to their home SNF for posthospital extended care services after discharge from a hospital. This new section would contain the definition of home SNF, the requirements for return to the home SNF, and the exceptions to the general rule.
- In § 422.210, we would revise paragraph (a) to reflect changes to the reporting requirements concerning physician incentive plans.
- In § 422.250, we would revise 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 would also revise paragraph (a)(2) to redesignate paragraph (a)(2)(i)(B) as (a)(2)(i)(C) and add a new paragraph (a)(2)(i)(B) to reflect that when we establish ESRD rates, we would apply appropriate adjustments, including risk adjustment factors.
- In § 422.256, we would revise paragraph (b) to reflect that we would make appropriate payment adjustments for new legislative changes in benefits that would result in significant costs to M+C organizations, based on an analysis by our chief actuary of the costs associated with the new legislative change in benefits.
- In § 422.266, we would revise paragraph (c) to clarify that when enrollees of M+C plans elect to receive hospice care under § 418.24, we would 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 would redesignate paragraph (d) as paragraph (e) and add a 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 would add a new § 422.521 to indicate that we would not implement, other than at the beginning of a calendar year, regulations that would impose new cost or burden on M+C organizations or plan, unless a different effective date is required by statute.
- In § 422.566, we would revise paragraph (c) to delete the cross-reference to § 422.574 and enumerate who can request an organization determination.
- In § 422.618, we would revise paragraph (c) to add an effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board in the case of a standard reconsidered determination.
- In § 422.619, we would revise paragraph (c) to add an effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board in the case of an expedited reconsidered determination.
- In § 422.758, we would revise paragraph (b) to include the new maximum amount of the civil money penalty 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 would be $100,000 or $250 per Medicare enrollee from the terminated plan or plans, whichever is greater.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 417.479(h)—This section states that each HMO must provide to us information concerning its physician incentive plans as requested, and each HMO must provide information to any Medicare beneficiary who requests it.

This section requires the HMOs to disclose information to us and to Medicare beneficiaries. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938–0700, with an expiration date of April 30, 2004.

Section 422.50(a)(2)—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, due to expire October 31, 2002 (currently at OMB awaiting re-approval).

Section 422.74(d)(4)(i)—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, from us 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 estimate that there will be approximately 200 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 400 hours.

Section 422.106(c)(2)—This section states that approved waivers or modifications under this paragraph may be used by any M+C organization on developing its Adjusted Community Rate Proposal (ACRP). Any M+C organization using a waiver or modification must include that information in the cover letter of its ACRP 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 ACRP 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)—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 422.210(a)(1)—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)—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 collections 0938–0753 and 0938–0302.

In summary, the total burden hours for this proposed rule is calculated to be 400 hours. The breakdown is as follows:

Section 417.479(h)—burden captured in 0938–0700
Section 422.50(a)(2)—burden captured in 0938–0753
Section 422.74(d)(4)(i)—burden captured in 0938–0753
Section 422.106(c)(1)—400 hours
Section 422.106(c)(2)—burden captured in 422.106(c)(1)
Section 422.111(f)(8)(iii)—burden captured in 0938–0788
Section 422.210(a)(1)—burden captured in 0938–0700
Section 422.266(a)—burden captured in 0938–0753 & 0302

If you comment on these information collection and recordkeeping requirements, please mail one original and three copies directly to the following: Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn: Dawn Willinghan, CMS–4041–P, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in § 422.106. This requirement is not effective until it has been approved by OMB.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 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).

As a result of the proposed changes to the M+C regulations that reflect the provisions of the BIPA in this proposed rule, this proposed rule 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 proposed rule would result in increases in total expenditures of less than $100 million per year.

However, we are providing estimates of the budgetary impact of section 605 of the Act, which mandated revised ESRD payments. The revised rates affect those M+C organizations that enroll the approximately 18,000 ESRD beneficiaries in their plans. The additional cash expenditures for these M+C ESRD beneficiaries under this provision of the BIPA are estimated to be—

- $35 million in FY 2002 (for 9 months of costs based on the effective date of January 2002);
- $55 million in FY 2003;
- $55 million in FY 2004;
- $60 million in FY 2005; and
- $65 million in FY 2006.

These estimates assume continuation of the current restrictions on enrollment in the M+C program for ESRD beneficiaries. These estimates also include the impact of adjusting for age and sex and the impact of raising the ESRD base rates by 3 percent.

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 $5.0 million and $25 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 proposed rule on M+C organizations, including those that are tax-exempt, and thus small entities, and we find that overall the economic impact is positive, due to the revised ESRD rates mandated by section 605 of the BIPA, thus generating an increase in payments; we certify that this proposed rule would 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 impact or regulatory burden of this proposed rule because no burden is imposed.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside 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 proposed rule would have 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 proposed rule would impose no direct requirement costs on State and local government, would 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 proposes to amend 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 changes are made to read 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 *posthospital 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

6. In § 417.479, paragraph (h)(1) and the heading of paragraph (h)(2) are revised and paragraph (h)(2) introductory text is added to read as follows:

§ 417.479 Requirements for physician incentive plans.

* * * * *

(h) *Disclosure requirements for organizations with physician incentive plans.* (1) *Disclosure to CMS.* Each HMO must provide to CMS information concerning its physician incentive plans as requested.

(2) *Disclosure to Medicare beneficiaries.* An HMO 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.

(iii) 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) of this section also is terminated or discontinued in the area in which the individual resides.

* * * * *

10. In § 422.74, the following changes are made to read 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 only disenrolls a Medicare enrollee when the organization has not received payment within 90 days after the date the premium was due.

* * * * *

(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.

* * * * *

Subpart C—Benefits and Beneficiary Protections

11. In § 422.101, the following changes are made to read 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 plan, except that M+C plans that cover areas encompassing more than one local coverage policy area may elect to have the local coverage decisions for the part of the area that is the most beneficial to the M+C enrollees apply with respect to all M+C enrollees in the plan. M+C plans that elect this option must consult with CMS prior to selecting the area that has local coverage policies that are most beneficial to M+C enrollees.

(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 changes are made to read 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 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, and the marketing materials associated with the benefits, are not subject to review or approval by CMS. M+C plan benefits provided to enrollees of the employer, labor organization, or trustees of the fund established to furnish benefits, and the associated marketing materials, are subject to CMS review and approval.

(3) * * *

(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 Proposal (ACRP). Any M+C organization using a waiver or modification must include that information in the cover letter of its ACRP 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.

(b) *General rule.* If CMS determines and announces that an NCD or legislative change in benefits meets the criteria for significant cost described in paragraph (a) of this section, an 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.

(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 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 and deductible 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.* Beginning with contracts entered into or renewed on or after December 20, 2000, 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 E—Relationships with Providers

16. 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

17. In § 422.250, the following changes are made to read 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. For 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.

* * * * *

18. 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 adjusts capitation rates or makes other payment adjustments for the next calendar year to take account of the new service or benefit. The change in payment amounts is based on an analysis by the CMS chief actuary of the costs associated with the NCD or legislative change in benefits. CMS will pay or arrange for payment of these additional costs until the adjusted payments are in effect.

* * * * *

19. In § 422.266, the following changes are made to read 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

20. In § 422.312, the following changes are made to read 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.* Beginning 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

21. 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, regulations 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

22. 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).

23. 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. An 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.

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

§ 422.619 How an 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. An 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

25. In § 422.758, the following changes are made to read as set forth below:

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

B. Paragraph (a) is redesignated as paragraph (a)(1).

C. Paragraph (b) is redesignated as paragraph (a)(2).

D. A new paragraph (b) is added.

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

* * * * *

(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: July 16, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 17, 2002.

Tommy G. Thompson,

Secretary.

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