August 10, 1999), because it merely proposes to approve a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order.

This proposed rule to approve revisions to the Virginia SIP that update the definition of ''volatile organic compound'' does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: March 29, 2006.

**Donald S. Welsh,**

*Regional Administrator, Region III.*

[FR Doc. E6–4940 Filed 4–4–06; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Parts 405, 412, 422, and 489

**[CMS–4105–P]**

**RIN 0938–AN85**

## Medicare Program; Notification Procedures for Hospital Discharges

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule sets forth new requirements for hospital discharge notices under both original Medicare and the Medicare Advantage program. This proposed rule would require hospitals to comply with a two-step notice process when discharging patients from the hospital level of care that is similar to the notice requirements regarding service terminations applicable to home health agencies, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, and hospices.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 5, 2006.

**ADDRESSES:** In commenting, please refer to file code CMS–4105–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4105–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4105–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

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

**FOR FURTHER INFORMATION CONTACT:** Eileen Zerhusen, (410) 786–7803, (For issues related to Original Medicare).

Tim Roe, (410) 786–2006, (For issues related to Medicare Advantage).

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4105–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments

received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

**I. Background**

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

On April 4, 2003, we published a final rule (68 FR 16652) in the **Federal Register** implementing changes to the Medicare+Choice (now Medicare Advantage (MA)) program in connection with the 1993 *Grijalva* v. *Shalala* class action lawsuit, which was brought by beneficiaries enrolled in Medicare risk-based managed care organizations. That final rule requires home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) to comply with a two-step notice process in connection with the termination of Medicare coverage of services to an enrollee in an MA plan. HHAs, SNFs, and CORFs must deliver a standardized, largely generic notice that informs each MA plan enrollee when Medicare coverage ends and explains the enrollee's appeal rights. If the enrollee is dissatisfied with the decision to terminate services, the MA organization is obligated to deliver a detailed notice providing specific information about the organization's decision to terminate services.

On November 26, 2004, as part of our implementation of changes to the Medicare appeals process required by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), we published a final rule in the **Federal Register** (69 FR 69252), establishing a similar, two-step notice process for the termination of Medicare coverage of SNF, HHA, CORF, and hospice services to original Medicare beneficiaries. As specified under these rules, which took effect July 1, 2005, HHAs, SNFs, CORFs, and hospices (and swing beds by instruction, see CMS Manual System Pub 100–04 Medicare Claims Processing, Transmittal 594, Change Request 3903, and dated June 24, 2005) must provide a standardized, largely generic notice to each beneficiary before a service termination. Similar to the MA notice, the standardized notice of non-coverage informs the beneficiary when Medicare coverage ends and includes information about the beneficiary's appeal rights. In situations where a beneficiary chooses to exercise his or her right to an expedited appeal, a detailed notice is furnished before the termination of services.

For both MA enrollees and beneficiaries in original Medicare, separate requirements apply for hospital discharges. (Note that in the hospital process, we generally use the term ''discharge'' rather than the phrase ''termination of services,'' as used in the non-hospital process.) In a proposed rule published in the **Federal Register** on January 24, 2001 (66 FR 7593), we had proposed to require hospitals to provide a notice of appeal rights and the reasons for the discharge to all hospital inpatients (including both original Medicare beneficiaries and MA enrollees) at least 1 day before the effective date of discharge. Hospitals opposed this proposal and commented that requiring hospitals to deliver a second, more detailed notice of appeal rights to all patients (the first being the ''Important Message from Medicare,'' which is a standard notice issued at or about the time of the patient's admission, as required under section 1866(a)(1)(M) of the Social Security Act (the Act)) would pose a significant administrative burden. In response to those comments, we determined that a detailed notice was not necessary in every case. Therefore, in the April 4, 2003 final rule, we eliminated the requirement that all patients receive a detailed notice.

Currently, hospitals do not follow the same two-step discharge notice process that applies to HHAs, SNFs, CORFs, and hospices. In the November 26, 2004 final rule, we left largely unchanged our longstanding requirement that, consistent with § 412.42(c)(3), a hospital must provide a hospital-issued notice of noncoverage (HINN) to any original Medicare beneficiary that expresses dissatisfaction with an impending hospital discharge. Hospitals also continue to be required to deliver the Important Message from Medicare to all Medicare beneficiaries at or about the time of admission. Similar to the policy in original Medicare, MA organizations are required to provide enrollees with a notice of noncoverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.

**II. Provisions of the Proposed Rule**

[If you choose to comment on issues in this section, please include the caption ''PROVISIONS OF THE PROPOSED RULE'' at the beginning of your comments.]

*Proposed Two-Step Notice Process*

This proposed rule would establish a two-step notice process for hospital discharges that is similar to the process in effect for service terminations in HHAs, SNFs, CORFs, and hospices. We propose this change because we believe that the two-step notice process, including a standardized, largely generic notice of non-coverage, is helpful to beneficiaries. We also believe that the new approach we are proposing would not be overly burdensome for providers or MA organizations. Further, because all Medicare beneficiaries who are hospital inpatients have the right to an expedited review, we also believe it is preferable that these beneficiaries have the same notice of appeal rights to which other beneficiaries are entitled. Extending the two-step notice process to inpatient hospitals would provide a more consistent approach to communicating appeal rights to beneficiaries in both original Medicare and MA and across provider settings.

For these reasons, we are proposing to require hospitals to deliver, prior to discharge, a standardized, largely generic notice of non-coverage to each Medicare beneficiary whose physician concurs with the discharge decision. The notice would contain substantially the same information that is contained in the standardized notices that HHAs, SNFs, CORFs, and hospices must provide, including the prospective discharge date and a description of appeal rights. The notice processes as specified in § 405.1208, addresses the situation where the hospital requests a Quality Improvement Organization (QIO) review because the physician does not concur with the discharge decision, would remain unchanged. However, we are proposing one technical correction to § 405.1208(e)(1).

HHAs, SNFs, and CORFs generally must provide the standardized notice to both original Medicare beneficiaries and MA enrollees at least 2 days in advance of the service termination. Hospices

must provide the standardized notice to original Medicare beneficiaries in the same general timeframe. (Hospice services are not part of the benefits covered by MA plans, so MA rules for the delivery of a standardized service termination notice do not apply to hospices.) The 2-day rule is intended to balance the demands of provider practice patterns with potential beneficiary liability in those settings.

However, section 1869(c)(3)(C)(iii)(III) of the Act provides that hospitals generally may not charge beneficiaries for services provided before noon of the day after a QIO issues its decision. Therefore beneficiary liability is not as significant an issue in this setting. Given the greater volatility of hospital discharge patterns, we propose that hospitals be required to provide the standardized notice on the day before the planned discharge from any inpatient hospital stay. As specified in section 1869(c)(3)(C)(iii)(III) of the Act, if a beneficiary requests a QIO review no later than noon of the day after receiving a notice, he or she is not financially liable (other than for cost sharing) until at least noon of the day after the QIO's decision. Beneficiaries who do not dispute the discharge decision can be held liable as of the date given on the notice.

In proposing to require a simple, standardized notice for hospital discharges, we would maintain the requirement for delivery of a more detailed notice in those relatively rare situations where beneficiaries wish to dispute the discharge. However, rather than using the NODMAR or the HINN as a discharge notice for MA enrollees and original Medicare beneficiaries, respectively, the hospitals would issue a single detailed notice similar to that used in the HHA, SNF, CORF and hospice settings. We also would leave unchanged beneficiaries' claim appeal rights (both under original Medicare and MA) with respect to hospital discharges.

Our proposal to require a two-step notice process is intended only to provide hospital inpatients with the same two-step notice of appeal rights afforded to beneficiaries in other settings. Similar to the expedited review procedures for other providers, a beneficiary would be instructed to contact the QIO to request an expedited review if he or she wishes to dispute the discharge, at which point the beneficiary would receive the second, more detailed notice. We welcome suggestions on the appropriate interaction between these notices and the QIO review process, given the proposed introduction of the new standardized notices.

As noted above, we would require hospitals to deliver the notice on the day before discharge. We expect that the hospital would deliver the standardized notice as soon as the discharge decision is made (or in the case of a discharge decision by an MA organization, as soon as the discharge decision is communicated to the hospital). By requiring the standardized notice to be delivered on the day before discharge, a beneficiary would have at least 1 night to think about the discharge decision and decide whether to pursue an expedited review, consistent with 1869(c)(3)(C)(iii)(III) of the Act.

In proposing this approach, our goal is to design hospital notice procedures that balance a beneficiary's need to be informed about his or her appeal rights in an appropriate manner, and at an appropriate time, without imposing unnecessary burdens on hospitals. The notification process also needs to accommodate the statutory requirements associated with the ''Important Message from Medicare'', which now provides much of the same information about appeal rights, although earlier in the hospital stay and not in an individualized form. We welcome comments on ways to achieve an appropriate balance of interests.

For example, we would appreciate comments on whether there are exceptional circumstances under which a hospital should be able to deliver the standardized notice on the day of discharge (for example, in cases of a 1-day stay). For an anticipated 2 or 3-day stay, would it be necessary to deliver both the ''Important Message from Medicare'' at admission and the standardized discharge notice just prior to discharge given that the notices would be delivered at virtually the same time? In addition, we welcome comments on the maximum time before the end of Medicare-covered services the discharge notice may be delivered.

In general, we are interested in obtaining commenters' input on all aspects of the hospital discharge notice process, both the process proposed here and the current process, in order to establish the most efficacious process possible for hospitals, beneficiaries, and MA plans.

Although this proposal bears some resemblance to the provisions set forth in our January 24, 2001 proposed rule (66 FR 7593), the new proposal incorporates significant advantages. Most notably, this proposal would require the delivery of a standardized notice containing only three beneficiary-specific elements—(1) the beneficiary's name; (2) the date covered services would end; and (3) the date financial liability would begin—with all other information standardized. We believe that by proposing to require the delivery of a largely generic notice in all discharge situations, the notice delivery burden on hospitals would be substantially less than under our previous proposal, without any adverse effect on patient rights. Only when a beneficiary contacts the QIO to request immediate review would a detailed notice have to be provided. However, a hospital may provide a detailed notice to the beneficiary who requests more information before contacting the QIO.

*Proposed § 405.1205*

To implement the changes we are proposing, we would add a new § 405.1205, to require hospitals to deliver a standardized, largely generic notice to original Medicare beneficiaries. The provisions of proposed § 405.1205 substantially parallel the provisions of § 405.1200, applicable to HHAs, SNFs, CORFs and hospices, as set forth in the November 26, 2004 final rule. We are proposing in § 405.1205 that hospitals would be required to deliver a standardized notice of non-coverage to beneficiaries on the day before discharge from an inpatient hospital stay. The notice would include: (1) The date that coverage ends; (2) the beneficiary's right to an expedited determination including a description of the expedited determination process as specified in § 405.1206, and the availability of other appeal procedures if the beneficiary fails to meet the deadline for an expedited determination; (3) the beneficiary's right to receive more information as provided in § 405.1206(e); (4) the date that financial liability for continued services begins; and (5) any other information required by CMS. Proposed § 405.1205 would specify that if a beneficiary refuses to sign the standardized notice to acknowledge receipt, the hospital may annotate its notice to indicate the refusal. The date of refusal would be considered the date of receipt of the notice. The hospital would be required to maintain a copy of the signed or annotated notice.

As with existing notice requirements, hospitals generally must determine whether a patient is capable of comprehending and signing the notice. Hospitals must comply with applicable State laws and CMS guidance regarding the use of representatives and have procedures in place to determine an appropriate representative. (See CMS Manual System Pub 100–04 Medicare Claims Processing, Transmittal 594, Change Request 3903, and dated June 24, 2005.)

*Proposed § 405.1206*

Similarly, we propose to replace existing § 405.1206 with a new provision that is more consistent with the expedited process requirements for home health, hospice, skilled nursing, and CORF settings set forth in § 405.1202. Proposed § 405.1206 contains the responsibilities of the hospitals, QIOs, and beneficiaries relative to the expedited determination process. We believe that making these conforming changes to promote uniformity across provider types would be helpful to beneficiaries.

In proposed § 405.1206, hospitals would be required to deliver a detailed notice to beneficiaries if beneficiaries exercise their right to an expedited review. The hospital would be required to deliver the detailed notice by the close of business of the day of the QIO's notification of the beneficiary's request for an expedited review. (Note that because hospitals operate 24 hours a day, ''close of business'' generally would be considered as the end of the administrative business day.)

The detailed notice would include: (1) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered; (2) 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 beneficiary may obtain a copy of the Medicare policy; (3) facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and (4) any other information required by CMS. The information that is inserted on the detailed notice should be individualized and written in plain language to facilitate beneficiary understanding.

*Proposed Definitions Pertaining to § 405.1206 and § 405.1206*

For purposes of § 405.1204, § 405.1205, § 405.1206 and § 405.1208, we define the term ''hospital'' at proposed § 405.1205(a)(1) to mean any free-standing facility or unit providing services at the inpatient hospital level of care, whether that care is short term or long term, acute or non-acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care, or providing a broader spectrum of services. This means all hospitals paid under the Inpatient Acute Prospective Payment System (IPPS), sole community hospitals/regional referrals centers or any other type of hospital receiving special consideration under IPPS (for example, Medicare dependent hospitals, Indian Health Service hospitals); hospitals not under IPPS, including, but not limited to: hospitals paid under State or United States territory waiver programs, hospitals paid under certain demonstration projects cited in regulation (§ 489.34), rehabilitation hospitals, long-term care hospitals, psychiatric hospitals, critical access hospitals, children's hospitals, and cancer hospitals. Swing beds in hospitals are excluded, because they are considered to be a lower level of care. Religious nonmedical health care institutions are also excluded.

We also propose defining the term ''discharge'' at § 405.1205(a)(2) as a formal release from the hospital level of care. For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, a discharge from the inpatient hospital level of care is a formal release of a beneficiary from the inpatient hospital level of care or, a complete cessation of coverage of the inpatient hospital level of care. This includes when the patient is physically discharged from the hospital as well as when the patient is discharged ''on paper''—meaning the patient remains in the hospital but at a lower level of care (for example, moved to a swing bed).

*Proposed § 422.620 and § 422.622*

To implement these changes for MA enrollees, we propose to replace the existing NODMAR notice and review regulations in § 422.620 and § 422.622 with new regulations substantially similar to the notice and review requirements for HHAs, SNFs, and CORFs under § 422.624 and § 422.626. In addition, we would reference the same definition of hospitals that is in proposed § 405.1205. We believe that the hospital is in a better position than the MA organization to carry out the routine delivery of the generic discharge notice to enrollees.

However, we propose that responsibility for delivery of the detailed notice would still rest with the MA organization, who may delegate the authority for making the discharge decision, but not shift liability, to the hospital. For this reason, proposed § 422.620 would require the hospitals to deliver the generic notice to all inpatient enrollees, and § 422.622 would require the MA organization to deliver the detailed notice to those patients who request an immediate QIO review of the discharge decision.

As specified in proposed § 422.620, hospitals would be required to deliver a standardized notice of non-coverage to MA enrollees on the day before discharge from an inpatient hospital stay. The notice would include: (1) The date that coverage ends; (2) a description of the enrollee's right to an immediate QIO review as specified in § 422.622, including information about how to contact the QIO, the availability of other MA appeal procedures if the enrollee fails to meet the deadline for immediate QIO review, and the fact that immediate QIO review would not be granted unless the enrollee disagrees with the discharge from the inpatient hospital level of care; (3) the enrollee's right to receive more information as provided in § 422.622(c); and (4) the date that financial liability for continued services begins.

Proposed § 422.620 also would specify that if an MA enrollee refuses to sign the standardized notice to acknowledge receipt, the hospital would annotate its notice to indicate the refusal. The date of refusal would be considered the date of receipt of the notice. The hospital would be required to maintain a copy of the signed or annotated notice.

Again, hospitals should have procedures in place to determine if an enrollee is capable of comprehending and signing the notice, and follow applicable State law regarding use of a representative. Further instructions regarding use of a representative can be found in Chapter 13, Section 60 of the Medicare Managed Care Manual.

As specified in proposed § 422.622, MA organizations would be required to deliver a detailed notice to enrollees if enrollees choose to exercise their right to an immediate QIO review. The detailed notice would include: (1) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered; (2) 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; (3) 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; and (4) any other information required by CMS. The MA organization would be required to deliver the detailed notice by the close of business of the day of the QIO's notification of the enrollee's request for an immediate QIO review. The information that is inserted on the detailed notice should be individualized and written in plain language to facilitate enrollee understanding.

Furthermore, we also propose to replace existing § 422.622 with a new provision consistent with the expedited process requirements for home health, skilled nursing and CORF settings in § 422.626. Proposed § 422.622 contains the procedural responsibilities of the MA organizations, hospitals, and QIOs as well as any possible liability for hospitals and MA organizations during the expedited determination process. We believe that making these conforming changes to promote uniformity across provider types would be helpful to beneficiaries.

The notices proposed in this proposed rule would be subject to public review and comment through the Office of Management and Budget (OMB) Paperwork Reduction Act process before implementation. If you wish to comment on these notices see CMS–10066, ''Agency Information Collection Activities; Proposed Collection; Comment Request'' published elsewhere in this issue.

*Conforming Changes Proposed to § 489.27 and § 412.42*

In conjunction with the proposed hospital notice provisions, we are proposing to make conforming changes to two related existing regulatory provisions. First, we would amend the provider agreement requirements in § 489.27(b) to cross-reference the proposed notice requirements. Thus, proposed § 489.27(b) would specify that delivery of the hospital discharge notices consistent with proposed § 405.1205 and § 422.620 is required as part of the Medicare provider agreement. This parallels the implementation approach used for expedited review notices by other providers, such as HHAs and SNFs. The other conforming change would affect § 412.42(c), which involves limitations on charges to beneficiaries in hospitals operating under the prospective payment system.

As revised, proposed § 412.42(c)(3) would simply include a cross-references to the notice and appeal provisions set forth in § 405.1205 and § 405.1206. This change would clearly establish that the provision of the appropriate expedited review notices would be one of the prerequisites before a hospital could charge a beneficiary for continued hospital services. We welcome comments on these conforming changes.

**III. Collection of Information Requirements**

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

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

The information collection requirement associated with administering the hospital discharge notice is subject to the PRA.

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

*Section 405.1205 Notifying Beneficiaries of Discharge From Inpatient Hospital Level of Care*

For any discharge from the inpatient hospital level of care, the hospital must notify the beneficiary in writing of the impending non-coverage and discharge. The hospital must use a standardized, largely generic notice, required by the Secretary, in accordance with the requirements and procedures set forth in this section.

Since we have developed a standardized format for the notice, and the notice would be disseminated during the normal course of related business activities, we estimate that it would take hospitals 5 minutes to deliver each notice. In 2002 there were approximately 10.9 million fee-for-service Medicare inpatient hospital discharges. The total annual burden associated with this proposed requirement is 908,333 hours.

*Section 405.1206 Expedited Determination Procedures for Inpatient Hospital Level of Care*

Section 405.1206(b) requires any beneficiary wishing to exercise the right to an expedited determination to submit a request, in writing or by telephone, to the QIO that has an agreement with the hospital. We project that 2 percent of the 10.9 million fee-for-service beneficiaries, (that is, 218,000 beneficiaries) will request an expedited determination. (We note that this estimate may be high since our experience with the non-hospital expedited determination process in both original Medicare and MA has shown that approximately 1 percent of patients request an expedited review.)

The burden associated with this requirement is the time and effort it would take for the beneficiary to either write or call the QIO to request an expedited determination. We estimate it would take 5 minutes per request. Therefore, the total estimated burden hours associated with this requirement is 18,166 hours.

Section 405.1206(e) requires hospitals to deliver a detailed notice of discharge to the beneficiary and to make available to the QIO (and to the beneficiary upon request) a copy of that notice and any necessary supporting documentation. For these 218,000 cases, we estimate that it would take providers 60 to 90 minutes to prepare the detailed termination notice and to prepare a case file for the QIO. Based on 218,000 cases at 90 minutes, the total annual burden associated with this proposed requirement is approximately 327,000 hours.

*Section 422.620 Notifying Enrollees of Discharge From Inpatient Hospital Level of Care*

For any discharge from an inpatient hospital, the hospital must notify the enrollee in writing of the impending non-coverage and discharge. The hospital must use a standardized, largely generic notice, required by the Secretary, in accordance with the requirements and procedures set forth in this section.

Again, we estimate that it would take hospitals 5 minutes to deliver each notice. In 2002 there were approximately 1.6 million MA inpatient hospital discharges. The total annual burden associated with this proposed requirement is 133,333 hours.

*Section 422.622 Requesting Immediate QIO Review of Decision To Discharge From Inpatient Hospital Level of Care*

This section states that an enrollee who wishes to appeal a determination by an MA organization or hospital that inpatient care is no longer necessary, may request QIO review of the determination. On the date the QIO receives the enrollee's request, it must notify the MA organization that the enrollee has filed a request for immediate review. The MA in turn must deliver a detailed notice to the enrollee.

We project that 2 percent of affected individuals (that is, 32,000 beneficiaries) will request an expedited determination. We estimate that it will take 5 minutes for an enrollee who chooses to exercise his or her right to an

expedited determination to contact the QIO. For these 32,000 cases, the total estimated burden hours is 26,666 hours.

As specified in § 422.622(c) and (d), MA plans would be required under this rule to deliver a detailed notice to the beneficiary and to make a copy of that notice and any necessary supporting documentation available to the QIO (and to the beneficiary upon request). We estimate that it would take plans 60 to 90 minutes to prepare the detailed notice and to prepare a case file for the QIO. Based on 32,000 cases at 90 minutes, the total annual burden associated with this proposed requirement is approximately 48,000 hours.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto, CMS–4105–P, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–4105–P, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

## IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## V. Regulatory Impact

[If you choose to comment on issues in this section, please include the caption ''REGULATORY IMPACT'' at the beginning of your comments.]

### *A. Overall Impact*

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule would not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of this RFA, all providers affected by this regulation are considered to be small entities.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. (We estimate a total cost of approximately $7000 a provider as discussed below.) Although a regulatory impact analysis is not mandatory for this proposed rule, we believe it is appropriate to discuss the possible impacts of the new discharge notice on beneficiaries, enrollees, and hospitals, regardless of the monetary threshold of that impact. Therefore, a brief voluntary discussion of the anticipated impact of this proposed rule is presented below.

In addition, section 1102(b) of the Act requires us 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We do not expect these entities to be significantly impacted.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This proposed rule does not require an assessment under the Unfunded Mandates Reform Act.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation would not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

### *B. Overview of the Changes*

This proposed rule sets forth new requirements for hospital discharge notices for all Medicare inpatient hospital discharges. This proposed rule specifies that hospitals must issue a standardized, largely generic notice of non-coverage to all Medicare beneficiary inpatients, prior to discharge from the inpatient hospital level of care, followed by a detailed notice if the beneficiary requests QIO review of the decision. As discussed in detail above, these notices would replace existing notice requirements, under which beneficiaries receive detailed notices only when they express dissatisfaction with a hospital's discharge decision. We also propose conforming changes to the expedited review process for hospitals to promote uniformity among requirements applicable to different provider types. In general, we believe that these changes would enhance the rights of Medicare beneficiaries without imposing any significant or undue financial burdens on hospitals.

### *C. Notifying Beneficiaries and Enrollees of Discharge From the Inpatient Hospital Level of Care (§ 405.1205 and § 422.620)*

We project that providers would be responsible for delivering a standardized, largely generic notice of non-coverage to approximately 12.5 million Medicare beneficiaries a year. This includes about 10.9 million fee-for-service beneficiaries and 1.6 million MA enrollees. The generic notice of discharge would require only the insertion of the beneficiary or enrollee's name, date that coverage ends, and date that financial liability for continued hospital services begins. We estimate that it would take no more than 5 minutes to deliver a notice, at a per-notice cost of no more than $2.50 (based on a $30 per hour rate if the notice is delivered by health care personnel). Based on an estimated 12.5 million notices annually, we estimate the

aggregate cost of delivering these new notices to be roughly $31.2 million. Since there are roughly 6000 affected hospitals, the average costs associated with this provision would be about $5,200 per provider.

*D. Providing Beneficiaries and Enrollees With a Detailed Explanation of the Hospital Discharge Decision (§ 405.1206 and § 422.622)*

We project that providers would be responsible for delivering detailed notices to approximately two percent of the 12.5 million Medicare recipients a year or 250,000 beneficiaries and enrollees. The detailed notice would require a detailed explanation of why services are either no longer reasonable and necessary or are no longer covered; a description of any relevant Medicare (and Medicare Advantage as applicable) coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy; facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and any other information required by CMS.

We estimate that it would take approximately 60 to 90 minutes to fill out and deliver a detailed notice, and make available to the QIO (and to the beneficiary upon request) copies of the notices and any necessary supporting documentation. The per-notice cost would be no more than $45 and is based on a $30 per hour rate if the notice is prepared and delivered by health care personnel. Based on an estimated 250,000 notices annually, we estimate the aggregate cost of delivering these notices to be roughly $11,250,000. This estimate may be high since, in many cases, non-professional staff would be asked to make copies of medical records. Since there are roughly 6000 affected hospitals, the average costs associated with this provision would be about $1875 per provider.

We do not anticipate that the provisions of this proposed rule would have a significant financial impact on individual hospitals. We note that the actual discharge notices must be approved through OMB's Paperwork Reduction Act process and are also subject to public comment. We intend to publish the draft standardized notices concurrent with the publication of this proposed rule. For more information on the PRA process see Section III of this proposed rule.

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

**List of Subjects**

*42 CFR Part 405*

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

*42 CFR Part 412*

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

*42 CFR Part 422*

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare Advantage, 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 Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

## PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 1102, 1861, 1862(a), 1871, 1874, 1881 and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

## Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

2. Section 405.1205 is added to read as follows:

### § 405.1205 Notifying beneficiaries of discharge from inpatient hospital level of care.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1204, 405.1205, 405.1206, and 405.1208, the term hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, a discharge from the inpatient hospital level of care is a formal release of a beneficiary from the inpatient hospital level of care or, a complete cessation of coverage within the inpatient hospital level of care.

(b) *Advance written notice of non-coverage of services at the inpatient hospital level of care.* Before any discharge from the inpatient hospital level of care, in cases where the physician concurs with the discharge decision, the hospital must deliver valid written notice of non-coverage and the hospital's decision to discharge. The hospital must use a standardized, generic notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A hospital must notify the beneficiary of non-coverage and the hospital's decision to discharge the beneficiary on the day before the planned discharge.

(2) *Content of the notice.* The generic notice of non-coverage must include the following information:

(i) The date that coverage of inpatient hospital services ends.

(ii) The beneficiary's right to request an expedited determination including a description of the process under § 405.1206, and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination.

(iii) A beneficiary's right to receive additional detailed information in accordance with § 405.1206(e).

(iv) The date that the beneficiary's financial liability for continued inpatient hospital services begins.

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the generic notice of non-coverage described in this section is valid if—

(i) Except as provided in paragraph (b)(4) of this section, the beneficiary (or the beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

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

(4) *If a beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

3. Section § 405.1206 is revised to read as follows:

**§ 405.1206 Expedited determination procedures for inpatient hospital level of care.**

(a) *Beneficiary's right to an expedited determination by the QIO for an inpatient hospital discharge.* A beneficiary has a right to request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be in writing or by telephone, by no later than noon of the day after receipt of the notice of non-coverage as set forth in § 405.1205.

(2) The beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The beneficiary may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) A beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraphs (f)(1) and (f)(2) of this section, as applicable.

(5) A beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, and remains in the hospital without coverage, still may request an expedited review at any time during the hospitalization. The QIO will issue a decision in accordance with paragraph (d)(6)(ii) of this section, however, the financial liability protection under paragraph (f)(1) and (f)(2) of this section does not apply.

(6) A beneficiary who fails to make a timely request for an expedited determination in accordance with paragraph (b)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after receipt of the generic notice of non-coverage, or at any time for good cause. The QIO will issue a decision in accordance with paragraph (d)(6)(iii) of this section; however, the financial liability protection under paragraph (f)(1) and (f)(2) of this section does not apply.

(c) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of proof rests with the hospital to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. The hospital should supply any and all information that a QIO requires to sustain the hospital's discharge decision, consistent with paragraph (e)(2) of this section.

(d) *Procedures the QIO must follow.* (1) On the day the QIO receives the request for an expedited determination under paragraph (b) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice of non-coverage consistent with § 405.1205(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the beneficiary (or the beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the discharge is appropriate.

(6) *Notification.* (i) When the beneficiary requests an expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination by close of business of the first day after it receives all requested pertinent information.

(ii) When the beneficiary makes an untimely request consistent with paragraph (b)(5) of this section, and remains an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 2 calendar days following receipt of the request and pertinent information.

(iii) When the beneficiary makes an untimely request for an expedited determination consistent with paragraph (b)(6) of this section, and is no longer an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(7) If the QIO does not receive the information needed to sustain a hospital's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the hospital may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues an expedited determination, the QIO must notify the beneficiary, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services.

(iv) Information about the beneficiary's right to a reconsideration of the QIO's determination as set forth in § 405.1204, including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of hospitals.* (1) When a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary by close of business of the day of the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation why 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 beneficiary may obtain a copy of the Medicare policy.

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

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required as specified in § 405.1205(b) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the hospital of the request for an expedited determination. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate such a request by no later than close of business of the first day after the material is requested.

(f) *Coverage during QIO expedited review.* (1) *General rule and liability while QIO review is pending.* If the beneficiary remains in the hospital past noon of the day after he or she received the generic notice of non-coverage, and the hospital, the physician who concurred in the hospital's determination on which the generic notice was based, or the QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductible) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO and notifies the beneficiary in accordance with § 405.1205.

(2) *Timely filing and limitation on liability.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, the beneficiary is not financially responsible for inpatient hospital services (other than applicable coinsurance and deductible) furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely filing and limitation on liability.* When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, that beneficiary may be responsible for charges that extend beyond the date specified on the generic notice or as otherwise stated by the QIO.

(4) *Hospital requests expedited review.* When the hospital requests review in accordance with § 405.1208, and the QIO concurs with the hospital's decision, a hospital may not charge a beneficiary until the date specified by the QIO.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When the beneficiary remains in the hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 405.1204.

(2) *When the beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

**§ 405.1208 [Amended]**

4. In § 405.1208(e)(1), after the words ''in accordance with,'' remove the words ''paragraph (d)(1) of this section'' and add in their place, ''§ 405.1204(b)(1)''.

## PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

5. The authority citation from part 412 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), Sec. 124 of Pub. L. 106–113, 113 Stat. 1515, and Sec. 405 of Pub. L. of 108–173, 117 Stat. 2266, 42 U.S.C. 1305. 1395.

6. Section 412.42(c) is amended by—

A. Republishing the introductory text.

B. Revising paragraphs (c)(2) and (c)(3).

The revisions read as follows:

**§ 412.42 Limitations on charges to beneficiaries.**

* * * * *

(c) *Custodial care and medical unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 411.15(g) of this chapter (custodial care) or § 411.15(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

* * * * *

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the QIO as described in § 405.1208 of this chapter. Concurrence by the QIO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or his or her representative) in writing consistent with § 405.1205 and § 405.1206 of this chapter (if applicable) that in the hospital's opinion, and with the attending physician's concurrence or that of the QIO, the beneficiary no longer requires inpatient hospital care.

* * * * *

## PART 422—MEDICARE ADVANTAGE PROGRAM

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

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

8. Section 422.620 is revised to read as follows:

**§ 422.620 Notifying enrollees of discharge from inpatient hospital level of care.**

(a) *Applicability and scope.* (1) For purposes of § 422.620 and § 422.622, the term hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of § 422.620 and § 422.622, a discharge from the inpatient hospital level of care is a formal release of a beneficiary from the inpatient hospital level of care or, a complete cessation of coverage within the inpatient hospital level of care.

(b) *Advance written notification of discharge from inpatient hospital level of care.* Before any discharge from the inpatient hospital level of care, the hospital must deliver valid written notice of non-coverage of the MA organization's or hospital's discharge decision to the enrollee. A standardized, largely generic notice, as specified by CMS, must be used in accordance with the following procedures:

(1) *Timing of notice.* The hospital must notify the enrollee of non-coverage and the MA organization's or hospital's decision to discharge the enrollee on the day before the planned discharge.

(2) *Content of the notice.* The standardized, generic notice of non-coverage must include the following information:

(i) The date that coverage of inpatient hospital services ends.

(ii) A description of the immediate QIO review process as specified under § 422.622, including information about how to contact the QIO, the availability of other MA appeal procedures if the

enrollee fails to meet the deadline for immediate QIO review, and the fact that immediate QIO review will not be granted unless the enrollee disagrees with the discharge decision.

(iii) The enrollee's right to receive additional information in accordance with § 422.622(c).

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

(v) Any other information required by CMS.

(3) *When delivery of notice is valid.* Delivery of the generic notice of non-coverage described in this section is valid if—

(i) Except as provided in paragraph (b)(4) of this section, the enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

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

(4) *If an enrollee refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Physician concurrence required.* Before discharging an enrollee from the inpatient hospital level of care, the MA organization must obtain concurrence from the physician who is responsible for the enrollee's inpatient care.

9. Section 422.622 is revised to read as follows:

**§ 422.622 Requesting immediate QIO review of decision to discharge from inpatient hospital level of care.**

(a) *Enrollee's right to an immediate review.* (1) An enrollee who wishes to appeal a determination by an MA organization or hospital that inpatient care is no longer necessary may request immediate QIO review of the determination in accordance with paragraph (b) of this section. An enrollee who timely requests immediate QIO review in accordance with paragraph (b) of this section may remain in the hospital with no additional financial liability (other than applicable cost sharing) as described in paragraph (e) of this section.

(2) When an enrollee fails to make a timely request in accordance with paragraph (b) of this section, he or she may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (e)(1) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate QIO review process, the enrollee must submit the request for immediate review to the QIO, in writing or by telephone by noon of the first day after he or she receives written notice of non-coverage that the MA organization or hospital has made a decision to discharge the enrollee.

(c) *Notification responsibilities of the MA organization and the QIO.* (1) On the date it receives the enrollee's request, the QIO must notify the MA organization that the enrollee has filed a request for immediate review.

(2) When the QIO notifies an MA organization that an enrollee has requested an immediate QIO review, the MA organization must deliver a detailed notice to the enrollee by close of business of the day of the QIO's notification of the enrollee's request. The detailed notice must include the following information:

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

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

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the discharge decision was based.

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

(v) Any other information required by CMS.

(3) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO by the MA organization, including records of any information provided by telephone. The MA 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 MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO no later than close of business of the first day after the day the material is requested.

(4) Upon notification by the QIO of an immediate review, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the QIO needs to decide on the review. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the QIO notifies the MA organization that a request for immediate review has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of any information not transmitted initially in writing) and/or in writing, as determined by the QIO.

(5) An MA organization is financially responsible for coverage of services as provided in paragraph (e) of this section, regardless of whether it has delegated responsibility for authorizing coverage or discharge decisions to its providers.

(6) If the QIO reverses an MA organization's discharge decision, the hospital must provide the enrollee with a new notice consistent with § 422.620(b).

(d) *Procedural responsibilities of the MA organization, hospital, and the QIO.* (1) The MA organization must supply any information that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the day after the enrollee submits the request for review.

(2) In response to a request from the MA organization, the hospital must submit medical records and other pertinent information to the QIO by close of business of the first day after the organization makes its request.

(3) The QIO must solicit the views of the enrollee (or his or her representative) who requested the immediate QIO review.

(4) The QIO must make a determination and notify the enrollee, the hospital, and the MA organization by close of business of the first day after it receives all necessary information from the hospital, or the organization, or both.

(e) *Liability for hospital costs.* (1) When the MA organization determines that hospital services are not, or are no longer, covered.

(i) Except as provided in paragraph (e)(1)(ii) of this section, if the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in § 422.2 and § 422.112(c)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the day after the QIO notifies the enrollee of its review determination. If coverage of the hospital admission was never approved by the MA organization or the admission does not constitute emergency or urgently needed care as described in § 422.2 and § 422.112(c),

the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the non-coverage determination made by the MA organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the day after the QIO notifies the enrollee of its review determination.

(f) Effect of an immediate QIO review. The QIO determination is binding upon the enrollee, physician, hospital, and MA organization except in the following circumstances:

(1) When the enrollee remains in the hospital. If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(f).

(2) When the enrollee is no longer an inpatient in the hospital. If the enrollee is no longer an inpatient in the hospital and is dissatisfied with this determination, the enrollee may appeal to an ALJ, the MAC, or a federal court, as provided for under this subpart.

## PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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

**Authority:** Secs. 1102, 1819, 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, and 1395hh).

11. Section 489.27(b) is revised to read as follows:

**§ 489.27 Beneficiary notice of discharge rights.**

(a) * * *

(b) *Notification by hospitals and other providers.* Hospitals and other providers (as identified at 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or representative, applicable CMS notices in advance of discharge or termination of Medicare services, including the notices required under § 405.1205, § 422.620, § 405.1200, and § 422.624 of this chapter.

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

Dated: February 15, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: March 7, 2006.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. 06–3264 Filed 3–31–06; 4:02 pm]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 622

**[Docket No. 051128312–5312–01; I.D. 111605A]**

**RIN 0648–AS15**

## Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Amendment 13

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS issues this proposed rule to implement Amendment 13 to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (Amendment 13), as prepared and submitted by the Gulf of Mexico Fishery Management Council (Council). This proposed rule would establish a 10-year moratorium on issuance of Federal Gulf shrimp vessel permits; require owners of vessels fishing for or possessing royal red shrimp from the Gulf of Mexico exclusive economic zone (EEZ) to have a royal red shrimp endorsement; require owners or operators of all federally permitted Gulf shrimp vessels to report information on landings and vessel and gear characteristics; and require vessels selected by NMFS to carry observers and/or install an electronic logbook provided by NMFS. In addition, Amendment 13 would establish biological reference points for penaeid shrimp and status determination criteria for royal red shrimp. The intended effects of this proposed rule are to provide essential fisheries data, including bycatch data, needed to improve management of the fishery and to control access to the fishery.

**DATES:** Written comments on this proposed rule must be received no later than 5 p.m., eastern time, on May 22, 2006.

**ADDRESSES:** You may submit comments on the proposed rule by any of the following methods:

• E-mail: *0648–AS15.Proposed@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: 0648–AS15.

• Federal e-Rulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Mail: Steve Branstetter, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

• Fax: 727–824–5308.

Copies of Amendment 13, which includes an Environmental Assessment, an Initial Regulatory Flexibility Analysis (IRFA), and a Regulatory Impact Review, may be obtained from the Gulf of Mexico.

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted in writing to Jason Rueter at the Southeast Regional Office address (above) and to David Rostker, Office of Management and Budget (OMB), by e-mail at *David__Rosker@omb.eop.gov*, or by fax to 202–395–7285.

**FOR FURTHER INFORMATION CONTACT:** Steve Branstetter, telephone: 727–551–5796; fax: 727–824–5308; e-mail: *Steve.Branstetter@noaa.gov*.

**SUPPLEMENTARY INFORMATION:** The shrimp fishery in the Gulf of Mexico is managed under the FMP. The FMP was prepared by the Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

### Amendment 13

*Royal Red Shrimp Permit Endorsements*

For a person aboard a vessel to fish for royal red shrimp in the Gulf of Mexico EEZ or possess royal red shrimp in or from the Gulf of Mexico EEZ, this rule would require that a valid commercial vessel permit endorsement for royal red shrimp be issued to the vessel and be on board. Note that this would be in addition to the requirement to have a Federal commercial vessel permit for Gulf shrimp.

An owner of a vessel who desires a commercial vessel permit endorsement for royal red shrimp would be required to obtain a permit application form from and submit it to the Regional