

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 422 and 489

[HCFA-4024-P]

RIN 0938-AK48

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth several improvements to the Medicare+Choice (M+C) appeal and grievance procedures. Most notably, this proposed rule would ensure that M+C enrollees receive written notice, including information about appeal rights, at least 4 calendar days before the proposed termination date of provider services; and establish a new fast-track independent review process for appealing decisions to terminate services. (Affected providers include skilled nursing facilities (SNFs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs)). The proposed rule also discusses and solicits comments on how to provide appropriate notice and appeal procedures in situations where an M+C organization decides to reduce provider services. We note that publication of this proposed rule is a required element of the settlement agreement entered into between the parties in *Grijalva, et al. v. Shalala*, Civ. 93-711 (U.S.D.C. Az), a class action lawsuit in which the Department agreed to promulgate a notice of proposed rulemaking addressing certain notice and appeal procedures for enrollees when an M+C organization decides to terminate coverage of provider services.

This proposed rule also would specify hospitals' responsibility for issuing discharge notices under both the original Medicare and the M+C

programs, amend the Medicare provider agreement regulations with regard to beneficiary notification requirements, and set forth M+C beneficiary grievance procedures.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 26, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-4024-P, 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 443V/G, 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 HCFA-4024-P. 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 to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Nydia Tirado Peel, (410) 786-1619.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the "Medicare+Choice 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 regard to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f), 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) 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 continue to receive, a health service, and the amount the enrollee is expected to pay for that service. An organization determination may also concern an enrollee's request for reimbursement for services obtained without plan approval. As discussed in detail below, only disputes concerning organization determinations are subject to the reconsideration and other appeal requirements under section 1852(g). All other disputes are subject to the grievance requirements under section 1852(f). For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term "appeal" to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review.

As indicated in our June 29, 2000 M+C final rule (65 FR 20272), we made limited changes in the appeal procedures in that rule, but intended to publish a proposed rule addressing other improvements to the M+C dispute resolution process, including both appeals and grievances. This rule fulfills that commitment, as well as meeting the Department's obligation pursuant to the *Grijalva, et al. v. Shalala* lawsuit, as discussed below.

B. *Grijalva v. Shalala*

Grijalva v. Shalala is a class action lawsuit brought in 1993 by Medicare managed care enrollees. The lawsuit involved, among other things, the adequacy of the notice and appeals process provided by managed care organizations contracting with Medicare on a risk basis, and whether HCFA properly ensured that these contractors afforded appropriate rights to enrollees when the contractors denied, reduced, or terminated health care coverage.

On August 9, 2000, the Department and the plaintiffs agreed to settle the lawsuit. The settlement agreement was approved by the Arizona District Court on December 4, 2000. Under the settlement, we agreed to publish proposed regulations to establish new notice and appeal procedures when an M+C organization decides to terminate coverage of provider services to an enrollee. Affected providers under the settlement agreement include skilled nursing facilities (SNFs), home health agencies (HHAs) and comprehensive outpatient rehabilitation facilities (CORFs). M+C organizations would be required to provide written notices to M+C enrollees at least four calendar days before the proposed termination date of provider services. The notices, which will be subject to public review and comment through OMB's Paperwork Reduction Act process, will include a detailed explanation why services are no longer medically necessary or covered and a description of the appeals process. Additionally, we agreed to establish a new fast-track independent review process for appealing decisions to terminate services.

Under the proposed fast-track appeal process, if an enrollee disagrees with an M+C organization's decision to terminate the provider services at issue, an enrollee may request an immediate review of such decision by an independent review entity (IRE) under contract with HCFA. This entity would be independent of any managed care organization, or company affiliated with a managed care organization. The enrollee would have a right to continued coverage of the provider services in question, without financial liability, until at least noon of the day following the IRE's decision, or the date that the M+C organization proposes for termination of services, whichever is later. If the IRE is unable to make a decision because the M+C organization did not timely supply necessary information or records to the IRE, the M+C organization would continue to be liable for the costs of any extended

coverage resulting from the delayed IRE decision.

We note that an enrollee would not be required to use the fast-track IRE appeals process and could use other appeal procedures available under the M+C regulations (that is, the reconsideration procedures described under §§ 422.582, 422.584, and 422.592); however, the right to continued coverage during the appeals process would not apply if the enrollee does not use the fast-track IRE appeals process.

The *Grijalva* settlement agreement included a great deal of specificity with regard to the relevant M+C notice and appeal requirements, and these proposed requirements are set forth below in section II.A. The agreement explicitly establishes that publication of these proposed requirements shall in no way be construed as a promise or predetermination regarding the content of a subsequent final rule on notice and appeal procedures for M+C organization decisions to terminate provider services. Thus, we will consider fully all public comments on all aspects of this proposed rule, including the *Grijalva*-related provisions.

II. Provisions of This Proposed Rule

A. *Proposed Notice and Appeal Procedures*

1. Applicability

As noted above, under the terms of the *Grijalva* settlement agreement, the types of Part A Medicare providers to whom the proposed notice and appeal provisions would apply include SNFs, HHAs, and CORFs. (Note that similar notice and appeal requirements are already in effect for M+C enrollees admitted to inpatient hospitals, under 42 CFR 422.620 and 422.622.) For purposes of this proposed rule, subsequent uses of the term "provider" should be assumed to refer to these three provider types, unless otherwise indicated.

In addition, as stated in the settlement agreement, § 422.624(a)(2) would establish that for purposes of these provisions, "terminations" refer to the discontinuation or discharge of an enrollee from covered provider services where 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. Under this definition, terminations would include (but not be limited to) cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that services should end. Examples of terminations

would include both discontinuations of a length of stay in a SNF, or of a preauthorized number of visits in an HHA or CORF setting. (See section II.B below for a discussion of situations involving reductions in services.)

2. Termination Notices to M+C Enrollees

Section 422.624(b) sets forth the proposed advance notification requirements when an M+C organization decides, either directly or by delegation, to terminate coverage for provider services to an enrollee. In general, for any termination of a provider service, the provider of the service would be required to notify the enrollee (or the enrollee's authorized representative—see parenthetical note below) using a standardized notice, of the M+C organization's decision to terminate provider services. In developing the standardized notice, HCFA would obtain public comment and subsequent approval through the Office of Management and Budget (OMB), consistent with section 3506(c)(2) of the Paperwork Reduction Act.

(Consistent with the existing M+C appeal regulations at § 422.561, as revised in the June 29, 2000 final rule, an "authorized representative" means any individual authorized by an enrollee, or under State law, to act on an enrollee's behalf in obtaining an organization determination or in dealing with any of the levels of the appeals process, including for example an enrollee's legal guardian, attorney, or other legally authorized person. Section 422.561 clearly establishes that the term "enrollee" encompasses an enrollee's authorized representative for all aspects of any M+C appeal procedures. Thus, references to the "enrollee" in subsequent preamble and regulatory language can be assumed to apply to an enrollee's authorized representative as well, unless the context clearly indicates otherwise (such as a reference to the enrollee's health status).)

a. Provider Notification of Termination. An important feature of the proposed notice provisions is that we would charge providers with the actual delivery of the required notices. We believe that the providers themselves are in the best position to deliver the notices to enrollees, and that it would be placing an unreasonable burden on M+C organizations to require that they deliver the notices to affected enrollees. The M+C organization would retain ultimate responsibility for the decision to terminate services and for financial coverage of the services, however. The services would remain

covered until four calendar days after an enrollee receives the termination notice, or if the IRE reviews the decision, until noon on the day after an IRE decision upholding the M+C organization's decision. Thus, we believe that the requirement that providers issue these notices, in effect on behalf of M+C organizations, best ensures that beneficiaries receive these notices in a timely manner. To facilitate implementation of this policy, we are proposing under § 422.502(i) that all contracts between M+C organizations and their providers must specify that the providers will comply with the notice and appeal provisions in subpart M.

We note that the proposal that providers issue termination notices for Part A Medicare services to M+C enrollees is consistent with the policy position we outlined in the preamble to the recent M+C final rule with respect to hospitals (65 FR 40284). We accordingly are also proposing regulations addressing how M+C enrollees are notified of terminations of hospital care, as promised in the M+C final rule. Specifically, under proposed § 422.620(a), we would specify that in situations involving inpatient admissions of M+C enrollees, hospitals must provide a written notice of termination of coverage to each enrollee that includes the reasons for the discharge. Consistent with existing § 422.620, an enrollee would be entitled to coverage of hospital services, generally at the expense of the M+C organization, until at least noon of the day after the hospital issues such notice.

We also are amending § 489.27 to provide expressly for this hospital responsibility and to provide that this responsibility applies for all inpatient hospital Medicare discharges, including both discharges of original Medicare beneficiaries and discharges of M+C enrollees. Section 489.27 implements the requirement in section 1866(a)(1)(M) that hospitals provide a notice to all Medicare beneficiaries of the individual's rights (referred to as the "Important Message from Medicare" for beneficiaries). Section 1866(a)(1)(M) provides that this notice must include "such additional information as the Secretary may specify." We are specifying in proposed revisions to § 489.27 that this information include the reasons for the discharge and the right to PRO review, and that this information be provided to each beneficiary the day before the effective date of the discharge.

b. Timing of Notices. Section 422.624(b)(1) addresses the timing of the required notices. In general, the

provider would notify the enrollee of the M+C organization's decision to terminate covered services four calendar days before the scheduled termination. If the provider services are expected to be furnished to an enrollee for a time span of fewer than four calendar days in duration, the enrollee should be given the notice upon admission to the provider (or at the beginning of the service period if there is no official "admission" to a noninstitutional provider, such as in an HHA setting). The notice must be given in all situations, regardless of whether an enrollee agrees with the decision that his or her services should end.

As noted in section I. B above, this proposed rule also provides that an enrollee may obtain review by an IRE of a decision to terminate services after the enrollee receives proper notice of a decision to terminate. As discussed further below, we believe that the 4-day period between enrollee notification and the proposed termination of services generally should provide sufficient time for all aspects of the proposed IRE appeal process. That is, the IRE can obtain the necessary documentation from the parties to the appeal, make a decision on the enrollee's appeal, and if applicable, notify the enrollee of a decision to uphold an M+C organization's termination decision, with coverage terminating at noon of the day after the IRE's notification—the fourth day of the process. We note that, like the process established under § 422.620 for Peer Review Organization (PRO) reviews of appeals of hospital discharges, these regulations would establish 12 noon as the time when an M+C organization's coverage of an enrollee's services would end, if the IRE upholds the M+C organization's decision to terminate services.

A closely related issue on which we are particularly interested in receiving public comments involves what constitutes four-day advance notice. We are proposing to in effect allow providers a full working "day" within which to deliver the termination notice, with any notification delivered during normal business hours on a given day serving to initiate the four-day standard on that day, even if the timing of the delivery of the notice resulted in fewer than 24 hours to ask for an IRE appeal, and fewer than 96 hours between notification and the proposed termination of services. That is, a notice delivered to an enrollee at 2:00 p.m., Monday, would indicate that the enrollee has until noon, Tuesday, to appeal to the IRE, with termination of services scheduled for noon, Friday.

(Consistent with long-standing administrative policy with respect to PRO review of appeals of hospital discharges, we would instruct providers that termination notices should be delivered no later than 3:00 p.m. on the fourth day before the proposed termination of services.) HCFA will develop and publish a mandatory standardized notice for distribution by providers, subject to public comment through OMB's Paperwork Reduction Act procedures. We specifically invite public comment on this approach.

c. Content of Notices. Section 422.624(b)(2) sets forth proposed requirements governing the content of the required termination notices. Essentially, each notice would include a specific and detailed explanation why services are either no longer medically necessary or are no longer covered, with a description of any applicable Medicare coverage rule, instruction or other policy (including an appropriate citation or information about how to obtain a copy of the Medicare policy from the M+C organization). The notice would explain any applicable M+C organization policy, contract provision, or rationale upon which the termination decision was based. It would include specific, relevant information to an extent sufficient to advise the enrollee of how a Medicare or M+C organization policy applies to the enrollee's case, as well as the date and time that the organization's coverage of services ends (and the enrollee's liability would begin).

In addition to these enrollee-specific items, we would include on the standardized termination notices a description of the enrollee's fast-track appeal rights under § 422.626, including how to contact the IRE to initiate an appeal, as well as the availability of other M+C appeal procedures if the enrollee fails to meet the deadline for (or decides not to pursue) a fast-track IRE appeal. The standardized notice would also inform enrollees of their right, but not obligation, to submit evidence to the IRE that the services in question should continue.

As noted above, the termination notice would be subject to public review and comment through the OMB's Paperwork Reduction Act process before implementation.

d. Delivery of Notices. Proposed § 422.624(c) specifies that "delivery" of a notice is valid only if an enrollee has signed the notice to indicate that he or she both received the notice and can comprehend its contents. This proposed policy is consistent with our requirements governing delivery of similar notices, such as the

requirements set forth in HCFA program memoranda A-99-52 and A-99-54 for HHA advanced beneficiary notices. Under this concept, an enrollee who is comatose, confused, or otherwise unable to understand or act on his or her rights could not validly "receive" the notice, necessitating the presence of an authorized representative for purposes of receiving the notice. Similarly, presenting the standardized notice to a person who is illiterate, blind, or unable to understand English would not constitute successful "delivery" of the notice. Such situations could be remedied either through use of an authorized representative if that person has no barriers to receiving the notice or through other steps (such as use of a translator or language accessible version of the notice) that overcome the difficulties associated with notification. Note that we would not interpret the requirement for successful delivery to 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.

Paragraph (c) describes what constitutes an effective delivery of a termination notice. The notice would have to be delivered timely, using standardized format and language, and include all of the elements required under § 422.624(b)(2).

3. Enrollee Appeal Rights

Proposed § 422.626 would establish an enrollee's right to a fast-track appeal of an M+C organization's decision to terminate provider services, including the procedures to be followed by the various entities involved in the appeal. Under proposed § 422.626(a), an enrollee who wishes to appeal a termination decision to the IRE must contact the IRE, in writing or by telephone, by noon of the first calendar day after receiving the termination notice. (We note that in our contract with the IRE, we intend to require that the IRE have the capability to log in an enrollee's appeal on a daily basis at any time, barring emergencies.) The regulations explain that an enrollee who fails to meet this deadline would still be able to ask the M+C organization for an expedited reconsideration of its determination that services should be terminated, consistent with existing § 422.584, but the provision in this rule for the completion of IRE review prior to the end of coverage would not apply.

Under § 422.584, the M+C organization has 72 hours to conduct an

expedited reconsideration, and must do so when a physician makes or supports the request or when not doing so could jeopardize an enrollee's health or ability to regain maximum function. We considered proposing to amend these regulations to mandate that an M+C organization automatically grant any request for an expedited reconsideration that involves a situation where an enrollee failed to submit a timely request for an IRE appeal of a provider termination of services. However, we concluded that the existing standard remains appropriate, since it allows a broad spectrum of cases to be considered on their merits for reconsideration, rather than inadvertently narrowing the types of cases that can be expedited by establishing a more specific standard. We welcome comments on this issue.

Note that when an enrollee receives a termination notice, he or she is free to choose to discontinue receiving the covered services (for example, leave a SNF) before the termination date specified in the notice. Proposed § 422.626(a)(3) clarifies, however, that if the enrollee chooses to leave the facility or otherwise discontinue receiving covered services before the scheduled date for termination of services, the enrollee may not subsequently assert fast-track IRE appeal rights relative to the service or expect the services to resume, even if the enrollee newly requests the appeal or resumption of services before the discontinuation date in the notice. In such a situation, if the enrollee changes his or her mind after having discontinued receipt of covered services, the enrollee must seek an organization determination from the M+C organization for what would be considered a request for a new service.

Proposed § 422.626(b) specifies that an enrollee who timely seeks IRE review is 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 receives 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 is later. As noted above, if the IRE decision does not occur by the date designated on the termination notice as the result of the M+C organization's failure to provide the IRE with necessary information or records, the M+C organization would be liable for the costs of the resulting additional days of coverage. (Note that our contract with the IRE will specify whether the IRE or HCFA assumes financial liability in situations where the IRE fails to make a decision on a

timely basis.) If the IRE finds that the enrollee did not receive proper notice of the termination (discussed below), coverage would continue until 4 calendar days after proper notice has been received, or until noon on the day after notice of an IRE decision upholding the M+C organization's decision, whichever is later. Continuation of coverage under these circumstances would not be required in the unusual situation where the IRE finds that continuation could pose a threat to the enrollee's health or safety (e.g., unsafe conditions were found to exist at the provider in question).

Proposed § 422.626(d) and (e) address the basis for the IRE's decision, and the procedures it must follow in making the decision. Section 422.626(d) would establish that when an enrollee appeals an M+C organization's decision to terminate provider services, the burden is on the M+C organization to prove to the IRE that the termination is the correct decision, either on the basis of medical necessity or other Medicare coverage policies. To meet this burden, the M+C organization must supply any and all information that the IRE requires to sustain the M+C organization's termination decision, including a copy of the termination notice. The enrollee may submit evidence to the IRE in support of an appeal, but is under no obligation to do so; however, the M+C organization or the IRE may require an enrollee to authorize access to his or her medical records to the extent reasonably necessary for the M+C organization to demonstrate the correctness of its decision or for the IRE to determine the appeal. Moreover, as part of its decision-making process in each appealed case, an IRE would be required under proposed § 422.626(e)(4) to solicit the enrollee's views regarding the reason(s) specified in the notice for termination of services, or any other reason upon which the IRE intends to base its review determination.

Other IRE obligations under proposed § 422.626(e) include:

- On the date it receives the enrollee's appeal request, notifying the M+C organization and the provider of the appeal and of their documentation submission responsibilities.
- Determining whether an enrollee received proper notice of the termination decision, and informing HCFA in each instance of improper notification.
- Making a decision on the appeal and notifying the enrollee, the M+C organization, and the provider of its decision by close of business of the day after it receives the information necessary to make the decision.

Assuming that the IRE receives all needed information on a timely basis, this process would result in an IRE decision by close of business on the second full day after the deadline for an enrollee's appeal request, with termination of services to take place at noon the next day if an M+C organization's termination decision were sustained by the IRE. We recognize, however, that in some instances the IRE will not receive sufficient information to sustain an M+C organization's decision to terminate services. In such a case, the IRE may make a decision based on the information at hand that services should not be terminated, or it may defer its decision until it receives the necessary information. If the IRE makes a decision 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 defers its decision, coverage of the services would continue until the decision is made but no additional termination notice would be required.

In the event that the M+C organization's decision to discontinue services is upheld by the IRE, coverage of the enrollee's services would end at noon on the day after the IRE makes its decision or as specified in the termination notice, whichever is later. The enrollee would then be financially liable for any services provided to him or her after the effective date identified in the notice. However, if the enrollee further appeals the IRE's determination, and the enrollee ultimately receives a determination that overturns the M+C organization's decision to discontinue coverage of services, the enrollee would be reimbursed by the M+C organization.

Section 422.626(f) sets forth the M+C organization's responsibilities upon contact by the IRE. As noted above, when an enrollee requests IRE review of an M+C organization's proposed termination of provider services, the burden of proof rests with the M+C organization to demonstrate that discontinuation of Medicare coverage is the correct decision, either on the basis of medical necessity or because of Medicare coverage rules. Accordingly, proposed § 422.626(f)(1) requires that the M+C organization supply any and all information, including a copy of the termination notice sent to the enrollee, that the IRE needs to decide on the appeal. The M+C organization must supply such information, either by phone or in writing (as determined by the IRE), as soon as possible but no later than the close of business of the first day after the day the IRE notifies the

M+C organization that the enrollee has requested a review. (If information is transmitted by phone, there should be a written record made of what is transmitted in this manner, so that a record of what was said can be accessed by the enrollee).

Section 422.626(f)(2) would require that, if an enrollee requests a copy of (or access to) documentation sent to the IRE, the M+C organization must accommodate the enrollee's request by no later than the day after the request is made. To accommodate such a request, we believe that an M+C organization must make every reasonable effort to make such information available, such as allowing the enrollee to view or obtain the material at a plan location or faxing or express mailing the material to an address specified by the enrollee. The M+C organization would be permitted to charge the enrollee a reasonable amount, for example, the costs of mailing and/or an amount comparable to the charges established by a PRO for duplicating case file material. We would expect that the M+C organization could provide the enrollee with a reasonable estimate of the costs of duplicating and mailing the material to the enrollee at the time of the enrollee's request.

The proposed regulations clarify that the M+C organization remains financially responsible for continuation of coverage throughout the IRE appeal process (that is, until the later of the date and time specified in the notice of termination or noon of the day after the IRE issues its decision on an appeal), regardless of whether it has delegated responsibility for authorizing coverage of termination decisions to its provider. Again, services that were never authorized by an M+C organization, such as services obtained out of the plan, are not subject to the IRE appeal process.

Section 422.626(g) sets forth proposed requirements related to reconsiderations of the IRE's decisions. This section would provide 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 available to an ALJ, the DAB, and a federal court, consistent with the procedures set forth in the existing M+C regulations beginning at § 422.600. Because the protection against enrollee liability associated with IRE appeals extends only to the initial appeal, proposed § 422.626(g)(4) specifies that if on reconsideration an

IRE's initial decision is subsequently reversed in the enrollee's favor, the M+C organization must reimburse the enrollee, consistent with the reconsidered decision, for the costs of any covered services for which the enrollee has already paid the M+C organization or provider.

B. Reductions of Service

As part of the *Grijalva* settlement, we agreed to solicit comments on how to provide new notice and appeal procedures for decisions by M+C organizations to reduce provider services. The issue of what constitutes appropriate notice and appeal procedures in these reduction of service situations has also been raised by commenters on the M+C regulations, most recently in the June 29, 2000 final rule (65 FR 40277). As discussed in detail in that rule, we made several changes to § 422.566(b), which describes actions that constitute organization determinations. For example, 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 they should be furnished or arranged for. We stated in the preamble to that rule (65 FR 40277) that we agreed that "a reduction in services can be considered an organizational determination that is subject to appeal. To the extent that a reduction results in an enrollee no longer receiving services to which the enrollee believes he or she is entitled, this would be subject to appeal under the language in the first sentence in section 1852(g)(5) of the Act, which addresses appeals based on failure to receive a health service." We also noted that to the extent that the organization was refusing to continue to provide all or part of the services the enrollee believes should be furnished, and the enrollee has not received the services, this would also fall within the language in § 422.566(b)(3). However, the existing M+C regulations do not specify that notices are routinely required in connection with a reduction of a service. Instead, § 422.566 effectively requires written notifications in connection with service reductions only if the enrollee disagrees that the services are no longer medically necessary, while § 422.568 specifies that notices are required for "denial" of services.

We have consulted extensively on this issue with industry, provider, consumer, and government groups, and have reviewed numerous public comments. Clearly, it is a complicated

issue, and we recognize that there are many reasonable, divergent viewpoints. Industry representatives generally point out the administrative and financial burden associated with notice requirements. They maintain that is unnecessary to require notification to enrollees for a reduction of an ongoing course of treatment and argue that once an M+C organization has authorized treatment for a set period of time, the organization never retracts the authorization. Some commenters have argued that providing detailed notice in all reduction situations would be confusing, burdensome and intrusive upon the physician/patient relationship. Other commenters urged that written notice should take place in all instances where services are reduced, in order to ensure that enrollees are always made aware of their appeal rights.

Based on our review of previous comments on this issue, as well as an examination of analogous Medicaid requirements, we are considering adopting the position that a written notice should be required if there is a reduction in any previously authorized ongoing course of treatment. That is, notice would not be required at every reduction, but only when there is a change in an authorized plan of treatment that reduces the level of services from those previously authorized. We note, however, that unlike under the Medicaid program, the current M+C regulations do not call for a required plan of treatment in all cases, and we are not proposing that plans of care should be routinely required. (Existing § 422.112(a)(4)(iii) does require a treatment plan for individuals with serious medical conditions.) In cases where a plan of treatment is in place, however, we believe that enrollees should be entitled to written notification when the prescribed treatments are to be reduced. We believe that this approach could serve to balance the need for adequate notice with the potential burdens or beneficiary confusion that might ensue if notice were required in all cases of reductions of services. Note that we are not putting forth specific regulatory language that would implement this approach; rather, we are soliciting comments on this proposal. We particularly welcome comments that include specific revisions to the existing regulations with respect to enrollee notification requirements.

C. Grievance Procedures (§ 422.564)

Section 1852(f) of the Act requires that each M+C organization provide “meaningful procedures for hearing and resolving grievances.” Existing

§ 422.561 defines a grievance as any complaint or dispute other than one that involves an “organization determination” (as described under § 422.566(b)). (This definition retains the meaning of grievance used in part 417.) An enrollee might file a grievance if, for example, the enrollee received a service but believed that the service was not carried out properly or that the demeanor of the person providing the service was insulting or otherwise inappropriate. Grievance procedures also apply when an enrollee disagrees with an M+C organization’s decision not to expedite an enrollee’s request for an organization determination or a reconsideration.

In the June 26, 1998 interim final rule that implemented the M+C program (63 FR 35030), we set forth the general requirement that an M+C organization must resolve grievances in a timely manner and have grievance procedures that meet HCFA guidelines, in anticipation of future HCFA policy direction on grievance procedures. At that time, we indicated that we intended to establish more detailed requirements for grievance procedures through a notice of proposed rulemaking (NPRM). To inform the NPRM development process, we requested public comments on the necessary elements of a meaningful grievance procedure (such as recommended time frames, the types of issues that should be considered grievances, need for an expedited grievance process, and the type of notification enrollees should receive concerning the outcome of their grievance.) As anticipated, commenters had varied recommendations related to organization-level grievance procedures.

Subsequently, we consulted with representatives of the managed care industry, beneficiary advocacy groups, and PROs, reviewed comments we received from the public, and examined recent standards in this area, such as those developed by the National Association of Insurance Commissioners (NAIC). (NAIC has developed and adopted a Model Grievance Act setting forth standards for grievance procedures.) We also took into consideration that section 1852(c)(2)(C) requires M+C organizations to provide data on the number of grievances and their disposition in aggregate data reporting. The proposals set forth below are the result of this consultation and public comment process.

First, we propose to include the following revised definition of a grievance under § 422.561: “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.” Under § 422.564(a), we would retain the general rule that each M+C organization must provide meaningful procedures for timely hearing and resolution of 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. We would also retain current regulatory text under §§ 422.564(b) and (c) describing how grievances are distinguished from organization determination and appeal procedures and from the PRO complaint process, respectively. (Under section 1154(a)(14) of the Act, a PRO 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 M+C organization’s grievance procedures.) We would add to § 422.564(b) a proposed 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.

We note that in our consultations on grievance issues, there were conflicting views on the most appropriate means for dealing with quality of care issues; for example, should a quality of care issue first be raised with the M+C organization and subsequently sent to the PRO, immediately referred to the PRO, or allowed to proceed on separate, simultaneous tracks. As reflected under proposed § 422.564(c), we concluded that the appropriate course was to permit maximum discretion to M+C enrollees in this regard. Accordingly, § 422.564(c) explains that, for quality of care issues, an enrollee may file a grievance with the M+C organization, file a written complaint with the PRO, or both.

We considered including a definition of “quality of care” issue in the proposed regulations, such as the following suggestion developed by a workgroup we formed to discuss grievance procedures: “Quality of care

issues may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided health service, procedure, or item. Quality of care issues may also include complaints that a covered health service, procedure or item during a course of treatment did not meet accepted standards for delivery of health care.” However, we concluded that the term “quality of care” does not lend itself to the specificity that would be implied by a regulatory definition and instead believe that it would be in the best interests of M+C enrollees not to unduly limit the types of complaints that could be viewed as quality of care issues. We intend to adopt a more flexible approach that would rely on providing general guidance as to the types of issues that could fall into the quality of care category. We welcome comments on this approach, the definition above, and the appropriateness of including such a definition in the M+C regulations as opposed to issuing other forms of guidance in this area.

Section 422.564(d) specifies that an enrollee must file a grievance, either orally or in writing, no later than 60 days after the event or incident that precipitates the grievance. We welcome comments on whether this or any time limitation is appropriate.

Proposed § 422.564(e) sets forth procedures for grievance disposition and enrollee notification. Proposed § 422.564(e)(1) would establish that an M+C organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee’s health status, but no later than 30 calendar days after the date the organization receives the grievance. In arriving at this time frame, we researched recent standards in this area, such as the NAIC’s model Grievance Act. Additionally, our research indicated that a majority of M+C organizations have procedures that require resolution of a grievance within time frames between 5 and 30 days, with a possible 10 to 15 day extension. Thus, we believe that a maximum time frame of 30-calendar days for resolving a grievance is a reasonable standard. Given that a majority of the M+C organizations are already resolving grievances within less than 30 days, achieving this time frame should not be burdensome, while still satisfying the statutory requirement that an M+C organization provide “meaningful procedures for resolving grievances.”

In conjunction with this time frame, we are also proposing under § 422.564(e)(2) that the M+C organization may extend the time frame

by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and the delay is in the interest of the enrollee. This extension period is consistent with the extensions currently permitted for standard and expedited organization determinations.

Section 422.564(e)(3) would require an M+C organization to inform the enrollee of the disposition of the grievance as follows: (1) All grievances submitted in writing must be responded to in writing; and (2) grievances submitted orally may be responded to either orally or in writing unless a written response is specifically requested by the M+C enrollee. 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 PRO review. (Again, we intend to issue further guidance on what constitutes a quality of care issue, but we generally believe that an M+C organization should err on the side of a broad interpretation of this concept.) For any complaint involving a PRO, the M+C organization must cooperate with the PRO in resolving the complaint. Thus, regardless of whether an enrollee pursued the grievance with an M+C organization, the M+C organization would have an obligation to provide necessary records to the PRO and/or implement a PRO-directed action with regard to a written quality of care complaint.

Section 422.564(f) addresses expedited grievances. Under proposed § 422.564(f), an M+C organization would be required to expedite a grievance under any of the following circumstances: (1) The grievance involves an M+C organization’s decision to invoke an extension relating to an organization determination or reconsideration; (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; or (3) applying the standard time frame for resolving a grievance seriously jeopardize the enrollee’s life, health or ability to regain maximum function (if, for example, a quality of care dispute required immediate resolution). We are proposing 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, consistent with the time frame for expedited appeals.

The new grievance procedures would conclude with the proposed requirement under § 422.564(g) 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 should maintain, at a minimum, date of receipt, disposition and date the response was given. We believe such a system is necessary to ensure that an M+C organization can comply with the requirement under section 1852(c)(2)(C) of the Act that it be able to provide aggregate information on the number and disposition of appeals.

D. Sanctions for a Failure To Comply With IRE Appeal Requirements

As in the case of all other grievance and appeal requirements in subpart M of part 422, under § 422.510(a)(6), a substantial failure to comply with the new requirements proposed in this notice of proposed rulemaking would be grounds for termination of an M+C organization’s contract. Pursuant to § 422.752(b), such a failure to comply would also be grounds for intermediate sanctions under § 422.756(c)(1) and (c)(3), and pursuant to § 422.758, would be grounds for civil money penalties.

E. Proposed Changes to the Medicare Provider Agreement Regulations (§§ 489.20 and 489.27)

In this proposed rule, we would also set forth changes to the provider agreement regulations at 42 CFR part 489 that would specify that distribution of the notices required under this proposed rule is one of the basic commitments that the providers subject to the IRE process must fulfill as part of their agreement to provide Medicare services. Specifically, we would amend §§ 489.20(p) and 489.27 to set forth these provider obligations under the IRE appeals process. As noted above, we have also proposed to revise the provision implementing the “important message” requirement in section 1866(a)(1)(M) to require that hospitals provide notices with information on the reasons for a discharge in accordance with § 422.620. We are proposing that such notification requirements could only be implemented when the notices in question have been approved by the Office of Management and Budget under section 3506(c)(2)(A) of the Paperwork Reduction Act. We believe these changes are critical to facilitating and enforcing the required distribution of notices similar to those that would be under this proposed rule as a mandatory responsibility of the affected Medicare providers.

III. Collection of Information Requirements—Paperwork Reduction Act

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

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 422.564 Grievance Procedures

An enrollee may file a grievance either orally or in writing. For quality of care issues, an enrollee may file a grievance with the M+C organization or file a written complaint with the PRO, or both.

We conducted a random sampling of M+C enrollees in ten states from the most recent Medicare Health Plan Compare data. In rating the overall quality of their managed care plans on a scale of 0–10 (0—worst possible care, 10—best possible care), an average of 17% of M+C enrollees gave their plans the lowest ratings of seven or less. Based on the results of the sampling, we extrapolated that approximately 17% of all M+C enrollees likely would experience some dissatisfaction with their M+C organizations. Since there are currently 6.2 million M+C enrollees, we determined that 1,054,000 enrollees likely would experience some dissatisfaction with their M+C organizations in a given year. Based on the General Accounting Office's (GAO) April 1999 report, Medicare Managed Care: Greater Oversight Needed to Protect Beneficiary Rights, M+C organizations resolved approximately 75% of appeals between January 1996 and May 1998. HCFA's current managed care independent review entity, the Center for Health Dispute Resolution

(CHDR), received approximately 20,000 appeals from M+C organizations for 2000. Therefore, we estimate that approximately 80,000 (approx. 8% of the total number of those dissatisfied) enrollees filed appeals during 2000. Since grievances are broader in scope than appeals, we believe that there are likely to be twice as many grievances than appeals. Thus, we estimate that it will take approximately 160,000 enrollees (approx. 16% of the total number of those dissatisfied) 15 minutes to file a written grievance on an annual basis. The total annual burden associated with this requirement is 40,000 hours.

The M+C organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, no later than 30 calendar days after the date the organization receives the oral or written grievance. Generally, only written grievances will be responded to in writing.

It is estimated that it will take M+C organizations 15 minutes to prepare and furnish each notice and that each M+C organization will be required to provide an estimated 160,000 notices on an annual basis. The total annual burden associated with this requirement is 40,000 hours.

An M+C organization may extend the 30-day time frame by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the M+C organization extends the deadline, it must immediately notify the enrollee in writing, in accordance with the requirements and procedures set forth in this section.

We believe that M+C organizations generally will be able to meet the 30 day time frame. However, M+C organizations are more likely to invoke an extension for quality of care complaints since they often require investigations. We estimate that of the 160,000 grievances filed, approximately 20% (32,000) will be related to quality of care issues. It is estimated that it will take M+C organizations 15 minutes to prepare and furnish each notice and that each M+C organization will be required to provide an estimated 32,000 notices on an annual basis. The total annual burden associated with this requirement is 8,000 hours.

For an expedited grievance, the M+C organization must notify the enrollee of its decision within 72 hours of receipt of the enrollee's grievance. In accordance with paragraph (e)(2) and (f)(1) through (3) of this section.

We believe that most expedited grievances will be related to quality of care issues and the M+C organization's decision not to process an appeal on an expedited basis. As explained above, we estimate that there will be 32,000 quality of care grievances. Because all quality of care grievances must be responded to in writing irrespective of the time frame in which they are being processed (*i.e.*, 30 days + 14 day extension for standard and 72 hours for expedited grievance requests), the number of written decisions already have been accounted, *i.e.*, 8,000 hours.

CHDR data show that it will process approximately 3800 (19% of the IRE's total number of appeals) expedited appeals for 2000. On the basis of GAO's finding that 75% of appeals are resolved at the M+C organization level (see above discussion), we infer that M+C organizations will process approximately 15,000 expedited cases per year (19% of 80,000 appeals at the M+C organization level). Although we have no data at the M+C organization level to deduce the number of expedited appeal requests in a given year, we estimate that M+C organizations deny processing approximately 10% (1500) above the total number expedited. Of the 1500 denied expedited requests, we estimate that approximately 20% (300) will file a grievance. It is estimated that it will take M+C organizations 15 minutes to prepare and furnish each decision and that each M+C organization will be required to provide an estimated 300 notifications on an annual basis. The total annual burden associated with this requirement is 75 hours.

An M+C organization must maintain records on all grievances received both orally and in writing, including the final disposition of the grievance.

It is estimated that it will take M+C organizations 30 minutes (per enrollee who files a grievance) to maintain records on all grievances on an annual basis. Of the 1,054,000 enrollees likely to be dissatisfied with their M+C organizations, we estimate that approximately 420,000 will file an oral or written grievance. The total annual burden associated with this requirement is 210,000 hours.

Section 422.620 How Hospitals Must Notify Enrollees of M+C Organizations 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 §§ 422.2

and 422.113), the hospital must provide a written notice of termination of coverage to each enrollee, consistent with paragraph (c) of this section.

Based on 1998 statistics, approximately 11,000,000 beneficiaries (original Medicare and M+C) received inpatient hospital services. It is estimated that it will take hospitals 20–30 minutes to prepare and furnish each notice and that each hospital will be required to provide an estimated 11,000,000 notifications on an annual basis. The total annual burden associated with this requirement is approximately 3,666,667—5,500,000 hours. There are approximately 6,200,000 (16% of the total Medicare population) M+C enrollees out of approximately 39 million Medicare beneficiaries. We extrapolate that approximately 1,760,000 M+C enrollees received inpatient hospital services. Thus, the total annual burden associated with providing notices to M+C enrollees is approximately 586,667—880,000 hours. (Note that issuance of these notices will not take effect until a separate PRA statement has been published.)

Section 422.624 Notifying Enrollees of Provider Service Terminations

For any termination of service, the provider of the service must notify the enrollee in writing 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 requirements and procedures set forth in this section.

It is estimated that it will take providers (skilled nursing facilities (SNFs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs)) 15 minutes to prepare and furnish each notice. In 1997, there were 1,503,000 Medicare beneficiaries receiving SNF services and 3,505,000 Medicare beneficiaries receiving HHA services. (Note that the amount of Medicare business with CORFs is so small that Medicare statistical summaries do not include a separate line item for patient encounters with these facilities. Thus, we are unable to extrapolate under original Medicare. The number of possible M+C CORF cases, and the analysis below, is necessarily limited to SNF and HHA services.) The total annual burden associated with this requirement is 200,320 hours. We extrapolate that providers will be required to give an estimated 801,280 (16% of 5,008,000 Medicare beneficiaries) notices to M+C enrollees.

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.

Based on our figures above, approximately 8% of all enrollees file appeals. Thus, 8% of the 801,280 M+C enrollees who receive notices are likely to file appeals with the IRE. It is estimated that it will take approximately 64,000 enrollees 15 minutes to file an appeal on an annual basis. The total annual burden associated with this requirement is 16,000 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 10% of the 64,000 enrollees who file appeals will also submit additional evidence. It is estimated that it will take 6,400 enrollees 60 minutes to submit evidence on an annual basis. Since beneficiaries will not be functioning at their maximum capacity and it will take them longer to gather their thoughts and evidence, we estimate that it will take them 4 times longer than providers to submit additional information. The total annual burden associated with this requirement is 6400 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 first day after the day that the IRE notifies the M+C organization, that the IRE needs to decide on the appeal.

It is estimated that it will take M+C organizations 60–90 minutes to furnish any and all information, including a copy of the notice sent to the enrollee, and that each M+C organization will be required to provide an estimated 64,000 disclosures on an annual basis. The total annual burden associated with this requirement is 64,000–96,000 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 64,000 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 information provided to the IRE, to the enrollee, and that each M+C organization will be required to provide an estimated 12,800 disclosures on an annual basis. The total annual burden associated with this requirement is 3,200 hours.

If the IRE upholds an M+C organization's termination decision in whole or in part, the enrollee may file, no later than 60 days after notification that the IRE has upheld the decision, a request with the IRE for an IRE reconsideration of its original decision.

It is estimated that 40% of the 64,000 appeals (25,600) will be overturned by the IRE. Of those, we estimate that 20% of the enrollees will request a reconsideration by the IRE. It is estimated that it will take 5,120 enrollees 30 minutes to file a request for reconsideration on an annual basis. The total annual burden associated with this requirement is 2,560 hours.

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. 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 60 days of this publication date directly to the following:

Health Care Financing Administration,
Office of Information Services,
Information Technology Investment
Management Group, Division of
HCFA Enterprise Standards, Room
N2-14-26, 7500 Security Boulevard,
Baltimore, MD 21244-1850. Attn:
John Burke HCFA-4024-P.
And, Office of Information and
Regulatory Affairs, Office of
Management and Budget, Room
10235, New Executive Office
Building, Washington, DC 20503,
Attn: Allison Heron Eydt, HCFA Desk
Officer.

IV. Regulatory Impact Statement

A. Introduction

We have examined the impact of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health

and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually.

The Unfunded Mandate Reform Act of 1995, in section 202, requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year. This rule has no consequential effect on State, local, or tribal governments.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

As discussed in detail above, this proposed rule would establish new notice and appeal procedures for enrollees when an M+C organization decides to terminate coverage of services by SNFs, HHAs, and CORFs. This proposed rule also would specify hospitals' responsibility for issuing discharge notices, amend the Medicare provider agreement regulations with regard to beneficiary notification requirements, and set forth 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 specific provisions of the proposed rule on M+C organizations and providers is discussed below.

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

Although some aspects of this proposed rule do not lend themselves to quantifiable cost estimates, we believe that the most significant costs associated with the new M+C notice and appeal procedures will result from the Secretary's commitment to contract with an independent review entity to conduct an expedited review of all

provider termination cases appealed by M+C enrollees. In order to project the number of appeals that may be involved, we examined the latest available appeals data from the Center for Health Dispute Resolution (CHDR), the organization with whom HCFA now contracts to conduct appeals of M+C reconsiderations. (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.) In 1999, CHDR reviewed approximately 3,000 cases involving services provided by SNFs, HHAs, or CORFs. (Note that we have no way of knowing the proportion of these cases that involved service terminations but, for impact analysis purposes, will assume that all cases could be subject to the new expedited appeal procedures.) According to 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 determinations in approximately 75 percent of appealed cases; thus 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 believe that the minimum number of provider appeals that would likely be heard by an IRE under the procedures proposed in this NPRM would be 12,000 cases, with contracting costs to HCFA estimated at a minimum of \$10 million.

For each of these 12,000 cases, M+C organizations would be required under these proposed rules to make available to the IRE, and to the enrollee upon request, a copy of any documentation needed to decide on the appeal. Although we recognize the 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 reconsidered determination. Moreover, any burden on M+C organizations would be more than offset by the fact that M+C organizations would no longer be required to conduct reconsideration of any cases covered under this proposed rule. That is, the new IRE would conduct reviews not just of the 3,000 cases that now go to CHDR but also of the 9,000 cases which are now subject to the M+C organization reconsideration process.

Currently, we have no M+C encounter data that would permit a precise count of the annual number of SNF, HHA, and CORF admissions, and thus the number

of notices that must be issued under this proposed rule. Based on comparisons with data available from original Medicare admissions (as well as extrapolating from the original Medicare appeals rate of 1 percent), we estimate a total of approximately 800,000 to 1 million provider terminations for which notices would be required under this proposed rule, with an associated aggregate financial impact of \$8 to \$10 million.

Another important element of this proposed rule is the provision that an M+C organization would be financially liable for services provided during the 4-day period between issuance of the termination notice and resolution of the enrollee appeal, if any. However, our expectation is that notices would be provided four days before care is expected to be no longer medically necessary, with any appeals completed by the end of those four days. Moreover, we believe that M+C organizations are generally covering all medically necessary care for their enrollees under the existing regulations. Thus, this proposed provision should have minimal, if any financial impact on M+C organizations.

C. Grievance Procedures (§ 422.564)

Proposed § 422.564 includes several provisions that clarify the existing requirement that each M+C organization provide meaningful procedures for timely hearing and resolution of grievances between enrollees and the M+C organization. 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. We have no data on the the number of grievances that are currently brought to the attention of M+C organizations, and would welcome any quantifiable estimates from commenters. As discussed in detail in section II.C of this proposed rule, however, 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 our proposed procedures. We believe that M+C organizations are in large measure already in compliance with proposed grievance procedures set forth here, and that these proposals would not result in any substantial impact on most M+C organizations.

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

This proposed rule would clarify that hospitals are required to notify M+C

enrollees of terminations of hospital care. This proposal is consistent with the policy position we outlined in the preamble to the recent M+C final rule with respect to hospitals (65 FR 40284). Specifically, proposed § 422.620(a) would specify that in situations involving inpatient admissions of M+C enrollees, hospitals must provide a written notice of termination of coverage to each enrollee that includes the reasons for the discharge. We also are amending § 489.27 to provide expressly for this hospital responsibility. Section 489.27 implements the requirement in section 1866(a)(1)(M) that hospitals provide a notice to all Medicare beneficiaries of the individual's rights (referred to as the "Important Message from Medicare" for beneficiaries). Section 1866(a)(1)(M) provides that this notice must include "such additional information as the Secretary may specify."

As a general rule, we believe that hospitals are already issuing these notices and thus that these proposed regulatory changes will not have a substantial financial impact, with one exception as discussed below. Under the M+C program, for example, hospitals are required under section 1866(a)(1)(M) of the Act to issue the "Important Message from Medicare" to each enrollee upon admission. In addition, existing § 422.620(c) requires that written notice of discharge (the "Notice of Discharge and Medicare Appeal Rights"—NODMAR) be provided M+C enrollees no later than the day before hospital coverage ends. Although the regulations now do not specify who must issue these notices, our understanding is that hospitals generally carry out this function on the behalf of M+C organizations, and we would expect that practice to continue.

Similarly, under original Medicare, hospitals are now required (1) under section 1866(a)(1)(M) of the Act to issue the "Important Message from Medicare" upon admission; and (2) in order to be protected from liability under section 1879 of the Act, to issue the "Hospital Issued Notice of Noncoverage" (HINN) near the time of discharge. These notices are necessary to ensure that beneficiaries are aware of their rights to appeal a hospital's determination that inpatient care is no longer necessary under the Medicare program. To the extent that hospitals are issuing these notices, this proposed rule would not impose any additional costs on hospitals for original Medicare admissions; costs associated with patient notifications would be paid for under inpatient hospital standardized

payment amount, which encompasses all administrative costs.

However, our understanding is that although hospitals are routinely issuing the "Important Message from Medicare," many hospitals are not now routinely issuing HINNs to original Medicare beneficiaries, but are instead issuing them only for disputed discharges. Consistent with the estimates discussed above in section III of this proposed rule, we believe that the number of original Medicare hospital discharges where HINNs should be issued is roughly 9.4 million, at an estimated annual cost of approximately \$117,000,000 (30 minutes per notice at \$25 per hour). Based on an estimated 6,300 participating hospitals, the projected financial impact of distributing these discharge notices as required under this proposed rule would be \$18,500 per hospital, to the extent that hospitals are not now issuing the discharge notices. Given that we are unable to determine the extent to which the discharge notices are now being issued by hospitals to original Medicare beneficiaries, we believe that the associated costs may represent an additional financial impact on hospitals. We welcome comments on these estimates.

Therefore, this proposed rule would be a major rule as defined in Title 5, United States Code, section 804(2). In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Other Required Information

A. Federalism Summary Impact Statement

On August 4, 1999, the president signed Executive Order 13132 (effective November 2, 1999) establishing certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have federalism implications. Any such regulations must include a federalism summary impact statement that describes the agency's consultation with State and local officials and summarizes the nature of their concerns, the extent to which these concerns have been met, and the agency's position supporting the need to issue the regulation. In this NPRM, we are not proposing any changes to the existing M+C regulations that meet any of the criteria mentioned above that would require the inclusion of a federalism impact statement under Executive Order 13132.

B. Responses to Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble and respond to the comments a subsequent rulemaking document.

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 preamble, the Health Care Financing Administration proposes to amend 42 CFR chapter IV as set forth below:

PART 422—MEDICARE+CHOICE PROGRAM

A. 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 § 422.502, paragraph (i)(3)(iv) is added to read as follows:

§ 422.502 Contract provisions.

* * * * *
(i) * * *
(3) * * *

(iv) A provision specifying that these entities will comply with applicable notice and appeal provisions in subpart M of this part, including but not limited to, the notification requirements in §§ 422.620 and 422.624 and the requirements in § 422.626 concerning supplying information to an IRE.

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3. In § 422.561, the definition of "grievance" is revised to read as follows:

§ 422.561 Definitions.

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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.

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4. 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 resolution of 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 PRO complaint process.* Under section 1154(a)(14) of the Act, the PRO 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 PRO, or both.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the M+C organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The M+C organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance.

(2) The M+C organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the M+C organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The M+C organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the PRO. For any complaint submitted to a PRO, the M+C organization must cooperate with the PRO in resolving the complaint.

(f) *Exception—expedited grievances.* For a grievance that is required to be expedited as provided in this paragraph (f), the M+C organization must notify the enrollee of its response to the enrollee's grievance within 72 hours of receipt of the grievance. An extension is permitted consistent with the procedures set forth in paragraph (e)(2) of this section. The M+C organization must expedite a grievance under any of the following circumstances:

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

(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.

(3) Applying the standard timeframe could seriously jeopardize the enrollee's life, health, or ability to regain maximum function. The M+C organization's decision as to whether a grievance meets any of these criteria and thus must be expedited is not subject to further review.

(g) *Recordkeeping.* The M+C organization must have a system 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.

5. In § 422.620, the heading of the section and paragraph (a) are revised to read as follows:

§ 422.620 How hospitals must notify enrollees of M+C organizations of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* 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 §§ 422.2 and 422.113), the hospital must provide a written notice

of termination of coverage to each enrollee, consistent with paragraph (c) of this section, before the M+C organization may terminate coverage for such services. An enrollee is entitled to coverage until at least noon of the day after the notice is provided. If PRO review is requested under § 422.622, coverage is extended as provided in that section.

* * * * *

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

§ 422.624 Notifying enrollees of provider service terminations.

(a) *Applicability.* (1) For purposes of this section and § 422.626, providers include 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 discontinuation or discharge of an enrollee from 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 (but is not limited to) 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 four calendar days before the proposed end of the services. If the enrollee's services are expected to be fewer than four calendar days in duration, the provider should notify the enrollee at the time of admission to the provider.

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

(i) A specific and detailed explanation of the reason(s) services are either no longer reasonable and necessary or are otherwise 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 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 is 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) The date and time that coverage of services ends and the enrollee's financial liability for continued services begins.

(vi) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact the 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.

(vii) Any other information required by HCFA.

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

(1) Delivery of the termination notice is not valid unless—

(i) The enrollee has signed the notice to indicate that he or she has received the notice and can comprehend its contents; and

(ii) The notice is delivered timely, in the format and language specified by the Secretary, and includes all content elements required under paragraph (b)(2) of this section.

(2) If the provider does not deliver valid notice as specified in paragraph (c)(1) of this section, the M+C organization may not discontinue coverage for services until four calendar days after it provides such valid notice or, if later, until noon of the day after the enrollee receives notice of a decision by the IRE upholding the M+C organization as provided for in § 422.626(b).

§ 422.626 Fast-track appeals of service terminations to an independent review entity (IRE).

(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 the IRE under contract with HCFA, in writing or by telephone, by noon of the first day after the day of delivery of the written 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) If an enrollee fails to request a timely IRE review, he or she may request an expedited reconsideration by the M+C organization as described in § 422.584, but the protection against liability for services pending a decision described in paragraph (b) of this section would not apply.

(3) If, after delivery of the written 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) *Continuation of coverage during appeals to the IRE where the IRE upholds the M+C organization's decision.* If an enrollee files a timely appeal with the IRE, coverage of provider services continues until noon of the day after the enrollee receives notice of an IRE decision upholding the M+C organization's decision, or until the date and time designated on the termination notice, whichever is later. 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 four calendar days after valid notice has been received, or until noon of the day after the enrollee receives notice of an IRE's decision on the appeal, whichever is later. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Continuation of coverage during appeals to the IRE when the IRE does not uphold the M+C organization's decision.* If an enrollee timely files an appeal with the IRE, and the IRE does not uphold the M+C organization's determination, the M+C organization must continue coverage until four calendar days after a new valid notice of termination is provided.

(d) *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 the IRE requires to sustain the M+C organization's termination decision, consistent with paragraph (f) of this section, including a copy of the termination notice.

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

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

(e) *Procedures the IRE must follow.* (1) On the date the IRE receives the enrollee's request for an appeal, the IRE must 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 (f)(1) 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.

(3) The IRE must notify HCFA 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 written termination notice provided by the M+C organization, or any other reason that the IRE intends to use as the basis of its review determination.

(5) The 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 would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(f) *Responsibilities of the M+C organization.* (1) 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 first day after 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.

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

(g) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an M+C organization's termination decision in whole or in part, the enrollee may file, no later than 60 days after notification that the IRE has upheld the decision, a request with the IRE for a reconsideration of 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 is permitted to appeal the IRE's reconsidered determination to an ALJ, the DAB, or a federal court, as provided for under this subpart M.

(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

B. 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 provider agrees to the following:

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

3. In § 489.27, the existing text is redesignated as paragraph (a) and revised as follows; and a new paragraph (b) is added to read as follows:

§ 489.27 Beneficiary notice of discharge rights

(a) *Notification by hospitals.* A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or authorized representative, notice of the beneficiary's rights in the case of a termination of hospital services, as required under section 1866(a)(1)(M) and in the format specified by HCFA, provided that the notices have been approved by the Office of Management and Budget under section 3506(c)(2)(A) of the Paperwork Reduction Act. In the case of all Medicare beneficiaries, including those enrolled in an M+C plan, the notice specified in the previous sentence (specifying the reasons for the discharge and the right to PRO review of the discharge decision) must be provided to the beneficiary a day before the effective date of the discharge. In the case of beneficiaries enrolled in an M+C plan, notice must be provided in accordance with § 422.620. The hospital must be able to demonstrate compliance with this requirement.

(b) *Notification by other providers.* Other providers (that is, nonhospital providers identified at § 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable HCFA notices in advance of the termination of Medicare services, provided that the notices have been approved by the Office of Management and Budget under section 3506(c)(2)(A) of the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital

Insurance; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: January 2, 2001.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: January 5, 2001.

Donna E. Shalala,

Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01-60; MM Docket No. 01-5; RM-10028]

Radio Broadcasting Services; Butler, GA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition for rule making filed by H. David Hedrick proposing the allotment of Channel 245A to Butler, GA, as the community's first local aural service. Channel 245A can be allotted to Butler in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction, at coordinates 32-33-25 NL; 84-14-18 WL.

DATES: Comments must be filed on or before March 5, 2001, and reply comments on or before March 20, 2001.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: H. David Hedrick, P.O. Box 27, 317 Stonegables Court, Gray, GA 31032 (Petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 01-5; adopted January 3, 2001 and released January 12, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor,