

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 422 and 489

[CMS-4024-FC]

RIN 0938-AK48

Medicare Program; Improvements to the Medicare+Choice Appeal and Grievance Procedures

AGENCY: The Centers for Medicare & Medicaid Services, HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period responds to comments on the January 24, 2001, proposed rule regarding improvements to the Medicare+Choice (M+C) appeal and grievance procedures. It establishes new notice and appeal procedures for enrollees when an M+C organization decides to terminate coverage of provider services. The January 24, 2001 proposed rule was published as a required element of an agreement entered into between the parties in *Grijalva v. Shalala*, civ. 93-711 (U.S.D.C. Az.), to settle a class action lawsuit.

This rule also specifies a Medicare-participating hospital's responsibility for issuing discharge or termination notices under both the original Medicare and M+C programs, amends the Medicare provider agreement regulations with regard to beneficiary notification requirements, and amends M+C enrollee grievance procedures.

DATES: *Effective date:* Except for §§ 422.564, 422.620, 422.624, and 422.626, which are subject to the Paperwork Reduction Act (PRA), this final rule with comment period is effective May 5, 2003. We will publish the effective dates of those sections of the rule that are subject to the PRA in the **Federal Register** when the sections have been approved by the Office of Management and Budget.

Comment date: We will consider comments on this final rule if received at the appropriate address, as provided below, no later than 5 p.m. on June 3, 2003.

ADDRESSES: 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-4024-FC, P.O. Box 8013, Baltimore, MD 21244-8013. To insure that mailed comments are received in time for us to consider them,

please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-8013.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-4024-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Chris Gayhead, (410) 786-6429 (for issues concerning improvements to the M+C appeals and grievance procedures); Rhonda Greene Bruce, (410) 786-7579 (for issues related to hospital discharge notices).

I. Background

A. *Balanced Budget Act of 1997*

Section 4001 of the Balanced Budget Act of 1997, (BBA) (Pub. L. 105-33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the "Medicare+Choice (M+C) Program." Implementing regulations for the M+C program are set forth in 42 CFR part 422. Subpart M of part 422 implements sections 1852(f) and (g), which set forth the procedures M+C organizations must follow with respect to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f) of the Act, an M+C organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its M+C plans.

Section 1852(g) of the Act addresses the procedural requirements concerning coverage determinations (called "organization determinations") and reconsiderations and other appeals of such determinations. In general, organization determinations involve the

question of whether an enrollee is entitled to receive, or should continue to receive, a health service, and the amount the enrollee is expected to pay for the service. An organization determination may also involve an enrollee's request for reimbursement for services obtained with or without prior authorization. Only disputes concerning organization determinations are subject to the reconsideration and other appeal requirements under section 1852(g) of the Act. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this final rule, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization or an independent review entity (IRE) or entities. We use the term "appeal" to denote any of the procedures that deal with the reviews of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Medicare Appeals Council (MAC) and judicial review.

B. *Grijalva v. Shalala*

Grijalva v. Shalala is a 1993 class action lawsuit brought by beneficiaries enrolled in Medicare risk-based managed care organizations. The plaintiffs challenged the adequacy of the managed care appeals process and claimed that CMS failed to assure that contracting managed care organizations afforded enrollees rights to which plaintiffs contended enrollees were entitled when the organization denied, reduced, or terminated health care coverage.

The Secretary and the plaintiffs reached a settlement agreement in the case, which the Arizona District Court approved on December 4, 2000. Under the settlement agreement, we agreed to publish a notice of proposed rulemaking (NPRM) proposing regulations that would establish new notice and appeal procedures when an M+C organization decides to terminate coverage of provider services to an enrollee. Providers that would be affected under the proposed rules published pursuant to the settlement agreement included skilled nursing facilities (SNFs), home health agencies (HHAs) and comprehensive outpatient rehabilitation facilities (CORFs). A key element of the agreement was that CMS would propose to establish an independent review entity to conduct fast-track reviews of appeals of decisions to terminate services. Under the proposed process, M+C enrollees would receive detailed written notices concerning their service

terminations and their appeal rights at least four days before a service termination. The proposed appeal process would be carried out during those four days. (See our January 24, 2001, proposed rule, 66 FR 7594, for a more detailed description of the settlement agreement.)

The settlement agreement contained a great deal of specificity with respect to both the notice and appeal procedures to be set forth in the proposed rule, and the timeframes for publication of proposed and final rules. However, consistent with Administrative Procedure Act (APA) standards for notice and comment rulemaking, the agreement explicitly established that publication of the proposed requirements "[should] not be construed as a promise or predetermination regarding the content of [the] final rule * * * on notice and appeal procedures for M+C organization decisions to terminate provider services."

II. Provisions of the Proposed Rule

On January 24, 2001, we published an NPRM (66 FR 7593) that, consistent with the settlement agreement, proposed regulations that would establish that an M+C enrollee who is dissatisfied with an M+C organization's decision to terminate SNF, HHA, or CORF services would have the right to a fast-track review by an independent entity. As described below, the proposed rule set forth the notification and appeals procedures for implementing this new appeal right. The proposed rule also addressed the notification procedures associated with similar appeal rights available to Medicare beneficiaries receiving inpatient hospital services as well as M+C beneficiary grievance procedures.

A. Proposed Notice and Appeal Procedures

We proposed that for any termination of services furnished by one of the affected types of providers, the enrollee would receive a standardized notice informing them of the M+C organization's decision to terminate the services. Under our proposal, the provider would be charged with the delivery of the notice four calendar days before the scheduled termination. If the services were expected to be furnished to an enrollee for a time span of fewer than four calendar days in duration, the enrollee would be given the notice upon admission. Valid delivery of the notice required the enrollee to sign the notice to indicate that he or she had received the notice and could comprehend it.

We proposed that the termination notice contain the following information:

A specific and detailed explanation why services were either no longer medically necessary or were no longer covered (with a description of any applicable Medicare coverage rule).

Any applicable M+C organization policy, contract provision, or rationale upon which the termination decision was based.

Specific, relevant information to an extent sufficient to advise the enrollee of how a Medicare or M+C organization policy applied to the enrollee's case, as well as the date and time that the organization's coverage of services would end (and the enrollee's liability would begin).

A description of the enrollee's fast-track appeal rights, including how to contact the IRE to initiate an appeal, as well as the availability of other M+C appeal procedures if the enrollee failed to meet the deadline for (or decided not to pursue) a fast-track IRE appeal.

Under our proposal, an enrollee who wanted to appeal a termination decision to the IRE needed to contact the IRE by noon of the first calendar day after receiving the termination notice. We specified that an enrollee who timely sought IRE review would be protected from liability for the costs of services during the fast-track appeals process. Coverage of provider services would continue until noon of the day after an enrollee received notice of an IRE's decision upholding the M+C organization's determination, or until the time and date designated on the termination notice, whichever was later.

We proposed that when an enrollee appealed an M+C organization's decision to terminate provider services, the burden was on the M+C organization to prove that the termination was the correct decision. The M+C organization would be required to supply any information that the IRE required to sustain the termination decision, including a copy of the termination notice. The M+C organization would be required to supply this information as soon as possible, but no later than the close of business of the first day after the day the IRE notified the M+C organization that the enrollee had requested a review.

Assuming that the IRE received all needed information on a timely basis, the proposed process would have resulted in a decision by the close of business on the second full day after the deadline for an enrollee's appeal request, with the following possible results:

If the IRE decided that services should not be terminated, a new termination notice would be required, with attendant appeal rights, before the M+C organization could terminate services.

If the IRE deferred its decision, coverage of the services would continue until the decision was made but no additional termination notice would be required.

If the IRE decided to uphold the M+C organization's decision to discontinue services, coverage of the enrollee's services would end at noon on the day after the IRE made its decision or as specified in the termination notice, whichever is later.

In the event that the M+C organization's decision was upheld, the enrollee would be financially liable for any services provided after the effective date identified in the notice. The proposed rule outlined that an enrollee's first recourse after an unfavorable IRE decision would be to request, within 60 days, that the IRE reconsider its decision. The IRE would have up to 14 calendar days from the date of the request for reconsideration to issue its reconsidered determination, with subsequent appeals possible to an ALJ and the MAC, consistent with the procedures set forth in the existing M+C regulations.

B. Hospital Notification Procedures

We also proposed in the January 24, 2001, rule requirements regarding hospitals' responsibility for issuing discharge notices under both the original Medicare and the M+C program. Specifically, we proposed that hospitals be required to provide to all Medicare beneficiaries (including those enrolled in M+C plans) a notice that includes the reasons for a discharge and information on their appeal rights. Under the proposed rule, hospitals would be responsible for delivering such a notice to each beneficiary the day before the date of the discharge. We noted that these notices would have to be approved by the Office of Management and Budget under section 3506(c)(2)(A) of the Paperwork Reduction Act.

C. Grievance Procedures

The January 2001 rule also proposed to revise the existing definition of a "grievance," and proposed that an M+C organization be required to notify the enrollee of its decision as expeditiously as the case required, but no later than 30 calendar days after the date the organization received the grievance. In conjunction with this timeframe, we also proposed that the M+C organization be permitted to extend the timeframe by

up to 14 calendar days if the enrollee requested the extension or if the organization justified a need for additional information and the delay was in the interest of the enrollee.

Our proposal would require an M+C organization to inform the enrollee of the disposition of the grievance in writing if the grievance was submitted in writing. Grievances submitted orally could under the proposal be responded to either orally or in writing unless a written response was specifically requested by the M+C enrollee.

We proposed that the M+C organization's written response to a grievance involving quality of care issues or concerns must describe the enrollee's right to seek Quality Improvement Organization (QIO) review. For any complaint involving a QIO, the M+C organization must cooperate with the QIO in resolving the complaint.

The proposed rule specified that an M+C organization would be required to expedite a grievance if: (1) The grievance involved an M+C organization's decision to invoke an extension relating to an organization determination or reconsideration; (2) the grievance involved an M+C organization's refusal to grant an enrollee's request for an expedited organization determination; or (3) applying the standard timeframe could seriously jeopardize the enrollee's life, health or ability to regain maximum function. We proposed that the M+C organization notify the enrollee of its decision on an expedited grievance within 72 hours of receipt of the enrollee's grievance. The proposed grievance procedures concluded with the requirement that the M+C organization have a system to track and maintain records on all grievances received both orally and in writing, including the final disposition of the grievance. The tracking system would be required to maintain, at a minimum, date of receipt, disposition and date the response was given.

D. Reductions of Service

As part of the *Grijalva* settlement, we agreed to solicit comments in the January 2001 rule on how to provide notice and appeal procedures for decisions by M+C organizations to reduce provider services. We stated in the January 2001 proposed rule that, based on our review of this issue, we were considering adopting the position that a written notice should be required whenever there was a reduction in previously authorized ongoing course of treatment. We did not put forth specific regulatory language to implement this

approach, but instead asked for public comments on the appropriateness of such a requirement and recommendations on specific regulatory revisions in this regard.

III. Analysis of and Responses to Public Comments

A. Overview of Comments on January 24, 2001 Proposed Rule

We received 33 timely comments from organizations representing hospitals and other providers, M+C organizations, beneficiary advocacy groups and others. Commenters representing providers and managed care organizations uniformly agreed that the new appeals procedures were unworkable as proposed. They raised a series of objections to the proposed provisions, with concerns focusing on the following areas:

- Creation of a fast-track appeals process.
- Timing of the termination notices.
- Content and delivery of the notices.

The commenters representing beneficiary groups generally supported the procedures as proposed and urged CMS to finalize the proposed provisions. Commenters also expressed concern over the revised procedures for notifying Medicare beneficiaries of their right to appeal when discharged from an inpatient hospital. We also received comments on the proposed grievance procedures and the appropriateness of establishing notice and appeal procedures for reductions in provider services. These comments and our responses are discussed below.

B. The Proposed Fast-Track Review Process (Sections 422.624 and 422.626)

1. Need for a New Fast-Track Appeals Process

Comment: Several commenters opposed the creation of a fast-track, independent appeals process. These commenters argued that the current expedited appeals process is effective to handle appeals of provider terminations. They pointed out that the appeals process had changed considerably since the *Grijalva* lawsuit was first filed in 1993, including the implementation of an expedited appeals process for Medicare managed care enrollees (through an April 30, 1997, final rule (62 FR 23375)) and the subsequent establishment of the M+C program appeals procedures (under the BBA and implementing regulations). They asserted that the new fast-track appeals process would be confusing, duplicative, burdensome and expensive.

Response: We recognize that many of the problems that led to the original

Grijalva lawsuit have been rectified through subsequent statutory and regulatory changes, and we believe that the existing expedited appeals process constitutes an important and effective beneficiary protection. However, the current expedited appeals process was designed primarily to address denials of the initiation of a service. The fast-track appeals process proposed in the January 24, 2001, rule would deal with decisions about the termination of provider services. Moreover, obtaining an independent review of an M+C organization's decision to terminate an enrollee's provider services now takes at least 6 days to complete, under a process where both the M+C organization and CMS's independent contractor must review an adverse organization determination about the need for further services. Our experience has been that decisions involving the termination of provider services, particularly in nursing homes, have been among the most contentious, and have often exposed enrollees to potentially significant financial liability for continuation of services. Under the fast-track process, an enrollee may appeal directly to an IRE, with greatly limited, if any, financial liability. This one-step process, carried out at government expense, can limit appeal processing costs for both the enrollee and the M+C organization.

We also note that section 1869(b) of the Act, as amended by section 521 of the Medicare Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), has introduced significant new appeal requirements for beneficiaries under the original Medicare program that substantially parallel those proposed pursuant to the *Grijalva* settlement. BIPA requires the Secretary to establish a new fast-track appeal process when a provider of services plans to terminate an individual's services or discharge the individual from the provider. Currently, this right to an expedited review only exists with respect to hospital discharges under sections 1154 and 1155 of the Act. Our decision to implement an independent review process for terminations of provider services furnished to M+C enrollees is entirely consistent with, and bolstered by, the Congressional intent and direction evidenced by the BIPA provisions. (See our November 15, 2002, proposed rule, at 67 CFR 69312 for further details on the BIPA statute and our proposed new appeal provisions.) We believe that CMS must assure that all Medicare beneficiaries are afforded a fair and equitable process to appeal

provider terminations whether the beneficiary is enrolled in M+C or original Medicare.

2. Timing of the Termination Notices

Comment: Many commenters stated that it is clinically improbable that an M+C organization or provider could accurately predict four days in advance when a discharge would be appropriate, particularly in the nursing home setting where discharge decisions are made "at most 48 hours prior to discharge." They argued that requiring delivery of the termination notices four days in advance would result in unnecessary appeals being initiated in situations where there could be a subsequent decision that services should not be terminated. They also believe that the four-day advance notice would greatly complicate the appeals decision-making process, since appeals would need to be decided as much as two days before the actual termination of services.

Commenters suggested a number of alternative requirements for delivery of the termination notice, including: three days before termination of services, two days before termination, one day before termination of services, and "promptly" after the M+C organization decides that termination is appropriate.

Several commenters representing home health providers expressed concern that providers of such intermittent care in effect would be required to arrange for their staff to make extra visits solely to deliver termination notices. Commenters also suggested that if CMS retained the four-day advance notice requirement, the requirement should be more flexible, *i.e.*, delivery could be carried out before the proposed four-day deadline if circumstances permitted.

Response: The primary intent of the proposed four-day advance notification requirement was to enable the appeals process to be completed by the time services were scheduled to end, and thus to protect enrollees from any financial liability during the course of the appeal process. However, we have become convinced based on our review of the comments and further research into medical practice patterns that providing these notices four days in advance of termination is often not practical, particularly in institutional settings. Therefore, in this final rule, we are requiring under 422.624(b)(1) that enrollees receive notices *no later than two days* in advance of termination of services. We are also revising the proposed requirements to state explicitly that if, in a noninstitutional setting, the span of time between services exceeds two days, the notice

may be provided the next to last time services are furnished.

We recognize that the result of this change would be that in some situations, enrollees will be exposed to potential liability for services that are found unnecessary by the independent review entity. However, we have concluded that it is not possible to construct a system that in all situations provides a meaningful notice about termination of services and still builds in complete financial protection for enrollees during the course of an appeal to an IRE. Note that we are also revising the appeals process itself (by shortening the time frame for records to be sent to the IRE, under 422.626(e)(3)) to ensure that it is completed within three days of the notice of termination. The effect of these changes is that an enrollee will face a maximum of one day of financial liability if the IRE rules that the disputed discharge date is appropriate.

In establishing this policy, we carefully considered how to balance two conflicting responsibilities—the need to ensure that an M+C enrollee has an opportunity to a meaningful appeal without undue financial exposure with the obligation not to impose inappropriate financial burdens on M+C organizations. Clearly, except in the inpatient hospital setting, the Medicare statute generally does not provide financial liability protection for either M+C enrollees or other Medicare beneficiaries who have chosen to continue to receive services pending the result of an appeal or claim determination. Absent a statutory mandate, we do not believe we have the authority to require M+C organizations to pay for services that are subsequently determined by an independent review entity not to be medically necessary, or otherwise covered, for the enrollee in question. (As noted above, section 521 of BIPA establishes a similar right to a fast track appeal of a termination of provider services (under section 1869(b)(1)(F) of the Act), but did not provide for continuation of Medicare coverage during the pendency of the appeal.)

It is important to note that an enrollee's potential financial liability for continuing provider services occurs only after valid delivery of the advance termination notice. That is, consistent with the requirements outlined at § 422.624(b), a standardized, signed and dated advance termination notice is required for financial liability to accrue to the enrollee. Providing this notice as soon as the termination date is known (rather than waiting until two days in advance of service termination) will in many cases serve the best interests of

both plan enrollees and the M+C organizations who are responsible for payment for the services.

Comment: Several commenters responded to our specific request for comments on what constituted four-day notice and expressed confusion over whether the deadline for notice delivery would be 3 p.m. or "close of business." Commenters indicated that requiring that the notices be delivered by 3 p.m. was not appropriate, given for example that physicians frequently visit nursing homes late in the afternoon or early in the evening after their office hours are over. Commenters recommended that CMS clarify that termination notices could be given until the end of the business day, which would still enable enrollees to request an appeal by noon of the next day.

Response: We agree with commenters that the deadline for notice delivery needs to be later than 3 p.m. to allow physicians and other practitioners enough time to visit nursing homes or other service settings late in the day. We recognize that practice patterns are different in these settings than in inpatient hospitals and thus that it may not be appropriate to apply the same standard across all provider settings. Thus, rather than establish a more precise time standard in regulations, the regulations will continue to indicate *the latest day* that a notice must be delivered. We intend to issue further program guidance that will be based on the prevalent practice patterns for the various service types. This guidance will reflect our general agreement that delivery of the advance termination notice by "close of business" will provide sufficient time for an enrollee to appeal by noon of the next day.

Comment: Two commenters raised concern over whether the four-day advance notice requirement should include weekends and holidays. One commenter asked that we consider the fact that many of the notices may be given on a day that would place the fourth day on a Saturday, Sunday, or holiday. Another commenter stated that since HHA and CORF services are not usually rendered on weekends or holidays, and M+C organizations have limited staff available on these days, CMS should consider using business rather than calendar days, where appropriate.

Response: As noted above, this final rule changes the requirement for advance notification of termination of services or discharge from the four day standard in the proposed rule to no later than two calendar days prior to termination of services or discharge. The new standard of "at least" two days

affords an M+C organization or provider the option of providing notice more than two days in advance if the second day before discharge is a non-business day (for example, for a Monday discharge). We have also provided that situations involving non-institutional settings, where the time-span between service delivery exceeds two days, an enrollee should be notified no later than the next to the last time services are furnished. We will work with provider and M+C organization representatives, and with the IRE to develop uniform procedures to deal with those rare situations where an enrollee needs to be given notice or discharged on a weekend. At a minimum, we intend to require, through its contract, that the IRE be able to accept expedited review requests on any day of the week and notify an M+C organization of that request.

3. Content and Delivery of the Termination Notice

Comment: Commenters raised a series of related concerns about both the delivery and content of the termination notices. Many commenters viewed as unnecessarily burdensome the requirement that each enrollee in a provider setting receive a detailed termination notice, regardless of whether the enrollee agreed with the termination of services. They generally believe that in most situations the contents of the required notice were too extensive and would provide little or no benefit to most enrollees.

Commenters were divided on the issue of who should be responsible for distributing the notices. Managed care industry commenters generally supported the proposed requirement that the providers of services deliver the notices, although they expressed concern over their liability in situations where the providers failed to do so. Commenters representing providers objected to being charged with this responsibility, particularly in view of the detailed nature of the notice. They indicated that it would be difficult to obtain all needed information from M+C organizations and that it was unfair to in effect shift the responsibilities of M+C organizations to providers. One commenter argued that a policy whereby providers would be responsible for giving notices does not comport with the settlement agreement.

Response: We continue to believe that providers clearly are in a better position than M+C organizations to carry out routine delivery of service termination notices to their patients. At the same time, although all enrollees need to be made aware of their appeal rights on a

timely basis, we recognize that only a small proportion are likely to object to the termination of their services. Thus, it is in the best interests of all parties that the notice delivery process be as streamlined and simple to administer as possible.

To that end, we are requiring a two-step notification procedure under this final rule. We are revising the proposed requirement that providers deliver a detailed termination notice to M+C enrollees. Instead, we are requiring under 422.624(b) that providers deliver a standardized, largely generic, notice to each M+C enrollee whose services are terminating that will explain the enrollee's appeal rights. The notice will contain only two enrollee-specific elements—the enrollee's name and the date services will end. These notices will contain standardized information on an enrollee's appeal rights and how to initiate an appeal if necessary. Unless the enrollee wishes to dispute the termination of services, no further notice will be required.

The notice will instruct the enrollee to contact the IRE if he or she believes that the services should continue. If the enrollee indicates to the IRE that he or she disagrees with the discharge, the IRE will immediately contact the M+C organization, which will be required under 422.626(e) to deliver a detailed notice to the dissatisfied enrollee and to the IRE. The detailed notice must contain the remaining elements required under the proposed rule, including an explanation of why services were no longer needed, a description of any applicable Medicare coverage rule or policy, a statement of any applicable M+C organization policy or rationale, and facts specific to the enrollee that establish the applicability of Medicare or M+C organization policies. We believe that M+C organizations are in the best position to give detailed notices regarding their specific policies and the criteria that they applied in deciding to terminate provider services. Moreover, in view of the fact that M+C organizations ultimately bear the responsibility for both the service termination/discharge decision and for paying for services covered under their plans, we believe that is appropriate that M+C organizations be responsible for preparing and delivering them under the limited circumstances when they are needed.

Comment: Commenters were concerned that providers would refuse to comply with instructions to deliver notices and wanted to know what incentives were in place to obligate providers to deliver notices.

Response: We believe that the streamlined notification process should greatly ameliorate this concern. Providers will be obligated to comply with notice requirements through the amendment of the provider agreement regulations at § 489.27(b), as well as through their contractual arrangements with M+C organizations. We recognize that M+C organizations may also choose to delegate to providers the responsibility for discharge and termination decisions, and for the delivery of detailed notices in disputed termination cases. M+C organizations may choose to offer incentives to providers for compliance with these responsibilities, or penalties for non-compliance, through these private contractual arrangements. However, consistent with 422.502(i), M+C organizations remain ultimately responsible for carrying out such delegated requirements.

We also note that section 1819(h) of the Act specifies remedies that may be used by the Secretary when a SNF is not in substantial compliance with the requirements for participation in the Medicare program. These penalties are applied on the basis of surveys conducted by CMS or by a survey agency. The regulations at § 488.406 include other penalties for non-compliance such as denials of payment, and corrective action plans. Also, HHAs are regulated in part by conditions of participation found at § 484.12, which indicate that HHAs must operate and furnish services in compliance with all applicable Federal, State and local laws and regulations.

Comment: Several commenters raised questions about financial liability in situations where a provider failed to deliver timely notice. They believe that it would be unfair for M+C organizations to be liable for services in such situations.

Response: Again, we believe that the prevalence of this sort of situation will be greatly lessened in light of the direction that we have taken in this final rule, which places a clear, reasonable obligation on both providers and M+C organizations with respect to informing enrollees of their rights. Nevertheless, the nature of the arrangement between an enrollee and a managed care organization dictates that the organization is ultimately responsible for payment for services that are found to be covered under the enrollee's plan. When an IRE makes a decision on an enrollee's appeal of a service termination, that decision will determine the extent to which liability rests on either the M+C organization or the enrollee. Consistent with

422.624(a)(2), an IRE's review will be available with respect to termination decisions where an enrollee first was "authorized, either directly or by delegation, to receive an ongoing course of treatment from that provider." Thus, the IRE's determination is limited to whether continuation of an ongoing course of treatment is covered under an enrollee's plan. The IRE will not be expected to assign liability between the provider and the M+C organization.

Accomplishing proper advance notification of termination by the provider requires coordination and information sharing between the provider and the M+C organization to ensure that the enrollee receives the correct information at the proper time. We believe that the interdependence between M+C organizations and SNFs, HHAs, and CORFs reflects the typical daily reality of health plans and insurers.

Comment: Some commenters suggested that the 4-day advance notice requirement could result in the overutilization of services. They were concerned, for example, that an enrollee could be kept in a SNF unnecessarily even if the individual's condition had improved sufficiently to permit an unexpectedly early discharge. Commenters also asked about situations where an IRE determined that services should continue only one or two additional days. They questioned the need for additional notices in such situations.

Response: The notice requirement is not intended to impede or substitute for appropriate medical decision-making practices. Nothing in these requirements precludes an enrollee from being discharged from a SNF or HHA when an enrollee and his or her physician are in agreement that the discharge is medically appropriate. To clarify this point, we have revised section 422.624(d) to specify that, although an M+C organization is financially liable for continued services until 2 days after an enrollee receives a termination notice, the enrollee may waive the right to continued services if he or she agrees with being discharged sooner than 2 days after receiving the notice. However, an enrollee who objects to the service termination would not be liable for the services until 2 days after receiving the notice.

Similarly, it is not our intent to require M+C organizations to provide more care than an IRE determines would be appropriate. If an IRE specifies the number of days that coverage should continue, the IRE's decision itself takes the place of any further notice. However, there may be instances where

an IRE will defer to an M+C organization to determine when coverage should end. In those cases, another advance termination notice must be given to the enrollee within a time frame consistent with the circumstances involved. Again, we believe that this concern is lessened or eliminated under the change to a 2-day advance notice.

Comment: Several commenters were concerned about the length and complexity of the notice, believing that this would cause delays in its preparation and create noncompliance with the delivery and appeals timeframes. Some commenters also argued that preparing these detailed notices about policies, coverage rules and contract provisions for every enrollee prior to provider services terminating would be administratively burdensome.

Response: As discussed above, we agree that it is not necessary to provide a detailed notice to all enrollees. We have learned through consumer testing that Medicare beneficiaries prefer to receive relevant information timed according to when they need to act. Thus, we have revised the proposed policy from requiring 100 percent distribution of a detailed notice from providers to all enrollees, to 100 percent distribution of a largely generic notice that explains when services will end, where to appeal if the enrollee disagrees, and potential liability for continued coverage during an appeal. For those enrollees who choose to appeal, M+C organizations would be required to provide a detailed notice that: explains why services are no longer covered or medically necessary, describes any applicable coverage rules, policies, or contract provisions, and contains facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee about the enrollee's care. We believe that this two-step notification process meet the needs of the large majority of enrollees who need to know when their services will end and what their appeal rights are, as well as the small minority of enrollees who want more specific information about why their services are ending. This approach also ensures that providers and M+C organizations are not faced with unnecessary administrative costs and burdens. CMS will develop both notices—the advance termination notice, and the detailed termination notice, through OMB's PRA process.

Comment: Some commenters viewed our proposal to require providers to deliver termination notices as evidence that CMS was unfairly favoring M+C

organizations over providers, by allowing M+C organizations to avoid responsibility for providing notices. Some commenters believed that making providers responsible for termination notices simply because they were in the best position to deliver notices was unprecedented and argued that this violated the Administrative Procedure Act (APA).

Response: In developing these proposals, as well as in developing this final rule, we have attempted to arrive at policies that balance the rights and responsibilities of all the involved parties, including Medicare beneficiaries, providers, and M+C organizations. We continue to believe that beneficiaries need to be informed of their appeal rights and that providers are in the best position to carry out this function. At the same time, we are very cognizant of the need to accomplish such notification in the most cost-effective and least burdensome manner. Thus, as explained above, we have made adjustments to the proposed provisions to reflect concerns raised by commenters. This is the essence of notice and comment rulemaking, and thus we believe that implementing the notification requirement through this rulemaking process is entirely consistent with the APA. That is, the preamble to the proposed rule satisfied the requirements of the APA by describing our proposed policies and explaining the reasoning behind the proposal that providers deliver the termination notices. This final rule then reflects our careful consideration of the comments received. In response to comments on the burden imposed by the proposal on providers, we have in this final rule lessened that burden.

Comment: Various commenters raised questions regarding whether a notice needed to be provided in certain scenarios, such as when services did not meet Medicare coverage criteria, or where a provider or attending physician disagreed with an M+C organization's decision to terminate services.

Response: M+C organizations must determine when services should end on the basis that services are no longer medically necessary, or otherwise are not covered under Medicare or the M+C plan's coverage policies. Once an M+C organization determines that provider services should end, providers must deliver notices to enrollees at least two days in advance of services terminating. The requirement to provide the notice is independent of the basis for termination of a course of treatment. In other words, it applies whether the decision is based on a medical necessity judgment or the application of a Medicare coverage rule.

Similarly, the provider's obligation to give an advance termination notice to the enrollee exists even if a provider or attending physician disagrees with the M+C organization that services should terminate. The M+C organization's decision to end services is not an indication that the provider necessarily agrees that services should end, but it is necessary to ensure that the enrollee has the opportunity to appeal the M+C organization's decision.

Comment: Commenters recommended that CMS permit providers to request appeals on behalf of enrollees and recommended that an IRE's decision bind an M+C organization to pay a provider for necessary services.

Response: Providers have the ability to file appeals on behalf of enrollees as authorized representatives in accordance with § 422.562(d). We have not created any additional provider appeal rights in this regulation. The purpose of these regulations is to ensure that enrollees receive the services that they are entitled to under their M+C plans, through the implementation of appropriate notice and appeal. CMS generally does not specify the payment arrangements between M+C organizations and providers; therefore, an IRE's reversal of an M+C organization's decision to terminate services is not a ruling on whether, or the extent to which, an M+C organization is financially obligated to the provider. Instead, the relevance of an IRE's reversal is that the M+C organization is obligated to continue services for the enrollee beyond the services that the M+C organization previously authorized.

Comment: Some commenters suggested that the requirement for a 4-day advance notice in situations where an IRE determined that services should continue only one or two additional days would result in the overutilization of health care services. They questioned the need for additional notices in such situations.

Response: It is not our intent to require M+C organizations to provide more care than an IRE determines would be appropriate. If an IRE specifies the number of days that coverage should continue, the IRE's decision itself takes the place of any further notice. However, there may be instances where an IRE will defer to an M+C organization to determine when coverage should end. In those cases, another advance termination notice must be given to the enrollee within a time frame consistent with the circumstances involved. Again, we believe that this concern is lessened or

eliminated under the change to a two-day advance notice.

Comment: Commenters expressed concern that an IRE might delay making a decision if it believed that it needed additional information from the M+C organization. The commenter proposed that CMS require an IRE to inform the M+C organization promptly, by fax or e-mail, if an IRE believed that it needed more information to make a decision, and to specify the precise information it required to make a decision on the merits.

Response: Section 422.626(d)(5) specifies that if an M+C organization fails to provide sufficient information to support its decision to terminate an enrollee's services, an IRE may defer issuing a decision until it receives needed information about the case. If an IRE chooses to do so (rather than simply decide the case in the enrollee's favor based on the evidence at hand), we agree that an IRE should make best efforts to promptly notify an M+C organization of the information the IRE needs, and that the submission of this information could affect the IRE's decision on the merits. However, M+C organizations should not expect IREs to routinely follow-up to complete the record. It is the M+C organization's responsibility to provide all relevant material necessary to sustain its termination decision by close of business of the day that the IRE notifies the M+C organization that an enrollee has requested an appeal. Thus, we will instruct IREs through their contracts with CMS that in the event that the M+C organization fails to submit documentation that would sustain the M+C organization's decision, and the IRE either cannot obtain the prompt cooperation of the M+C organization, or does not deem it practical to obtain additional information, the IRE should issue a decision based on the information available and err on the side of the beneficiary.

Comment: One commenter suggested that CMS should extend the same provider notice requirements to original Medicare beneficiaries whose services are being terminated.

Response: As noted above, section 1869(b)(1)(F) of the Act, as amended by section 521 of BIPA, establishes appeal rights for beneficiaries under original Medicare that are largely parallel to those available to M+C enrollees under this final rule. As discussed in detail in our November 15, 2002, proposed rule concerning those provisions, we believe that existing Advance Beneficiary Notices (ABNs) that are now used in Medicare fee-for-service settings are the appropriate vehicle to trigger the right to

an expedited appeal of a provider termination of services. (*See* 67 FR 69337.)

Comment: Several commenters were concerned that the standard for "valid delivery" of a termination notices is difficult to meet. They indicated that it would require a clinician to deliver the notice in order to determine the enrollee's level of consciousness, and ability to read and comprehend it, which would be expensive and burdensome.

Response: Section 422.624(c) specifies that "delivery" of a notice is valid only if an enrollee has signed and dated the notice to indicate that he or she both received the notice and can comprehend its contents. This policy is consistent with other CMS requirements governing the delivery of similar notices such as those set forth in CMS program memoranda A-99-52 and A-99-54 for HHA advanced beneficiary notices under original Medicare. We have no indication that this standard has proven problematic and believe that it is appropriate to apply similar protections to enrollees in the M+C program. Note that this requirement for successful delivery does not permit an enrollee to extend coverage indefinitely by refusing to sign a notice of termination. If an enrollee refuses to sign a notice, the provider would annotate its copy of the notice to indicate the refusal, and the date of the refusal would be considered the date of receipt of the notice.

By the time that termination notices are issued, providers will have already needed to assess an enrollee's ability to accept delivery of a notice, based on typical admission assessments, care planning evaluations and discharge planning activities that have taken place during the course of treatment. In the event a provider believes that an enrollee is not capable to receive the notice, providers should be well-acquainted enough with the enrollee's particular situation to make alternative arrangements, if necessary, to deliver a valid notice. For example, an incapacitated enrollee is not able to act on his or her rights and, therefore, could not validly "receive" the notice. This situation could be remedied through the use of an authorized representative under Federal or State law.

4. Other Comments

Comment: Several commenters objected to the proposed requirement under § 422.502(i)(3)(iv) that M+C organizations include specific provisions in their contracts with providers to require providers to comply with the notice requirements in 422.624. They believe it is burdensome to reopen

contracts with providers to incorporate these requirements, citing that the change in the conditions of participation at § 489.27(b) should be sufficient to ensure compliance.

Response: We agree that the change in conditions of participation at § 489.27(b) is sufficient to ensure that providers comply with the notice requirements at § 422.624. Although we believe that it would be in the best interests of providers and M+C organizations to include these notice requirements in their contracts, we do not intend to require that providers and M+C organizations renegotiate their contracts solely for the purpose of including a clause regarding notice delivery requirements. Therefore we have removed proposed § 422.502(i)(3)(iv).

Comment: One commenter wanted to know if M+C organizations could charge enrollees a reasonable flat fee for the costs of duplicating and mailing case files to enrollees upon request.

Response: In accordance with the Privacy Act and 45 CFR 5b.13, “[f]ees may only be charged where an individual requests that a copy be made of the record to which he is granted access.” No fee is permissible unless the copying costs are at least \$25. Thus, an M+C organization may not charge a fixed fee for the costs of duplicating and mailing case files to enrollees, but may apply the fee schedule outlined in § 5b.13(b). This would allow an M+C organization to charge \$.10 per page for photocopied records above the \$25 threshold, or the actual cost determined on a case-by-case basis for records not susceptible to photocopying.

Comment: One commenter noted that the proposed rule was silent on the type of entity that could serve as an IRE. The commenter (an organization representing Quality Improvement Organizations) recommended that QIOs should be designated as IREs since QIOs already interact on a daily basis with families who question whether the timing of a provider discharge is appropriate. The commenter indicated that relying on an entity other than QIOs would be confusing to enrollees. The commenter recommended that CMS change all references from IRE to QIO so that CMS would not have to develop and maintain a costly and unnecessary contractual and regulatory structure that duplicates the QIO program.

Response: Although we recognize that QIOs have experience with making similar determinations, we do not believe that it is appropriate to designate in a final rule that QIOs will carry out the fast-track reviews. We are still evaluating whether these reviews are more appropriately accomplished

through a single IRE, or multiple entities, as well as the extent to which these procedures can be linked with expedited reviews required under the new BIPA provisions. There are various independent entities, including QIOs, which already have contractual relationships with CMS to make coverage decisions. As we attempt to develop improved, more efficient appeals procedures under both M+C and original Medicare, CMS will determine whether it is prudent to use these existing contractors to fulfill the requirements of this regulation, or whether it is necessary to seek bids for this important work.

Comment: One commenter expressed concern that the proposed rule did not require that IRE reviewers include clinicians or practicing physicians. The commenter also believed that a reviewer should have a background in the specialty or subspecialty relevant to the case.

Response: The regulations at §§ 422.624 and 626 are part of the overall M+C appeals process under subpart M. These fast-track reviews effectively replace M+C organization’s reconsiderations on SNF, HHA, and CORF termination cases. Thus, similar to the requirement under § 422.590(g)(2) for reconsideration decisions by M+C organizations, we intend to require through our contract with the IRE(s) that decisions involving denial of coverage based on a lack of medical necessity “must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.”

C. Hospital Discharge Notices (§§ 422.620 and 489.27)

Comment: Many commenters strongly opposed the proposed requirements under 422.620 and 489.27 that hospitals issue a standardized notice of appeal rights for a second time on the day before discharge to all Medicare beneficiaries, including those that are enrolled in a Medicare managed care health plan. They believe that this requirement poses a significant administrative burden in both delivering and explaining the form and takes away from time better spent on providing services and discharge planning. They contend that the notice is unnecessary in either the managed care or fee-for-service context and indicated that, in many cases, beneficiaries are confused by the notice. One commenter stated that after the enactment in 1998 of the requirement

under 422.620 that all M+C enrollees receive discharge notices the day before the end of their hospital stay, the Quality Improvement Organizations (QIO) received many phone calls from confused beneficiaries not understanding the notice. The commenters believe that very few beneficiaries have any interest in disputing their hospital discharges and thus the cons of this requirement far outweigh any benefits.

Two commenters supported the proposal that hospitals issue notices, both near admission and the day before discharge, to all Medicare beneficiaries. They supported CMS’s efforts to combine the Important Message from Medicare (IM) with the Notice of Discharge & Medicare Appeals Rights (NODMAR), and Hospital Issued Notice of Noncoverage (HINN). The commenters found the notices largely duplicative and welcomed the simple one page document. (Please note that since the publication of the proposed rule, the required notices and the distribution process have also been the subject of public comment through the Office of Management and Budget (OMB) approval process required under section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA).)

Response: After careful consideration of the public comments on these requirements, the many comments received on the notices themselves through the PRA process, and evaluation of CMS data on the hospital discharge appeals process, we are convinced that changes are needed in the proposed notice requirements. Consistent with the notice requirements discussed above for other provider termination situations, we are revising 422.620 to eliminate the requirement that hospitals provide a written notice of noncoverage to each M+C enrollee the day before discharge. Section 489.27 will continue to require that hospitals furnish the Important Message from Medicare, which explains a beneficiary’s appeal rights to every Medicare inpatient during their stay, but will not specify that the notice be delivered the day before discharge.

We continue to strongly believe that all beneficiaries need to be informed of their Medicare appeal rights when admitted as inpatients to hospitals, and this will continue to take place in compliance with section 1866(a)(1)(M) of the Act. However, we have reached the conclusion that requiring that this notice in effect be delivered twice, once upon admission and again before discharge, would be an unnecessarily burdensome requirement on hospitals. We have reviewed data from the QIOs

via CMS's Standard Data Processing System covering the period November 1999–March 2001. During this time, there were approximately 11 million Medicare beneficiaries discharged from hospitals, only about 15,000 of whom (slightly more than one tenth of 1 percent) chose to appeal the hospital discharge decision. Tellingly, the proportion of M+C enrollees that exercised their right to appeal was no different than that for other beneficiaries, despite the ongoing requirement that all M+C enrollees receive notice of their discharge and Medicare appeal rights the day before discharge—a requirement that does not exist for other Medicare beneficiaries. Thus, we believe this evidence indicates the efficacy of the current practice under which hospitals issue detailed notices of noncoverage to beneficiaries under original Medicare only when they express dissatisfaction with the termination of hospital services.

Therefore, hospitals will continue to be responsible for issuing both the Important Message from Medicare to all Medicare inpatients, as well as for issuing HINNs to inpatients covered under the original Medicare program when they indicate that they disagree with a hospital's discharge decision. For enrollees in the M+C program, we are revising 422.620 to specify that M+C organizations are responsible for providing a written notice of noncoverage when an enrollee disagrees with a discharge decision. The notice must be issued no later than the day before hospital coverage ends and must explain the reason why care is no longer needed, the enrollee's appeal rights, and the effective date of time of the enrollee's liability for continued inpatient care. We believe that it is appropriate to place this responsibility on M+C organizations, given their financial liability for continued care in such situations.

We intend to submit updated versions of both the Important Message from Medicare and the detailed notices of noncoverage to OMB for public comment through the PRA process. (We anticipate that there will continue to be two notices of noncoverage—one for patients under original Medicare and one for patients enrolled in the M+C program.) Until that process is completed, hospitals and M+C organizations should continue to use the existing Important Message, HINN, and NODMAR for accomplishing the notification requirements of this final rule. We intend to continue our efforts to simplify the messages delivered by these notices, including limiting each notice to a one-page format.

Comment: One commenter stated that although the proposed rule made it clear that CMS intends to have hospitals administer the IM to all Medicare beneficiaries, it was unclear as to when and how often the notice is to be administered during an inpatient stay. The commenter acknowledges the value to beneficiaries of administering appeal notices for inpatient stays, but believes that hospitals should continue to distribute the IM only at admission, as they have done for years.

Response: We recognize the need for clarity in this regard. The intent of the proposed rule, in conjunction with the procedures set forth through the PRA process, was that hospitals generally would issue the notice twice during an inpatient stay, that is, once at or near the time of admission and again before discharge. However, that proposal has been superseded by the requirements of this final rule. As explained above, hospitals thus should continue their current practice of issuing the IM at or near admission to all Medicare inpatients, and issuing a notice of noncoverage before discharge only in situations where a beneficiary other than an M+C enrollee has indicated dissatisfaction with his or her scheduled discharge date. M+C organizations will be responsible for administering notices of noncoverage to inpatient M+C enrollees when they disagree with an M+C organization's discharge decision.

Comment: One commenter suggests that CMS increase its educational and outreach efforts to ensure beneficiaries' understanding of the notices they receive. The commenter stated that hospitals should not be relied upon to provide all of the education necessary for a beneficiary to understand their Medicare rights.

Response: We are committed to ensuring that notices provided to beneficiaries are clear and understandable, and that beneficiaries with questions can get prompt, reliable answers. To this end, we now routinely consumer test major beneficiary notices such as these hospital notices, as well as subject them to public comment through OMB's Paperwork Reduction Act process. Beneficiaries with questions can contact Medicare's toll free number (1-800-MEDICARE) or work with beneficiary outreach groups sponsored by CMS, such as the State Health Insurance Assistance Programs (SHIPs).

Comment: Two commenters were strongly opposed to CMS's practice of submitting standard termination and similar notices, such as the hospital Important Message, for review by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act (PRA). For notices like these, these commenters believe that this practice makes no sense, and introduces lengthy and they believe unnecessary delays in the implementation of legally required notices. The commenters, citing 44 U.S.C. 3501 *et seq.*, contend that these notices do not fall within the requirements of the PRA for agency actions involving collection of information. They allege that the delay in implementing standardized notices caused by CMS's practice delays compliance with legal requirements, as noted above. Another commenter contends that, while Congress created the PRA to reduce the amount of paperwork providers utilize, over the past five years, providers have seen nothing but increases in the amount of paperwork they must complete. The commenter further argues that the notices required under the proposed rule add to the paperwork burden that providers have to comply with instead of decreasing the burden, as outlined under the PRA.

Response: We do not agree with the commenter's interpretation of the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA). The PRA applies both to information collection and paperwork burden, and thus we believe it is required and appropriate to obtain public comment on notices that are required under Federal regulations. We intend to work closely with OMB to minimize any delays in the development and clearance of the revised standardized notices. We note that in this final rule, we have reduced the paperwork burden that would have been imposed under the proposed rule, including the elimination of certain notice requirements absent an objection to, or decision to appeal, a discharge.

Comment: Several commenters raised concerns about the discharge decision-making process for hospital inpatients who are enrollees of M+C plans. They contend that there will inevitably be disagreements between plans and providers about the timing of patient discharges and that the proposed rule would exacerbate these disputes by requiring hospitals to distribute detailed discharge notices to all M+C enrollees. This in effect requires a hospital to explain an M+C organization's decision. Another commenter stated that over the past few years, its member hospitals have encountered numerous instances in which M+C plans have reduced or denied payment to hospitals for days during which the plan and the beneficiary's physician have disagreed

about whether the beneficiary should be discharged.

Response: Clearly, the hospital discharge decision-making process requires substantial coordination and cooperation between M+C organizations and hospitals. We recognize that requiring detailed discharge notices for all M+C inpatients would have potentially increased the difficulties in this regard without achieving any demonstrable benefits for enrollees. Thus, we have revised the requirements in this final rule to make clear that such notices, when needed, are the responsibility of M+C organizations. However, we continue to believe that it is inappropriate for CMS to interfere in the business relationships between M+C organizations and their hospital providers and that any tension between these parties largely parallels that in the private health insurance sector.

Comment: One commenter noted that under the original Medicare, hospitals must provide QIOs copies of all HINNs given to beneficiaries. In view of the proposal that a detailed discharge notice be given to each Medicare inpatient, the commenter suggested that we eliminate the requirement that QIOs receive copies of every discharge notice.

Response: We believe that hospitals should continue to provide QIOs with copies of all HINNs, and that M+C organization should provide QIOs with copies of the noncoverage notices that they provide to dissatisfied beneficiaries. This is consistent with the policy described above for expedited reviews of other provider terminations, where M+C organizations will furnish copies of their detailed termination notices to both the IRE and the enrollee when there is a dispute over a discharge or service termination.

D. Grievance Procedures (§§ 422.561 and 422.564)

Comment: Some commenters argued that the proposed grievance procedures were overly prescriptive, while others supported establishing the proposed new standards. One commenter believed that grievance procedures should be flexible, given our interpretation of the preemption provision under section 1856(b)(3)(B)(iii), i.e., Federal rules do not specifically preempt State grievance requirements unless they relate to coverage determinations. One commenter stressed that any grievance requirements we imposed should be consistent with those applied by accrediting organizations, so that M+C organizations would not have to change current procedures to a great extent.

Response: In the June 26, 1998, interim final rule to establish the M+C program (63 FR 35,030), we set forth the general requirement that an M+C organization must resolve grievances in a timely manner and have grievance procedures to meet CMS guidelines. In both the interim final rule and the June 29, 2000, final rule (65 FR 40,170, 40,275), we indicated that we intended to establish more detailed requirements for grievance procedures.

We generally agree with the commenters that the regulations should not be overly prescriptive with respect to grievance procedures. We note that many States have processes to address complaints that involve issues other than coverage, and State grievance procedures, unlike appeal procedures, are not specifically preempted by Federal rules. We consulted with representatives of the managed care industry, beneficiary advocacy groups, and QIOs, and examined standards developed by the National Association of Insurance Commissioners (NAIC). We learned that M+C organizations already adhere to State requirements concerning grievances. Also, our experience has shown that enrollees overwhelmingly pursue appeals rather than grievances, and rarely raise concerns or problems associated with the existing grievance procedures. Therefore, as discussed below, we are not including in this final rule the proposed procedural provisions set forth in § 422.564(d) and (e), which pertain to the method for filing and the notification and time frames associated with grievances.

Nevertheless, we believe that a basic uniform grievance structure should be in place to address those issues that fall outside of the appeals process. In particular, we believe that grievance provisions are needed to address complaints involving procedural issues that arise during the appeals process. Thus § 422.564(d) establishes an expedited grievance process for the following circumstances: (1) The grievance involves an M+C organization's decision to invoke an extension related to an organization determination or reconsideration; or (2) the grievance involves an M+C organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

We believe that the changes we are setting forth in this final rule either have a direct effect on the M+C appeals process, or provide clarification in existing requirements, but allow M+C organizations the flexibility needed to

maintain current procedures that comply with State requirements.

Comment: Several commenters strongly encouraged CMS to establish mandatory time frames and notification procedures for resolving grievances. One commenter suggested that grievance time frames mirror those for standard and expedited organization determinations. Two commenters suggested a 30-calendar day time frame to render a grievance decision, with an opportunity for a 14-calendar day extension for peer review. Another commenter argued that the grievance procedure must have a mechanism to resolve a dispute regarding an M+C organization's denial to grant an expedited review within 24 hours, so that an inappropriately denied request can proceed quickly in the appeals process. Finally, one commenter expressed concern about State privacy requirements, which, in some cases, prevent health plans from providing specific information on how grievances get resolved.

Response: As noted above, we have not in this final rule adopted the proposed provisions that prescribed time frames for responding to grievances generally. We do not believe that establishing Federal requirements for the manner and timeliness within which grievances must be disposed is necessary, and as we have noted it could be unduly burdensome in light of varying State requirements. Furthermore, we have not received any reports that enrollees have encountered frustration or problems in getting M+C organizations to respond to enrollees' grievances timely or communicate in an effective manner. Enrollees will continue to have regulated formal avenues to pursue complaints involving all payment, coverage and quality of care issues.

We also agree with the commenter who suggested that grievances involving expedited appeals needed to be addressed as quickly as possible. Therefore, as noted above, we are specifying under § 422.564(d) that an M+C organization must notify the enrollee within 24 hours of receiving a grievance about the M+C organization's refusal to expedite a review, or the M+C organization's decision to invoke an extension to the organization determination or reconsideration time frames. This will ensure that any inappropriate procedural actions under the appeals process are resolved and that the appeal proceeds without delay. In this situation, any extension would clearly be inappropriate, since it would constitute a de facto denial of the

enrollee's request for an expedited review.

Comment: One commenter asked who will determine which route is more appropriate for the beneficiary in pursuing a remedy to a complaint, since we acknowledge that the same claim or circumstances that gave rise to an appeal could have elements of a grievance. This may cause the beneficiary to be confused as to which route is more appropriate. Another commenter asserted that M+C organizations should be required to provide clear, accurate and standardized information concerning grievance and appeal procedures.

Response: We are adding to § 422.564(b) a requirement that when an M+C organization receives a complaint, it must promptly determine and inform the enrollee whether the issue is subject to its grievance procedures or its appeal procedures. Note that we view "complaint" and "dispute" as generic terms that cover various expressions of dissatisfaction or disagreement that may be brought to the attention of an M+C organization or its providers. Thus, complaints or disputes can encompass grievable or appealable issues, but in either case would require resolution in accordance with the organization's internal procedures.

CMS already requires M+C organizations to provide clear and concise information to all enrollees regarding appeal and grievance procedures. M+C organizations include this information annually in their Evidence of Coverage (EOC). In addition to other information that M+C organizations wish to convey, CMS also provides standard information that all EOCs must contain regarding appeals and grievances.

Comment: Various commenters expressed conflicting views on the most appropriate means for dealing with quality of care issues. Some commenters believed that a quality of care issue should first be resolved by the M+C organization and subsequently sent to the QIO. Other commenters argued that quality of care issues should be referred immediately to the QIO for resolution, while others maintained that complaints should be processed by both M+C organizations and QIOs simultaneously.

Response: As reflected under new § 422.564(c), we decided that the most flexible approach would be to permit enrollees to file quality of care complaints with either the M+C organization, the QIO, or both. We expect M+C organizations and QIOs to coordinate and cooperate with one another to resolve enrollees' complaints.

Comment: Many commenters suggested that CMS should not include a definition of "quality of care" in the regulations because defining it would oversimplify the many issues that quality of care might encompass.

Response: We agree with the commenters that the term "quality of care" does not lend itself to a regulatory definition. Instead, we will rely on the States and M+C organizations to identify the types of issues that might fall into the quality of care category.

Comment: A commenter questioned how CMS would enforce record-keeping requirements for M+C organization grievances.

Response: Section 422.564(e) requires M+C organizations to maintain records associated with processing grievances. M+C organizations already should have a system to track and maintain records on all grievances in light of existing requirements under section 1852(c)(2)(C) and § 422.111(c)(3), whereby M+C organizations must report aggregate information on the disposition of grievances. Thus, the record-keeping requirement will be enforced through CMS' existing procedures to monitor grievance activities, and if appropriate, place M+C organizations on corrective action plans. We expect M+C organizations, at a minimum, to keep track of the receipt date and final disposition of the grievance, and the date that the M+C organization notified the enrollee of the disposition.

E. Reductions of Services

This final rule does not set forth any new regulations regarding reductions in services. As part of the *Grijalva* settlement, we agreed to solicit comments on whether new notice and appeal procedures were needed for decisions by M+C organizations to reduce health services. The issue of what constitutes appropriate notice and appeal procedures for reductions of service was also raised in the regulations to implement the M+C program.

In the M+C final rule, we made several changes to § 422.566(b), which describes actions that constitute organization determinations. We added language at § 422.566(b)(3) to clarify that an organization's refusal to pay for or provide services, in whole or in part, "including the type or level of services" can constitute an organization determination if the enrollee believes that services should be furnished or arranged. We stated in the preamble to the final rule that we agreed that a reduction in service could be considered an organization determination that was subject to an

appeal. To the extent that the organization refused to continue to provide all or part of the services that the enrollee believed should be furnished, the reduction constituted an appealable issue.

However, the existing M+C regulations do not specify that notices are routinely required in connection with reductions of services. The notices are required only if the enrollee disagrees that the services are no longer medically necessary.

We have reviewed several public comments on these issues, both after the publication of the M+C interim final rule on June 26, 1998, and again with respect to the January 24, 2000, proposed rule. Several commenters both times strongly urged us to consider the administrative and financial burden associated with notice requirements. They maintained that it is unnecessary to require notification to enrollees when services are reduced because the normal progression of a clinical course of treatment is from increased to decreased services. Some commenters have argued that providing detailed notices in all reduction situations would be confusing, burdensome and intrusive upon the physician/patient relationship.

Based on our review of current and previous comments on this issue, we believe that the process of changing the notice requirement for reductions of services is unnecessary, particularly in light of the requirement that all enrollees receive notice of their appeal rights before the termination of services in hospital and other provider settings. We will monitor the new policy on discontinuations of provider services, and if we find that it is necessary to create additional procedures for reductions of services, we will initiate the necessary rulemaking.

IV. Provisions of This Final Rule With Comment Period

A. Summary of Provisions

For the convenience of the reader, listed below are the major changes to the M+C regulations that are set forth in this final rule with comment period. This listing is intended solely as a reference aid rather than as a comprehensive statement of the policies set forth in the regulation text.

- New § 422.502(i)(3)(iv) specifies that M+C organization contracts with providers and other related entities entered into after (the effective date of this final rule) must contain a provision specifying that these entities will comply with the applicable notice and appeal provisions in §§ 422.620, 422.624, and 422.626.

- In § 422.561, the definition of grievance is revised to mean any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an M+C organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

- In § 422.564, paragraph (c) clarifies that an enrollee may file a quality of care complaint either with the QIO, the M+C organization, or both entities. New paragraphs (d) and (e) establish specific procedures for handling expedited grievances and for record-keeping with respect to grievances, respectively.

- Section 422.620 provides that an M+C organization (or a hospital that has accepted delegation of the authority to make the discharge decision) must issue a written notice of noncoverage to any M+C enrollee who disagrees with the M+C organization's decision to discharge the enrollee. As discussed above, this represents a change from the proposed provision that hospitals issue such notices for all discharges of M+C enrollees.

- Section 422.624 sets forth the requirements for notifying enrollees when their SNF, HHA, or CORF services are being terminated. These procedures require that the provider deliver, generally no later than two days before the termination of services, a standardized advanced termination notice that informs the enrollee of the date of discharge and how to file an appeal. As discussed above, the provisions set forth in this final rule represent a change from the proposed provisions, which would have required that more detailed notices be delivered four days in advance of service termination.

- Section 422.626 establishes an enrollee's right to a fast-track appeal of an M+C organization's decision to terminate these provider services, and the requirements and procedures associated with these fast-track appeals. This section explains the liability rules and evidence standards during these appeals, and establishes the procedures to be followed, including the responsibilities of M+C organizations and the IRE that makes the decisions on the appeals. As discussed above, this final rule with comment period provides that M+C organizations must furnish detailed termination notices only to enrollees who timely request a fast-track appeal but must furnish these notices to the enrollee and the IRE on the day of the request. This change from the proposed rule may result in a maximum of one day of potential

financial liability for services for an enrollee whose appeal is unsuccessful. (Note that under existing M+C appeal procedures, an enrollee's potential liability in an unsuccessful appeal would be at least 4 days.)

- Section 489.27 specifies that, as an element of the provider's agreement to participate in the Medicare program, hospitals and other providers must furnish beneficiaries with applicable OMB-approved notices concerning their discharge rights, including the hospital discharge notice required under section 1866(a)(1)(M) of the Act and the advance termination notice for M+C enrollees whose SNF, HHA, or CORF services are being terminated. This final rule with comment period does not specify that a hospital discharge notice must be provided the day before a discharge.

B. Decision To Issue a Final Rule With Comment Period

As discussed above, section 1869(b)(1)(F) of the Act, as revised by section 521 of BIPA, requires that the Secretary establish a process by which a beneficiary may obtain an independent, expedited determination if he or she receives a notice from a provider of services that the provider plans to terminate the services or discharge the individual from the provider. Currently, this right to an expedited review exists only with respect to hospital discharges (under sections 1154 and 1155 of the Act). On November 15, 2002, we published a proposed rule setting forth the procedures needed to implement this statutory directive.

Clearly, the new appeal rights proposed in accordance with section 1869 of the Act in many ways resemble those envisioned by the *Grijalva* settlement agreement and now set forth in this final rule. However, for the most part, the January 24, 2001, proposed rule that preceded this final rule was developed without the benefit of that statutory direction. We believe it is prudent and appropriate to consider further public comments on the requirements set forth here, now that the public has had an opportunity to review our proposal to implement the BIPA provisions. For example, we welcome comments on whether, and the extent to which, the procedures set forth here for M+C enrollees and those proposed to implement the BIPA expedited determination rights for original Medicare beneficiaries can or should be integrated or combined, or at least made uniform. If these additional comments result in changes to these requirements, we will publish a

subsequent final rule to set forth these changes. (Note that publication of such a final rule would not delay the implementation of the procedures established under this final rule, which will begin on January 1, 2004, consistent with our commitment not to implement significant changes to the M+C program on a mid-year basis.)

V. 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 comments in the preamble to the document.

VI. Collection of Information Requirements

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

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

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

The quality, utility, and clarity of the information to be collected; and

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Several commenters addressed the burden associated with the proposed termination notice provisions, and these comments are discussed in detail above in section III.B.3 of this final rule. As discussed there, this final rule contains changes to these provisions based on public comments. Our estimates of the revised information collection requirements are set forth below, and we welcome further comments on these issues.

Section 422.564—Grievance Procedures

As discussed in detail in section II.D of this preamble, this final rule does not include the proposed detailed requirements with respect to the general grievance procedures to be followed by

M+C organizations. Instead, we have largely maintained the existing standard. That is, an M+C organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the M+C organization notified the enrollee of the disposition. We have specified that an M+C organization must respond to an enrollee's grievance within 24 hours if the complaint involves an M+C organization's refusal to grant an enrollee's request for an expedited organization determination or an M+C organization's decision to invoke an extension on an appeal request. M+C organizations must routinely respond to such grievances, and although the 24-hour time frame represents a new requirement, it does not affect the information collection burden. (Note that M+C organizations already document their case files or notify enrollees when they process requests for expedited reviews under §§ 422.570 and 422.584, and invoke extensions to the organization determination and reconsideration times frames under §§ 422.568, 422.572, and 422.590.) Thus, while the new requirement is subject to the PRA, the burden associated with this requirement is captured by the requirements in §§ 422.568, 422.572 and 422.590, approved under OMB number 0938-0829.

Section 422.620—How M+C Enrollees Must Be Notified of Noncoverage of Inpatient Hospital Care

When an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in sections 422.2 and 422.113), the M+C organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when the beneficiary disagrees with the discharge decision.

Based on the 2002 CMS Data Compendium, (CMS Publication Number 03437), there are approximately 11.8 million Medicare beneficiaries discharged from hospitals each year. We extrapolate that approximately 1.8 million of these are M+C discharges. As discussed in section II.C of this preamble, based on previous inpatient hospital appeals data from the QIO's Standard Data Processing System, we estimate that about 0.1 to 0.2 percent (1,800 to 3,600) of M+C enrollees'

hospital discharges will be disputed. We project that it would take M+C organizations (or hospitals that have been delegated the authority to make the discharge decision) approximately 30 minutes to prepare and furnish the notice required in these cases. Thus, the total annual burden associated with providing notices to M+C enrollees is approximately 900 to 1800 hours. (Note that issuance of these notices will not take effect until a separate PRA statement has been published.)

Section 422.626—Fast-Track Appeals of Service Terminations to the IRE

An enrollee who desires a fast-track appeal must submit a request for an appeal to the IRE, in writing or by telephone, by noon of the first calendar day after receipt of the written termination notice. If the IRE is closed on the day the enrollee requests a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

In 1999, the Center for Health Dispute Resolution (CHDR), the entity with whom CMS now contracts to conduct appeals of M+C reconsiderations, reviewed approximately 3,000 cases involving services provided by SNFs, HHAs, and CORFs. (Note that we have no way of knowing the proportion of these cases that involved service terminations, but for purposes of this analysis, we will make the assumption that all of these 3,000 cases involve service terminations.) Based on the General Accounting Office's 1999 Report to the Special Committee on Aging, "Greater Oversight Needed to Protect Beneficiary Rights," managed care organizations reverse their original adverse organization determinations in approximately 75 percent of appealed cases. Therefore, we believe that the 3,000 cases that went to CHDR likely represent about 25 percent of all appeals (i.e., "reconsiderations") involving affected providers that are now conducted by M+C organizations. Thus, we estimate that the number of provider appeals that would likely be heard by an IRE would be 12,000 cases. This constitutes approximately 2 percent of the 616,500 M+C enrollees that we estimate will receive termination notices, which we believe is a reasonable estimate of the maximum number of enrollees that are likely to file appeals with the IRE. It is estimated that it will take 12,000 enrollees 15 minutes to file an appeal on an annual basis. The total annual burden associated with this requirement is 3,000 hours.

The enrollee may submit evidence to be considered by the IRE in making its

decision and may be required by the IRE to authorize access to his or her medical records in order to pursue the appeal. It is likely that no more than 10 percent of the 12,000 enrollees who file appeals will also submit additional evidence. It is estimated that it will take 1,200 enrollees 60 minutes to submit evidence on an annual basis. That is, since enrollees may not be functioning at their maximum capacity, they may need to contact family members, friends, or their personal physicians who might provide assistance in gathering additional evidence. The total annual burden associated with this requirement is 1,200 hours.

Upon notification by the IRE of a fast-track appeal, the M+C organization must supply any and all information, including a copy of the notice sent to the enrollee, no later than by close of business of the following day. It is estimated that it will take M+C organizations 60–90 minutes to gather and prepare a case file to send to the IRE. Since we have estimated that approximately 12,000 enrollees would request appeals, the total annual burden associated with this requirement is 12,000–18,000 hours.

Upon an enrollee's request, the M+C organization must provide a copy of, or access to, any documentation sent to the IRE no later than close of business of the first day after the day the material is requested. We estimate that 20% of the 12,000 enrollees who file an appeal will request copies of information forwarded to the IRE. It is estimated that it will take M+C organizations 15 minutes to provide a copy of all of the information provided to the IRE, to 2,400 enrollees. The total annual burden associated with this requirement is 600 hours.

If the IRE upholds an M+C organization's termination decision in whole or in part, the enrollee may appeal by requesting that the IRE reconsider its decision. It is estimated that 50 percent of the 12,000 appeals will result in the IRE upholding the M+C organization's termination decision. Of those 6,000 cases, we estimate that 20 percent of the enrollees will request a reconsideration by the IRE. It is estimated that it will take 1,200 enrollees 30 minutes to file a request for reconsideration on an annual basis. The total annual burden associated with this requirement is 600 hours.

Section 489.27—Beneficiary Notice of Discharge Rights

A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights required under section

1866(a)(1)(M) of the Act. In addition, providers (as identified at § 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable CMS notices in advance of the termination of Medicare services,

including the notices required under § 422.624 of this part.

The information collection requirements associated with § 489.27 are currently approved under OMB PRA approval number 0938-0692.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 422.564, 422.620, 422.624, and 422.626. The new hours associated with these collections are summarized in the chart below.

Section No.	Entity	Estimated Burden Hours
422.620	Hospitals	900-1800
422.624	SNFs/HHAs/CORFs	200,320
422.626 (a) and (c)	M+C Enrollees	4,200
422.626 (e)	M+C organizations	12,600-18,600
422.626 (f)	M+C organizations	600

These requirements are not effective until they have been approved by OMB. If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Office of Regulations Development and Issuances, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850. Attn: Julie Brown, CMS-4024-FC.

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.

VII. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule under the criteria of Executive Order 12866 (September 1993, Regulatory Planning and Review), section 1102(b) of the Social Security Act, the Regulatory Flexibility Act (RFA), Pub. L. No. 96-354, the Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, and Executive Order 13132. 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). We estimate a burden of not more than \$10 million associated with this final rule. Thus, this rule does not meet the \$100

million threshold and is not, therefore, a major rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The RFA requires agencies, in issuing certain rules, 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, SNFs, and HHAs are small entities, either by nonprofit status or by having revenues of \$25 million or less annually. For purposes of the RFA, all providers affected by this regulation are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for a final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. While it will have an impact on small entities, the economic impact on any particular entity will be negligible.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure

in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule would not have such an effect on State, local, or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that would impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This rule does not have a substantial effect on State and local governments.

Although a regulatory impact analysis is not mandatory for this final rule, we believe it is appropriate to discuss the possible impacts of the new appeals procedures on beneficiaries, providers, and M+C organizations, regardless of the monetary threshold of that impact. Therefore, a discussion of the anticipated impact of this rule is presented below.

B. Scope of the Proposed Changes

As discussed in detail above, this final rule establishes new notice and appeal procedures for enrollees when an M+C organization decides to terminate coverage of services by SNFs, HHAs, and CORFs. This rule specifies the responsibilities of M+C organizations and providers in issuing termination notices associated with these new appeal rights. It also clarifies the responsibilities of hospitals and M+C organizations for informing Medicare beneficiaries of their right to appeal a hospital discharge and amends the associated Medicare provider agreement regulations with regard to beneficiary notification requirements. Finally, it revises the existing regulations with respect to M+C grievance procedures. In general, we believe that these changes would enhance the rights of M+C enrollees and other Medicare beneficiaries, without imposing any

significant financial burden on these individuals. The impact of the final rule on M+C organizations and providers is discussed below.

C. New Notice and Appeal Procedures for Provider Terminations (§§ 422.624 and 422.626)

As explained in detail in the proposed rule, we examined available appeals data from the Center for Health Dispute Resolution (CHDR), the organization with whom CMS now contracts to conduct appeals of M+C reconsiderations to project the likely number of appeals that may be expected under these new provisions. (Under existing § 422.592, any case where an M+C organization's reconsideration results in affirming an adverse organization determination is automatically sent to CHDR for review.) Based on this analysis, we estimated that the annual number of possible appeals that will be heard by an IRE under the procedures set forth in this final rule will be approximately 12,000 cases. We received no comments on the validity of this estimate and continue to believe that it is realistic. (See our January 24, 2001, proposed rule for further details—66 FR 6600–6602.)

Although commenters generally did not object to this volume estimate, both provider and M+C industry commenters found the procedures associated with implementing the new expedited appeals very problematic. Throughout this preamble, we have acknowledged and responded to the comments concerning the unnecessarily burdensome nature of these procedures. As discussed in detail above, we have made several significant changes to the notification procedures that we believe should ameliorate these concerns. Most notably, this final rule greatly simplifies the notice that providers furnish to enrollees whose services are ending and provides that M+C organizations must furnish detailed termination notices only to enrollees who timely request a fast-track appeal.

Thus, for approximately 12,000 cases, M+C organizations will be required under this final rule to make available to the enrollee a copy of the detailed termination notice, and to the IRE, and to the enrollee upon request, a copy of any documentation needed to decide on the appeal. Although we recognize that there is an administrative burden associated with this requirement, we believe that the existing M+C reconsideration process would already result in the M+C organization gathering and reviewing the case file to reach a termination decision. Moreover, we note that this burden on M+C organizations

is largely offset by the fact that M+C organizations will no longer be responsible for conduct internal reconsiderations of any cases covered under this final rule. That is, IREs will conduct reviews not just of the 3,000 cases that now go to CHDR but also of the 9,000 cases that are now subject to the M+C organization reconsideration process.

Similarly, with respect to providers, the requirements of this final rule should prove much easier to implement than those in the proposed rule. The required termination notices will be largely standardized, requiring only the insertion of the enrollee's name and discharge date. We estimate that it should take no more than 5 minutes to deliver such a notice, at a per-notice cost of no more than \$7.50 (based on a \$30 per hour rate if the notice is delivered by health care personnel). Based on an estimated 600,000 notices annually, we estimate the aggregate cost of delivering these notices should be less than \$5 million.

Thus, we believe that the new notice and appeal provisions of this final rule should have minimal financial impact on M+C organizations and providers. We note that both the advance termination notice and the detailed termination notice will be developed through OMB's Paperwork Reduction Act process and thus will be the subject of further opportunity for public comment.

D. Hospital Discharge Notices (§§ 422.620 and 489.27)

Under the proposed rule, hospitals would have been required to issue a standardized discharge notice to each Medicare beneficiary twice during an inpatient stay, that is, once at or near the time of admission and again before discharge. The second notice (a revised version of the Important Message from Medicare now required under section 1866(a)(1)(M) of the Act and 489.27) would have included more detailed information about the reason for the discharge. Comments on this proposal, many of which focused on the administrative burden associated with this notice, are discussed in detail above. We estimated that the additional aggregate burden on hospitals would exceed \$100 million.

Under this final rule, hospitals instead will continue to be responsible for issuing the Important Message from Medicare to all Medicare inpatients, as well as for issuing HINNs to inpatients covered under the original Medicare program when they indicate that they disagree with a hospital's discharge decision. These requirements are

identical to those currently in effect and thus will entail no additional burden for hospitals.

All inpatient enrollees in the M+C program will also continue to receive the Important Message from their hospital during an admission. In addition, consistent with the notice requirement for other Medicare beneficiaries, we are revising 422.620 to specify that M+C organizations are responsible for providing a written notice of noncoverage when an enrollee disagrees with a discharge decision. The notice must be issued no later than the day before hospital coverage ends and must explain the reason why care is no longer needed, the enrollee's appeal rights, and the effective date of time of the enrollee's liability for continued inpatient care. Again, we estimate that the incidence of this notice will be no more than 0.1 to 0.2 percent of all M+C enrollee discharges, or roughly 1800 to 3600 notices, at an estimate aggregate annual cost to M+C organizations of \$15,000–\$30,000. Again, all of the required notices for hospital inpatient discharges will be published through the OMB PRA process.

E. Grievance Procedures (§ 422.564)

Grievances essentially include any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an M+C organization's or provider's operations. As discussed in detail above, the primary new requirements set forth under this final rule (422.564(d) and (e)) are that an M+C organization establish specific procedures for handling expedited grievances and for record-keeping with respect to grievances, respectively.

Again, we have carefully examined the grievance procedures now in use by M+C organizations, and in particular the grievance procedures spelled out in the NAIC's Model Grievance Act, in developing these procedures. We believe that M+C organizations are in large measure already in compliance with the grievance procedures set forth here, and thus these requirements will have no substantial impact on most M+C organizations.

F. Federalism Summary Impact Statement

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

This rule would not have a substantial effect on State or local governments.

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

List of Subjects

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.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the pre-amble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE+CHOICE PROGRAM

Part 422 is amended as set forth below:

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

Authority: Secs. 1102, 1851 through 1857, 1859, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395W–21 through 1395w–27, and 1395hh).

■ 2. In § 422.561, the definition of “grievance” is revised to read as follows:

§ 422.561 Definitions.

* * * * *

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an M+C organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

* * * * *

3. Section 422.564 is revised to read as follows:

§ 422.564 Grievance procedures.

(a) *General rule.* Each M+C organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any M+C plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in § 422.566(b). Upon receiving a complaint, an M+C organization must promptly determine and inform the enrollee whether the complaint is

subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process.* Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the M+C organization. For quality of care issues, an enrollee may file a grievance with the M+C organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the M+C organization must cooperate with the QIO in resolving the complaint.

(d) *Expedited grievances.* An M+C organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an M+C organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an M+C organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

(e) *Recordkeeping.* The M+C organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the M+C organization notified the enrollee of the disposition.

■ 4. Section 422.620 is revised to read as follows:

§ 422.620 How M+C enrollees must be notified of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* (1) Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), the M+C organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when—

(i) The beneficiary disagrees with the discharge decision; or

(ii) The M+C organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

(2) An enrollee is entitled to coverage until at least noon of the day after such notice is provided. If QIO review is

requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before notice of noncoverage is provided, the entity that makes the noncoverage/discharge determination (that is, the hospital by delegation or the M+C organization) must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee.* The written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date and time of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Additional information specified by CMS.

■ 5. New §§ 422.624 and 422.626 are added to subpart M to read as follows:

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability.* (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined.* For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the M+C organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination.* Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the M+C organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice.* The provider must notify the enrollee of the M+C organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at

the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other M+C appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid.*

Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice.* An M+C organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an M+C organization's termination decision.* An enrollee of an M+C organization has a right to a fast-track appeal of an M+C organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed

and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) When an enrollee fails to make a timely request to an IRE, he or she may request an expedited reconsideration by the M+C organization as described in § 422.584.

(3) If, after delivery of the termination notice, an enrollee chooses to leave a provider or discontinue receipt of covered services on or before the proposed termination date, the enrollee may not later assert fast-track IRE appeal rights under this section relative to the services or expect the services to resume, even if the enrollee requests an appeal before the discontinuation date in the termination notice.

(b) *Coverage of provider services.*

Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the M+C organization's decision. If the IRE's decision is delayed because the M+C organization did not timely supply necessary information or records, the M+C organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the M+C organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an M+C organization's decision to terminate services to an IRE, the burden of proof rests with the M+C organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the M+C organization must supply any and all information that an IRE requires to sustain the M+C organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The M+C organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the M+C organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the M+C organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the M+C organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the M+C organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the M+C organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an M+C organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the M+C organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the M+C organization.* (1) When an IRE notifies an M+C organization that an enrollee has requested a fast-track appeal, the M+C organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the M+C organization.

(iii) Any applicable M+C organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the M+C organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the M+C organization, including records of any information provided by telephone. The M+C organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The M+C organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the M+C organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The M+C organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the M+C organization that an appeal has been received from the enrollee. The M+C organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An M+C organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(5) If an IRE reverses an M+C organization's termination decision, the M+C organization must provide the

enrollee with a new notice consistent with § 422.624(b).

(f) *Reconsiderations of IRE decisions.*

(1) If the IRE upholds an M+C organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may to appeal the IRE's reconsidered determination to an ALJ, the DAB, or a federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the M+C organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the M+C organization or provider.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

Part 489 is amended as set forth below:

■ 1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, and 1395hh).

■ 2. In § 489.20, paragraph (p) is revised to read as follows:

§ 489.20 Basic commitments.

The introductory text of § 489.20 is republished without change and paragraph (p) is revised to read as follows:

The provider agrees to the following:

* * * * *

(p) To comply with § 489.27 of this part concerning notification of Medicare beneficiaries of their rights associated with the termination of Medicare services.

* * * * *

■ 3. Section 489.27 is revised as follows:

§ 489.27 Beneficiary notice of discharge rights.

(a) A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights required under section 1866(a)(1)(M) of the Act. The hospital must provide timely notice during the course of the hospital stay. For purposes of this paragraph, the course of the hospital stay begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission. The hospital must be able to demonstrate compliance with this requirement.

(b) Notification by other providers. Other providers (as identified at § 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable CMS notices in advance of the termination of Medicare services, including the notices required under 42 CFR 422.624. These notices must be approved by the Office of Management and Budget prior to implementation under section 3506(c)(2)(A) of the Paperwork Reduction Act.

Dated: February 10, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 25, 2003.

Tommy G. Thompson,

Secretary.

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