Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(52)(xiii)(E), (80)(i)(D), and (207)(i)(A)(*2*)to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(52) * * *

(xiii) * * *

(E) Previously approved and now deleted, Rule 104.

* * * * *

(80) * * *

(i) * * *

(D) Previously approved and now deleted, Rule 104.

* * * * *

(207) * * *

(i) * * *

(A) * * *

(*2*) Rules 101, 102, 103, 201, 202, 203, 204, 208, 209, 210, 211, 213, 214, 217, 219, 220, 221, 222, 225, 226, 228, 406, 407, and 408, adopted on October 19, 1993; deletion of 104 for Lake Tahoe Air Basin and Mountain Counties Air Basin submitted 08/21/79 and 10/15/79, respectively.

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[FR Doc. 97–11158 Filed 4–29–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 417

[OMC–025–FC]

RIN 0938–AH62

Medicare Program; Establishment of an Expedited Review Process for Medicare Beneficiaries Enrolled in Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period establishes a new administrative review requirement for Medicare beneficiaries enrolled in health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs). This rule implements section 1876(c)(5) of the Social Security Act, which specifies the appeal and grievance rights for Medicare enrollees in HMOs and CMPs. This rule requires that an HMO, CMP, or HCPP establish and maintain, as part of the health plan's appeals procedures, an expedited process for making organization determinations and reconsidered determinations when an adverse determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This rule also revises the definition of appealable determinations to clarify that it includes a decision to discontinue services.

DATES: *Effective date:* These regulations are effective June 30, 1997.

Compliance date: HMOs, CMPs, and HCPPs must comply with the requirements of this final rule beginning August 28, 1997.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided under **ADDRESSES,** no later than 5 p.m. on June 30, 1997.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: OMC–025–FC, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309/G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: OMC025FC@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OMC–025–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: Maureen Miller, (410) 786–1097.

SUPPLEMENTARY INFORMATION:

I. General Background

A. Program Background

Under title XVIII of the Social Security Act (the Act), Medicare beneficiaries have a choice of whether to obtain Medicare-covered services through the traditional fee-for-service program or through a managed care entity or ''prepaid health care organization.'' This final rule with comment period concerns appeal rights for Medicare beneficiaries who choose a prepaid health care organization. Under the prepayment method, health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs) enter into contracts or agreements with us to provide a range of services to Medicare beneficiaries who voluntarily enroll in these health plans.

Section 1876 of the Act provides the authority for us to enter into contracts with HMOs and CMPs to furnish

Medicare-covered services to beneficiaries on either a ''risk'' or a ''cost payment'' basis. Section 1833 of the Act provides the basis for regulations under which we enter into written agreements with HCPPs to furnish covered Medicare Part B services on a cost payment basis.

Section 1876 specifies the requirements that eligible health plans must meet in order to enter into and maintain a Medicare contract, including the provision of appeal and grievance rights to Medicare enrollees, as set forth under section 1876(c)(5) of the Act. Regulations implementing the beneficiary appeals requirements are found at 42 CFR, subpart Q, §§ 417.600 through 417.638. These regulations were most recently amended on November 21, 1994 with the publication of the final rule entitled ''Medicare Program: Appeal Rights and Procedures for Beneficiaries Enrolled in Prepaid Health Care Plans'' (59 FR 59933). That final rule (1) codified a program standard that HMOs and CMPs complete reconsiderations requested by a Medicare enrollee, referenced in this final rule as an ''enrollee,'' for denied services or claims, within 60 days from the date of receipt of the reconsideration request; (2) extended to HMO and CMP enrollees the right to request immediate review by a Utilization and Quality Control Peer Review Organization (PRO) of an HMO's, CMP's, or hospital's determination that an inpatient hospital stay is no longer necessary; and (3) required HCPPs to establish administrative review procedures for their Medicare beneficiaries who are dissatisfied with decisions to deny a service or a claim. In this final rule, we refer to HMOs, CMPs, and HCPPs as ''health plans.''

B. Current Requirements

Medicare-contracting health plans are required to maintain procedures for making ''organization determinations'' (decisions concerning whether to provide a service or pay a claim) and for reconsidering the organization determination. That is, if the organization determination is adverse to the beneficiary, the health plan also must provide a second level of review called a ''reconsideration'' upon request by the Medicare enrollee.

Current regulations, drafted in the early 1980's, permit health plans up to 60 days to issue a formal notice of an adverse organization determination if an enrollee's request for a service or payment is denied. This notice informs the beneficiaries of the reason for the determination and their right to file a request for reconsideration. The health plan has an additional 60 days to conduct the reconsideration and issue a reconsidered determination. These 60-day time frames stem from the fee-for-service appeals process, a process the Congress referenced in drafting section 1876 of the Act.

At the reconsideration stage, the health plan may uphold the decision to deny a service or payment of a claim, or it may overturn the decision and issue a reconsidered determination in favor of the enrollee. If, upon reconsideration, a health plan upholds its decision to deny, the appeal is automatically sent to an independent reviewer under contract with and acting for HCFA. No written request from the enrollee is necessary for this external review. The reconsideration contractor, on our behalf, is responsible for issuing the reconsidered determination. The reconsidered determination may uphold or overturn the plan's determination. If the contractor's determination upholds the plan's decision (in whole or in part) and if the amount in controversy is $100 or more, the enrollee may request an Administrative Law Judge hearing. At this point, the enrollee may pursue the same administrative and judicial review processes that are available to beneficiaries in fee-for-service. Thus, beneficiaries enrolled in HMOs, CMPs, and HCPPs have appeal rights equivalent to those available in the fee-for-service program.

II. Additional Background

A. Expedited Organization Determinations and Reconsiderations

The regulations pertaining to Medicare managed care appeals requirements do not include a specific provision requiring expedited organization determinations or reconsiderations in time-sensitive situations. However, increased program experience resulting from the growth and penetration of HMOs in the private insurance and Medicare markets has prompted us, along with other groups, to recognize the desirability of an expedited decision-making process for certain services in certain situations. In fact, the National Association of Insurance Commissioners (NAIC) has developed and recently adopted a model Grievance Act setting forth standards for grievance procedures that include provision for expedited appeals. (Although our regulations make a distinction between appealable organization determinations and ''grievances,'' which are not appealable, the model ''Grievance'' Act prepared by NAIC encompasses determinations of the type addressed in this rule.)

The need for an expedited process to address certain preservice denials, as well as reductions and discontinuations of service in certain time-sensitive circumstances, is further supported by reports and studies of the General Accounting Office (1995), the Physician Payment Review Commission (1996), and the Institute of Medicine (1996). Organizations that advocate for beneficiaries also have reported to us the urgent need for expedited decision-making, particularly when certain services are being discontinued. Therefore, we are amending part 417, subpart Q to establish and incorporate provisions for expediting organization determinations and reconsiderations in certain time-sensitive situations.

In developing the provisions for this final rule, we looked for guidance to the NAIC's model Grievance Act. This model act is the result of more than 2 years of deliberation among State regulators, in open consultation with consumer groups (including Medicare beneficiary advocacy groups), provider and physician associations, insurance and managed care representatives, HCFA staff, and others. We anticipate that many States will adopt this model act or amend existing regulations to conform with these new, state-of-the-art standards.

Because of the inclusive and exhaustive efforts invested in the development of the NAIC's model Grievance Act as well as the importance of acting rapidly to institute expedited appeals for the Medicare population, we have drawn on the NAIC's time lines and definition in developing the new Medicare requirement. In addition to the important precedent of NAIC's accountability standards, we believe that beneficiaries (particularly those enrolled in prepaid plans before Medicare eligibility) would benefit from consistent standards regarding appeal rights. We believe, too, that similar thresholds for expediting a review process and similar time lines will lessen the margin for error among health plan staff handling commercial as well as Medicare enrollee appeals, and strengthen the ability of enrollees to exercise appeal rights when making the transition to the Medicare managed care plan.

Under the provisions of this rule, health plans are required to incorporate into their appeals process a procedure for reviewing and issuing certain organization determinations and reconsiderations within a short time frame. Expedited reviews will be conducted for situations in which the standard (60-day) time frame for issuing determinations could jeopardize the life

or health of the enrollee or the enrollee's ability to regain maximum function. Also, requests for reconsideration of noncoverage determinations for inpatient stays, other than hospital discharges for which immediate Peer Review Organization (PRO) review is available, will be expedited, as well as requests for reconsiderations of determinations to discontinue a service (such as physical therapy) in the home or outpatient setting where a longer review time could jeopardize the enrollee's life, health, or ability to regain his or her maximum function. Health plans will be required to conduct the review within a time period appropriate to the condition or situation of the enrollee, but no more than 72 hours from the time of the request. Thus, expedited reviews could occur in 24 hours, 48 hours, or other appropriate time period. Similarly, an expedited organization determination to deny a service could be issued in 48 hours, but the expedited reconsideration could take the full 72 hours allotted for making a determination.

Because of the time-sensitive nature of these situations, certain requirements and conditions applicable to standard appeals are altered. For instance, the Medicare enrollee, or his or her representative, will be able to request an expedited review orally, such as by telephone. In a similar manner, the health plan's determination will be given to the enrollee or the representative, and to the appropriate physician or provider as necessary, in an expeditious manner. When the determination is given orally, a written follow-up version must be issued within 2 working days. Further, any physician will be permitted to request an expedited review on behalf of the enrollee, and the health plan must accept the physician's decision that the situation meets the criterion for expedited review, that is, that a longer review period could place the enrollee in jeopardy.

The health plan must receive the request for an expedited determination or reconsideration, make the procedural decision whether the determination will be made through the expedited process (or redirect it to the standard process), conduct the review, and issue its determination within the 72-hour time frame set forth in the regulation. In limited circumstances, health plans will be allowed to take more than 72 hours to issue a determination. Health plans will be permitted up to 10 additional working days beyond the 72-hour standard if the ''extension'' of time benefits the beneficiary, such as allowing for additional diagnostic testing or consultations with medical specialists, or if the beneficiary requests the extension in order to provide the plan with additional information for making its decision. Delays in meeting the 72-hour standard will also be permitted if an expedited organization determination or reconsideration is requested by a physician not affiliated with the health plan. In this case, the 72-hour time standard will begin only when the medical information necessary for making the determination has been communicated (orally or in writing by the out-of-plan physician) to the health plan. If the physician fails to provide necessary information, the health plan must notify the enrollee (or attempt to notify the enrollee who is out of the service area) in a timely manner, and no later than 72 hours after the request, that the information has not been provided. When a small amount of additional time is needed to make a determination and, overall, is in favor of the beneficiary, the beneficiary must be kept informed and written documentation made to the case file. However, delays in the communication of medical record information between affiliated physicians or providers and the health plan will not be accepted as reason for extending the time standard.

In those instances in which the health plan determines that the enrollee's request does not meet the criterion for expedited review, the HMO or CMP must notify the enrollee as soon as possible and follow up any oral communication with a written explanation. This is a procedural decision, and because the enrollee has requested an organization determination—or a reconsideration—the health plan must handle the request through standard appeals procedures. We anticipate that questions will arise on matters such as enrollee recourse and plan procedures if a request is not granted, and we plan to consult beneficiary advocacy groups and the managed care industry on needed action and operational guidance in areas such as notification of grievance rights, filing quality of care complaints with the local PRO, and modifying procedures to carry out the standard review process.

If a decision is made by the health plan not to expedite an organization determination, and at the completion of the standard review process there is a determination adverse to the enrollee, the enrollee could request an expedited reconsideration if he or she again believes that a longer (standard) time frame could jeopardize life, health, or functioning. On the other hand, a health plan may have a protocol that any reconsideration will be expedited if the organization determination was expedited.

If a health plan expedites a reconsideration, and upholds its decision that is adverse to the enrollee in whole or in part, it must forward the case to our reconsideration contractor in as expeditious manner as possible and within 24 hours of its decision. Our contractor will then conduct an expedited reconsideration. Currently, our contractor has an expedited process for time-sensitive situations involving preservice denials and terminations of coverage. As part of this rulemaking, we will review this process for possible improvement and assess the need for contract modification.

The expedited appeals process established by this rule, generally, will not affect the handling of hospital discharge disputes because, as noted earlier in this preamble, an ''expedited'' process is already in place for these appeals, that is, the right to immediate PRO review. The right to immediate PRO review for possible premature discharge would extend, also, to instances in which an enrollee is preauthorized for an inpatient procedure and only 1 or 2 days of hospital care. The HMO or CMP must assure that it (or its delegated hospital) has procedures in place that would allow an enrollee who is admitted for a very short stay to exercise this right to immediate PRO review. This independent review protection would not preclude a health plan from establishing a procedure for appealing before hospitalization, although this process could not replace the right to PRO review once hospitalized. If the enrollee does not request PRO review, an alternative appeals protection exists: The enrollee may remain in the hospital for extra days of care then submit a request for the health plan to pay the hospital charges.

Options Considered

In developing this rule, we consulted beneficiary advocacy groups and the managed care industry concerning several policy options. In particular, we considered several options before deciding to adopt a 72-hour time standard for expedited appeals. The beneficiary advocacy groups we consulted indicated that the expedited review process should take less, but no more, than 72 hours. Representatives of the HMO industry estimated a need for 5 days. We chose the 72-hour time standard because (1) it is consistent with the model standard recently adopted by the NAIC, (2) agency staff estimate that a majority of these cases could be reasonably resolved in this

time frame, and (3) the 72-hour time frame is similar to that established by the Congress for completion of immediate PRO review of fee-for-service and HMO hospital discharge decisions.

We also considered options regarding the procedural issue of deciding whether to expedite a review. Beneficiary advocacy groups recommended that the beneficiary decide whether determinations and reconsiderations are expedited, not the health plan, in order to ensure that these special appeal requests are granted. Representatives of the HMO industry believe that health plans should make these decisions because the criterion for expeditious treatment of a review requires the judgment of trained persons and health professionals. HMOs are also concerned that beneficiaries will overuse and misuse this process. In this final rule, we are modifying the NAIC language from ''would jeopardize * * *'' to ''could jeopardize'' the life, health, or functioning of the beneficiary, and are adding the mandatory granting of physician requests. We believe this language strikes the proper balance and provides beneficiaries with an expedited appeal in most cases, but allows HMOs some flexibility to refuse expedition in cases in which the beneficiary is misusing the new right.

The beneficiary groups and the HMO industry both recommended that our reconsideration contractor be held to similar expedited review requirements. The current contractor already expedites its review of preservice denial cases with a self-imposed time standard of 3 to 10 days. It is our intent to hold the contractor to a time limit of no more than 10 days to complete time-sensitive reconsiderations.

After publication of this rule, we will issue implementation instructions to all contracting health plans, including directives concerning notification of enrollees on the new appeals right and revising member documents. Furthermore, we will incorporate information about this new appeal right in various materials, including the Medicare Handbook.

We believe that the addition of regulations pertaining to an expedited process to part 417, subpart Q will provide a needed protection for beneficiaries while allowing health plans to manage effectively the resources that must be available for expediting urgent cases.

B. Clarification of Organization Determination Definition

In making payments to affiliated providers and physicians, prepaid health plans (including Medicare-contracting HMOs, CMPs, and HCPPs) commonly use financial arrangements that incorporate an incentive to utilize health resources efficiently. Some believe these incentives, which are designed to achieve quality outcomes without overutilizing the health care system, could have the untoward result of underutilization or failure to furnish medically necessary covered services in some situations. Thus, an important protection for beneficiaries enrolled in HMOs, CMPs, or HCPPs is the right to appeal denials of care (also known as preservice denials) and to seek reimbursement for the costs of services received out of plan following a preservice denial.

Regulations set forth at § 417.606 (''Organization determinations'') define those actions that are organization determinations and therefore subject to reconsideration and the Medicare appeals process, as well as those actions that are not organization determinations. These regulations do not expressly identify as organization determinations those situations in which an enrollee has been receiving services but the care is being discontinued, although the intent is that enrollees have the right to appeal decisions for which Medicare coverage is in dispute. These disputes are not limited to preservice denials or postservice claims for payment but must include situations in which services have been furnished, but the enrollee disagrees with his or her health plan's decision that continued care or the skilled level of care is no longer medically necessary, appropriate, or covered.

We have received information that some enrollees do not fully understand their appeal rights and that health plan administrators themselves are confused about appeal rights in these situations. Most recently, the Office of Inspector General of the Department of Health and Human Services found that, while enrollees ''were knowledgeable about their general right'' to register formal complaints, they were less aware of specifically when to exercise appeal rights. (Medicare HMO Appeal and Grievance Processes: Beneficiaries' Understanding, December 1996, OEI–07–96–11281.) Therefore, we are revising § 417.606(a) to clarify that the definition of organization determination includes discontinuations of covered services, when an enrollee believes there is a continuing need for the service, or level of service, that would be covered by Medicare. Examples of these situations are discharges from skilled nursing facilities, decisions to move an enrollee from a skilled level to custodial care in the nursing facility, and exhaustion of skilled nursing facility benefits.

Options Considered

We believe that the current definition of organization determination extends to reductions in services, such as changes in the intensity and mix of home health services furnished to an enrollee. However, because the definition in the regulations does not expressly identify reductions in services furnished to an enrollee, we considered including a clarification in this final rule. In assessing the ramifications of this clarification, we became aware of the potential scope and the complexity of addressing reductions in various medical services, as well as the interaction of such a provision with other improvements under consideration for improving appeals protections (see section III. of this regulation). Therefore, we have decided to include this provision in a subsequent rulemaking document. This will allow not only beneficiary and managed care representatives to comment, but also medical, other professional, and provider organizations. Commenters to this final rule, however, are invited to submit their initial comments, concerns, and ideas on establishing effective and efficient parameters for giving notice and providing appeal rights when services are being reduced (for example, in home health care, outpatient clinics, and physician offices), when reconsiderations of a reduction should be expedited, and when enrollees are participating in case management programs or other innovative treatment modalities for which there are pre-agreements regarding the services to be furnished.

C. Grijalva et al. and Balistreri et al. v. Shalala

Civ. 93–711 (D. Arizona) concerns the service denial appeal rights of members of Medicare health maintenance organizations. The District Court's October 17, 1996 decision and March 3, 1997 judgment are subject to appeal on or before May 2, 1997.

III. Additional Pending Revisions to the Regulations

We have undertaken a broad review of the overall appeals program and have identified a number of improvements that we believe are warranted. Therefore, in addition to the two changes being made in this rule, we intend to publish soon a separate proposed rule making a variety of other

improvements in Medicare managed care appeals processes.

IV. Provisions of This Final Rule

The provisions of this final rule with comment period follow:

In § 417.600 (''Basis and scope''), paragraph (b)(3)(ii) is modified to require that the HMO or CMP must ensure that Medicare enrollees have a complete written explanation of the availability of expedited reviews.

In § 417.604 (''General provisions''), paragraph (b)(4) is modified to allow physicians and other health professionals to act on behalf of an enrollee in time-sensitive situations when an organization determination or reconsideration is being requested.

The definition of ''organization determination'' set forth at § 417.606 (''Organization determinations''), paragraph (a), is revised to include discontinuations of services being furnished by an HMO or CMP.

In § 417.608 (''Notice of adverse organization determination''), paragraph (a) is modified to incorporate expedited organization determinations, and paragraphs (b)(2) and (c) are revised to require that the HMO or CMP must inform the enrollee of his or her right to and conditions for obtaining an expedited reconsidered determination and that failure to provide the enrollee with timely notification (72 hours in the case of certain expedited organization determinations) constitutes an adverse organization determination and may be appealed.

A new § 417.609 (''Expediting certain organization determinations'') is added to provide that an enrollee may request that certain organization determinations be expedited if the standard time frames could jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This new section also sets forth the procedures for expediting certain organization determinations. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

In § 417.614 (''Right to reconsideration''), a modification is made to extend the right to reconsideration to include expedited reconsiderations in time-sensitive situations.

In § 417.616 (''Request for reconsideration''), paragraph (a) (''Method and place for filing a request'') is modified to provide for an exception for expedited reconsiderations to the place for filing a request for a reconsideration.

A new § 417.617 (''Expediting certain reconsiderations'') is added to require that an enrollee may request expedition of a reconsideration of certain organization determinations when the longer time frames in § 417.620(c) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This section also sets forth the procedures for health plans to expedite reconsiderations. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

A modification is made to § 417.618 (''Opportunity to submit evidence'') to recognize and clarify the procedural limitation for providing evidence by enrollees, their representatives, or a health professional on the enrollee's behalf.

Section 417.620 (''Responsibility for reconsiderations; time limits'') paragraphs (c) and (e) are revised to incorporate the time limit for expediting certain reconsiderations. Paragraph (d) is revised to correct typographical errors.

V. Collection of Information Requirements

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

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

However, we believe that the information collection requirements referenced in this rule, as summarized below, are exempt from the Paperwork Reduction Act of 1995 for the following reasons:

Sections 417.608, 417.609, 417.616, 417.617, 417.618, and 417.620 of this rule, as well as the retention and possible audit of health plan records related to expedited requests, are exempt because they are performed in the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or organizations, as outlined in 5 CFR 1320.4(a)(2).

Below is a summary of information collection requirements referenced in this rule, which we believe are exempt from the Paperwork Reduction Act of 1995:

Section 417.608 requires that the HMO or CMP must inform the enrollee of his or her right to and conditions for obtaining an expedited reconsidered determination and that failure to provide the enrollee with timely notification (72 hours in the case of certain expedited organization determinations) constitutes an adverse organization determination and may be appealed.

Section 417.609 requires an HMO or CMP to establish and maintain procedures for expediting certain organization determinations. This section also requires an HMO or CMP to notify an enrollee of an expedited organization determination as expeditiously as the enrollee's health condition requires, but within 72 hours of the request. Finally, the section requires an HMO or CMP to accept the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the process for making an organization determination. Section 417.616 requires that an enrollee may request a reconsideration of an organization determination and specifies the method and place for filing a request, which, in the case of a request for an expedited reconsideration, as provided for in § 417.617 (concerning certain expedited reconsiderations), is the HMO or CMP.

Section 417.617 requires that an enrollee may request a reconsideration of certain organization determinations. It also requires an HMO or CMP to have and maintain procedures for expediting reconsiderations when the longer time frames permitted in § 417.620(c) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This section also requires an HMO or CMP to accept the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the reconsideration. Finally, this section requires that, if the HMO or CMP defaults on its obligation to provide an expedited reconsideration, it must forward the file to us.

Section 417.618 requires an HMO or CMP to provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in

dispute, in person as well as in writing. In the case of expedited reconsiderations, the opportunity to present the evidence is more limited, and the organization must inform the enrollee, or authorized representative of the enrollee, of the conditions for submitting evidence.

Section 417.620 requires an HMO or CMP to issue the reconsidered determination to the enrollee, or submit the explanation and file to us within the time frames specified. Failure by the HMO or CMP to provide the enrollee with a reconsidered determination within the time limits described constitutes an adverse determination, and the HMO or CMP must submit the file to us.

Although we believe the information collection requirements referenced in this document are exempt under 5 CFR 1320.4(a)(2), as required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review. Organizations and individuals desiring to submit comments should send to both of the following addresses:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

VI. Response to Comments

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

VII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

For the reasons that follow, we believe that it would be contrary to the public interest to delay the revisions made in this rule until after a public notice and comment process has been completed. The first provision concerns an expedited appeals process for certain preservice denials. This expedited decision-making would occur if the determination that services are not needed or no longer needed could seriously jeopardize the life or health of the enrollee or could jeopardize the enrollee's ability to regain maximum function. While a number of Medicare-contracting plans have an expedited review process in place for Medicare enrollees, not all do, and the opportunity to obtain the reviews may not be consistently applied. For this reason, the growing number of enrollees who could be adversely affected by a slow process, and the fact that the situations addressed by this provision are of such a serious nature, we find that there is good cause to waive proposed rulemaking.

We have reached the same conclusion about the provision in this rule that merely clarifies the original intent of the definition of an organizational decision. This clarification, however, could help ensure that a beneficiary has the appeal rights that the Congress intended when services the beneficiary believes the HMO should provide are terminated.

Clearly, the intent of section 1876(c)(5)(B) of the Act and regulations set forth in part 417, subpart Q is that enrollees have the opportunity to seek administrative review when they believe the health plan is not furnishing any health service to which they are entitled. The Medicare Health Maintenance Organization/Competitive Medical Plan Manual indicates this intent in the ''Benefits'' chapter with a requirement that health plans notify enrollees of their appeal rights at discharge from a skilled nursing facility (see section 2112.1). However, growing reports from beneficiaries and beneficiary advocacy groups indicate that many enrollees are not being informed, or appropriately informed, of appeal rights when services are being discontinued and the enrollee disagrees that services are no longer covered. When this occurs, the critical protection against underutilization provided by the appeals process is not available to enrollees.

We believe that it would be contrary to the public interest to leave HMO enrollees at risk of being denied this critical protection in cases in which health care service is being terminated while a notice and comment process is being conducted.

Although we find that it is in the public interest to waive proposed rulemaking in these two areas, there are a number of other improvements to part 417, subpart Q that we are developing. While these revisions are important, we did not believe that the standard for waiving notice of proposed rulemaking was met or we found that public comment is needed for the policy changes under consideration. We anticipate that a second rule addressing improvements to the appeals protections of Medicare enrollees will be issued as a proposed regulation for comment in the near future.

VIII. Regulatory Impact Analysis

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, many Medicare-contracting HMOs, CMPs, and HCPPs are considered to be small entities.

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

We require all Medicare-contracting HMOs, CMPs, and HCPPs to maintain systems for making initial organization determinations and conducting reconsiderations. Systems must also be in place so that hospitalized beneficiaries who disagree with an HMO's or CMP's discharge determination are given a written notice of noncoverage with instructions for requesting immediate review by a PRO. In addition, the Medicare Health Maintenance Organization/Competitive Medical Plan Manual requires that beneficiaries being discharged from a nursing home be given advance written notice of noncoverage and procedures for requesting an appeal.

The clarification in the regulations that organization determinations include discontinuations of care, and are thus appealable, could increase the number of written notices issued and the number of reconsiderations that a

health plan must conduct. However, because the majority of services provided by any health plan are ambulatory care and hospital care—where it is already required by statute, as mentioned above, that notices be given any time a beneficiary disagrees that the hospitalization can be ''discontinued''—this regulation will primarily affect discontinuations involving skilled nursing facility, rehabilitation, and home health care. In addition, not all changes in level of care or terminations of coverage are disputed by the beneficiary. Having considered the limited applicability of this important clarification, we believe the increased volume of notices and reconsiderations, and the associated increase in expenses, will not have a significant impact on contracting health plans and HCPPs.

The new process for making expedited determinations and reconsiderations in certain circumstances requires a modification of existing appeals processes. In particular, contracting health plans that do not currently have the process must develop procedures, train staff, and maintain a daily availability of health professionals necessary to handle an anticipated but unpredictable volume of cases and the diverse, complex coverage issues usually associated with serious, time-sensitive situations. We anticipate a net increase in the number of determinations and reconsiderations due to an increase in standard cases as well as a new, but smaller volume of expedited reviews. This will occur because of the public attention being given to appeal and expedited review rights, and, to a lesser degree, because of fewer disenrollments. The volume increase is anticipated despite the substitution of expedited reviews for a number of standard determinations and reconsiderations. We do not believe, however, that the net increase in the cost of the appeals system resulting from this modification will have a significant impact on HMOs, CMPs, and HCPPs as set forth in the RFA.

We estimate, based on 450 health plans, that the clarification regarding discontinuations will cost approximately $30 million across all plans (100,000 new reconsiderations × $300 per notice). Our estimates for the expedited review requirements for the same number of plans are the following: $9 million for development and training ($20,000 per plan); $20 million for expedited organization determinations (50,000 determinations × $400 per expedited determination); and $10 million for expedited reconsiderations (12,500 reconsiderations × $800 per reconsideration). The total estimated economic impact is $69 million in the first year and $60 million annually thereafter.

There is no direct impact on the Medicare trust funds from these costs to the plans because there is no payment adjustment to Medicare managed care plans associated with this rulemaking.

We anticipate that, while this final rule will affect our administrative costs associated with the Medicare reconsideration contract, these costs will be negligible. The availability of expedited reviews and the clarification regarding discontinuations of care may have a significant impact on the reconsideration contractor's volume of reviews. However, although it is difficult to estimate, we believe the additional cost of this contract will not exceed $1 million per year.

The number of Medicare enrollees in health plans that also have commercial (and often Medicaid) enrollments, varies greatly. Thus, it is very difficult to estimate the average net costs to contracting health plans. Given the degree of variability, we estimate average net costs to entities to implement the provisions of this regulation to range between $20,000 and $200,000 annually. Entities with revenues of $5 million or less annually or nonprofit organizations are considered small entities for purposes of this regulation. Although 99 of 353 current contracting health plans are nonprofit and considered small entities for the purpose of preparing an RFA, we do not believe the annual cost to prepaid plans of implementing these provisions will be significant since net cost to these entities will not constitute a substantial portion of their annual revenues.

Therefore, we are not preparing analyses of this final rule for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or a significant economic impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects in 42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as set forth below:

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

Part 417 is amended as set forth below:

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

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

2. In § 417.600, the introductory text of paragraphs (b) and (b)(3) is republished, and paragraph (b)(3)(ii) is revised to read as follows:

§ 417.600 Basis and scope.

* * * * *

(b) *Scope.* This subpart sets forth—

* * * * *

(3) The responsibility of the HMO or CMP—

* * * * *

(ii) To ensure all Medicare enrollees have a complete written explanation of their grievance and appeal rights, the availability of expedited reviews, the steps to follow, and the time limits for each procedure; and

* * * * *

3. In § 417.604, paragraph (b)(4) is revised to read as follows:

§ 417.604 General provisions.

* * * * *

(b) Limits on applicability of this subpart.

* * * * *

(4) Physicians and other individuals who furnish services under arrangement with an HMO or CMP have no right of appeal under this subpart, except as provided in §§ 417.609(c)(4) and 417.617(c)(4), which allow physicians and other health professionals to act on behalf of an enrollee in time-sensitive situations when an organization determination or reconsideration is being requested.

* * * * *

4. In § 417.606, the introductory text to paragraph (a) is republished, and new paragraph (a)(4) is added to read as follows:

§ 417.606 Organization determinations.

(a) *Actions that are organization determinations.* An organization determination is any determination made by an HMO or CMP with respect to any of the following:

* * * * *

(4) Discontinuation of a service (such as a skilled nursing facility discharge), if the enrollee disagrees with the determination that the service is no longer medically necessary.

* * * * *

5. In § 417.608, the introductory text of paragraph (b) is republished, and paragraphs (a), (b)(2), and (c) are revised to read as follows:

§ 417.608 Notice of adverse organization determination.

(a) If an HMO or CMP makes an organization determination that is partially or fully adverse to the enrollee, it must notify the enrollee of the determination—

(1) Within 60 days of receiving the enrollee's request for payment for services; or

(2) As specified in § 417.609(c)(3) for expedited organization determinations.

(b) The notice must—

* * * * *

(2) Inform the enrollee of his or her right to a reconsideration, including the right to and conditions for obtaining an expedited reconsidered determination.

(c) The failure to provide the enrollee with timely notification of an adverse organization determination as specified in paragraph (a) of this section or in § 417.609(b) (concerning time frames for expediting certain organization determinations) constitutes an adverse organization determination and may be appealed.

6. A new § 417.609 is added to read as follows:

§ 417.609 Expediting certain organization determinations.

(a) An enrollee, or an authorized representative of the enrollee, may request that an organization determination as defined in §§ 417.606(a)(3) and (a)(4) be expedited. The request may be made orally to the HMO or CMP.

(b) The HMO or CMP must maintain procedures for expediting organization determinations when, upon request from an enrollee or authorized representative of the enrollee, the organization decides that making the determination according to the procedures and time frames set forth in § 417.608(a)(1) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(c) The procedures must include the following:

(1) Receipt of oral requests, followed by written documentation of the oral requests.

(2) Prompt decision-making regarding whether the request will be expedited, or handled within the standard time frame set forth at § 417.608(a)(1), including notification of the enrollee if the request is not expedited.

(3) Notification of the enrollee, and the physician as appropriate, as expeditiously as the enrollee's health condition requires, but within 72 hours of the request. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

(i) Notification must comply with § 417.608(b), concerning the content of a notice of adverse organization determination.

(ii) If the initial notification is not in writing, written confirmation must be mailed to the enrollee within 2 working days.

(iii) In cases for which the HMO or CMP must receive medical information from a physician or provider not affiliated with the HMO or CMP, the time standard begins with receipt of the information.

(4) Granting the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the enrollee's request.

7. Section 417.614 is revised to read as follows:

§ 417.614 Right to reconsideration.

Any party who is dissatisfied with an organization determination or with one that has been reopened and revised may request reconsideration of the determination in accordance with the procedures of § 417.616, concerning a request for reconsideration, or § 417.617, concerning certain expedited reconsiderations.

8. In § 417.616, the introductory text to paragraph (a) is republished, and a new paragraph (a)(4) is added to read as follows:

§ 417.616 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with—

* * * * *

(4) In the case of a request for an expedited reconsideration, as provided for in § 417.617 (concerning certain expedited reconsiderations), the HMO or CMP.

* * * * *

9. A new § 417.617 is added to read as follows:

§ 417.617 Expediting certain reconsiderations.

(a) An enrollee, or an authorized representative of the enrollee, may request that a reconsideration be expedited. The request may be made orally to the HMO or CMP.

(b) The HMO or CMP must maintain procedures for expediting reconsiderations when, upon request from an enrollee or an authorized representative of the enrollee, the organization decides that the longer time frames permitted in § 417.620(c) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(c) The procedures must comply with the requirements for reconsidered determinations set forth in §§ 417.614 through 417.626 and include the following items:

(1) Receipt of oral requests, followed by written documentation of the oral requests.

(2) Prompt decision-making regarding whether the request will be expedited or handled within the standard time frame of § 417.620(c), including notification of the enrollee if the request is not expedited.

(3) Notification of the enrollee, and the physician as appropriate, as expeditiously as the enrollee's health condition requires, but within 72 hours of the request. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

(i) Notification must comply with § 417.624(b), concerning the content of a notice of a reconsidered determination.

(ii) If the initial notification is not in writing, written confirmation must be mailed to the enrollee within 2 working days.

(iii) In cases for which the HMO or CMP must receive medical information from a physician or provider not affiliated with the HMO or CMP, the time standard begins with receipt of the information.

(4) Granting the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the request.

8. Section 417.618 is revised to read as follows:

§ 417.618 Opportunity to submit evidence.

The HMO or CMP must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short time frames for making decisions, and

the organization must inform the enrollee, or the authorized representative of the enrollee, of the conditions for submitting the evidence.

9. In § 417.620, paragraphs (c), (d), and (e) are revised to read as follows:

§ 417.620 Responsibility for reconsideration; time limits.

* * * * *

(c) The HMO or CMP must issue the reconsidered determination to the enrollee, or submit the explanation and file to HCFA within 60 calendar days from the date of receipt of the request for reconsideration. In the case of an expedited reconsideration, the HMO or CMP must issue the reconsidered determination as specified in § 417.617(c)(3) or submit the explanation and file to HCFA within 24 hours of its determination, the expiration of the 72-hour review period, or the expiration of the extension.

(d) For good cause shown, HCFA may allow extensions to the time limit set forth in paragraph (c) of this section.

(e) Failure by the HMO or CMP to provide the enrollee with a reconsidered determination within the time limits described in paragraph (c) of this section or to obtain a good cause extension described in paragraph (d) of this section constitutes an adverse determination, and the HMO or CMP must submit the file to HCFA.

* * * * *

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

Dated: March 19, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: April 11, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–11182 Filed 4–29–97; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–54; RM–8989]

Radio Broadcasting Services; Poplar Bluff, Missouri

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action in this document allots Channel 223A to Poplar Bluff, Missouri, as that community's fifth FM broadcast service in response to a petition filed by The Word of Victory Outreach Center, Inc. *See* 62 FR 6929, February 14, 1997. The coordinates for Channel 223A at Poplar Bluff are 36–45–30 and 90–23–54. With this action, this proceeding is terminated.

DATES: Effective June 9, 1997. The window period for filing applications for Channel 223A at Poplar Bluff, Missouri, will open on June 9, 1997, and close on July 10, 1997.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 97–54, adopted April 16, 1997, and released April 25, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC. 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by adding Channel 223A at Poplar Bluff.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–11133 Filed 4–29–97; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96–217; RM–8880]

Radio Broadcasting Services; Humboldt, KS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Michael Sutcliffe, allots Channel 232C3 to Humboldt, Kansas, as the community's first local aural transmission service. *See* 61 FR 57359, November 6, 1996. Channel 232C3 can be allotted to the community in compliance with the Commission's minimum distance separation requirements with a site restriction of 19.5 kilometers (12.1 miles) southwest to avoid a short-spacing conflict with the licensed site of Station KFKF (FM), Channel 231C, Kansas City, Kansas. The coordinates for Channel 232C3 at Humboldt are 37–39–50 NL and 95–33–31 WL. With this action, this proceeding is terminated.

DATES: Effective June 9, 1997. The window period for filing applications will open on June 9, 1997, and close on July 10, 1997.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 96–217, adopted April 16, 1997, and released April 25, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Kansas, is amended by adding Humboldt, Channel 232C3.

Federal Communications Commission

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–11131 Filed 4–29–97; 8:45 am]

BILLING CODE 6712–01–P