

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 489

[CMS-4004-FC]

RIN 0938-AL67

Medicare Program; Expedited Determination Procedures for Provider Service Terminations

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period responds to comments on one discrete aspect of the proposed rule published in the **Federal Register** on November 15, 2002. The portion of that proposed rule addressed here involves the expedited determination and reconsideration procedures available to beneficiaries when a provider informs them of a decision that Medicare coverage of their provider services is about to end.

DATES: *Effective date:* This final rule with comment period is effective on July 1, 2005.

Comment date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 25, 2005.

ADDRESSES: In commenting, please refer to file code CMS-4004-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. Submit electronic comments to <http://www.cms.hhs.gov/regulations/ecomments> or to <http://www.regulations.gov>. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Attention: CMS-4004-FC, P.O. Box 8016, Baltimore, MD 21244-8016.

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

If you prefer, you may deliver, by hand or courier, your written comments (one original and two copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior 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 comments being filed.) Comments mailed to the addresses used for hand or courier delivery may be delayed and could be considered late.

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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site.

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

FOR FURTHER INFORMATION CONTACT: Janet Miller, (410) 786-1588.

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 4004-FC and the specific "issue identifier" that precedes the section on which you choose to comment.

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

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I. Overview of the Statutory Changes to the Appeals Process

[If you choose to comment on issues in this section, please include the caption "Overview—Statutory Changes" at the beginning of your comments.]

Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554, amended section 1869 of the Social Security Act (the Act) to require significant changes to the Medicare appeals procedures. Among these changes is a new requirement under section 1869(b)(1)(F) of the Act that the Secretary establish a process by which a beneficiary may obtain an expedited determination in response to the termination of provider services. (Note that other aspects of the changes required under BIPA 2000 were discussed in detail in our November 15, 2002 proposed rule (67 FR 69312), and will be addressed in a forthcoming final rule.) Currently this right to an expedited review exists only with respect to inpatient hospital discharges (under sections 1154 and 1155 of the Act). Specifically, section 1869(b)(1)(F)(i) of the Act provides for an expedited determination process when a beneficiary receives notice from a provider of services that the provider plans to: (1) Terminate services provided to the individual and a physician certifies that failure to continue services is likely to place the beneficiary's health at significant risk; or (2) discharge the beneficiary from the provider of services. The statute mandates that a beneficiary who receives notice may request an expedited determination on whether these services should end. If a beneficiary is dissatisfied with this determination, the beneficiary may request an expedited reconsideration of this determination. The statute does not specify what entity must carry out the expedited determination process, but we intend to contract with the Quality Improvement Organizations (QIOs) in each State for this purpose. QIOs currently conduct similar expedited reviews for inpatient hospital discharges.

Section 1869(c)(3)(C)(iii) of the Act sets forth the requirements for expedited reconsiderations. It specifies that Qualified Independent Contractors (QICs) conduct expedited

reconsiderations. This section also states that the QICs must provide their reconsideration decisions no later than 72 hours after receiving the appeal request and related medical records. The decisions must be provided by telephone and in writing to the provider of services, the beneficiary requesting the appeal, and the attending physician of the beneficiary. Further, the QIC must solicit the views of the beneficiary requesting the appeal.

II. Provisions of the Proposed Rule

[If you choose to comment on issues in this section, please include the caption "Provisions of Proposed Rule" at the beginning of your comments.]

On November 15, 2002, we published a proposed rule in the **Federal Register** (67 FR 69312) that set forth proposed regulations for implementing the changes to the Medicare appeals process required by BIPA, including both new claims appeal procedures and procedures for expedited determinations and reconsiderations associated with provider discharges and terminations of services. This final rule codifies only those portions (§§ 405.1200 *et seq.*) of the proposed rule that dealt with expedited determinations and reconsiderations. Thus, this final rule sets forth the provisions addressing the rights of a beneficiary who is dissatisfied with a provider termination or discharge to an expedited determination and reconsideration. The proposed rule provisions are summarized below, followed by a discussion of the comments we received on the proposed rule and the changes made based on those comments.

A. Expedited Determinations (Proposed § 405.1200)

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

Under § 405.1200(a), we proposed that the new expedited determination procedures be applicable to providers listed in section 1861(u) of the Act. We proposed under § 405.1200(b) that in order for a beneficiary to request an expedited review, the beneficiary must have received notice that: (1) A provider intends to terminate services and a physician must certify that termination of services is likely to place the beneficiary's health at significant risk; or (2) the provider intends to discharge the beneficiary from an inpatient provider setting. Rather than establish a notice specifically for this purpose, we explained that we intended to use advance beneficiary notices (ABNs) to

serve as the appropriate triggers for expedited determinations under section 1869 of the Act. We stated that we would revisit the content of the existing ABNs to ensure that they conformed to the requirements of the proposed rule. (See section III of this preamble for a discussion of this issue.) We proposed that if a beneficiary does not file a timely request for an expedited determination, the beneficiary may not later access this expedited review process.

Under § 405.1200(c), we identified Quality Improvement Organizations (QIOs) as the appropriate entities to conduct these expedited determinations of provider terminations. We then proposed the procedures a beneficiary must follow in order to make a valid request to a QIO. We specified that beneficiaries may make their request either in writing or by telephone no later than noon of the day following the beneficiary's receipt of the provider's notice. Beneficiaries or their representatives must be available to answer questions by the QIO, upon request.

Proposed § 405.1200(d) and (e) set forth the procedures that the QIO must follow when it receives a beneficiary's request for an expedited determination. The QIO must: (1) Notify the provider of the disputed services that an expedited determination request has been made; (2) request the medical record and if necessary, other pertinent records from the provider; (3) examine the requested necessary medical information; (4) solicit the views of the provider and the beneficiary; and (5) make a decision within 72 hours after receipt of the request for the QIO expedited review. We proposed that the provider be required to submit the information needed for a QIO determination no later than close of business on the day after the beneficiary requested an expedited determination. The QIO must immediately notify the beneficiary, physician and provider of its expedited determination, first by telephone and then following up with a written notice that would explain the decision and inform the beneficiary of his or her right to an expedited reconsideration.

We proposed under § 405.1200(f) that the QIO's expedited determination would be binding upon the beneficiary and the provider of the disputed services or stay, absent a beneficiary's request for a QIC reconsideration. Proposed § 405.1200(g) discussed the financial liability aspects of the QIO expedited review process. We proposed that a provider cannot bill a beneficiary for the disputed stay or services until

the beneficiary has received either an expedited QIO determination or an expedited QIC reconsideration determination, if requested. In this situation, if the QIO determines that the services or stay in dispute were medically necessary, the beneficiary is not responsible for the services or stay, as stipulated by the QIO. However, if the QIO determines that the services or stay in dispute were not medically necessary, the beneficiary is responsible for services that extend beyond the appropriate covered services or stay, or as otherwise stated by the QIO.

B. Expedited QIC Reconsiderations (Proposed § 405.1202)

[If you choose to comment on issues in this section, please include the caption "Expedited QIC Reconsiderations" at the beginning of your comments.]

Consistent with the statute, we proposed that upon receipt of an expedited determination from a QIO, a beneficiary who is dissatisfied with that determination may request an expedited QIC reconsideration. A beneficiary who desires an expedited QIC reconsideration must make that request no later than noon of the next calendar day following receipt of the QIO expedited determination. A beneficiary or authorized representative must be available to talk with the QIC about his or her case if the QIC solicits the beneficiary's views.

Proposed § 405.1202(c) set forth the procedures that the QIC must follow in conducting its expedited reconsideration. These are generally identical to those followed by the QIO except as noted below. Thus, consistent with section 1869(c)(3)(C)(iii) of the Act, we proposed that the QIC must make a decision within 72 hours from receipt of the request for an expedited reconsideration and the requested information. Unlike for a QIO determination, however, if a QIC does not render its decision 72 hours from receipt of the request and information, a beneficiary has the right to have the case escalated to an Administrative Law Judge (ALJ). Therefore, we proposed that a QIC must inform the beneficiary of this right, assuming that the amount remaining in controversy after the QIO's expedited determination was at least \$100.

We proposed under § 405.1202(d) that the QIC's notice of its expedited reconsideration determination must be issued first by telephone and then followed up with a written notice to the beneficiary, provider, and physician responsible for the beneficiary's care. The written notice would include the detailed rationale for the decision, a

statement that explains the beneficiary's subsequent appeal rights (an ALJ Hearing), and the timeframe for filing for the ALJ hearing request. The notice should also include a statement explaining the Medicare payment consequences of the reconsidered determination and the beneficiary's date of liability. A QIC reconsideration determination is binding on the beneficiary, subject to an ALJ hearing if the beneficiary is dissatisfied with the QIC's decision.

We proposed under § 405.1200(f) that a beneficiary may not be billed for the disputed services or stay until that beneficiary receives the expedited reconsideration decision from the QIC. (As we discuss further below, we expect that QICs will be in place at the time the expedited reviews are available under these regulations. However, in the event QICs have not been established at the time of implementation, we believe it would be in the public's interest to provide for expedited reconsiderations through some other means. Therefore, if QICs are not in place at time of implementation, QIOs will carry out this reconsideration function as they do now for expedited reviews of disputed discharges from inpatient hospitals. As discussed below, we believe that we have the administrative authority, for a short period of time, to allow for a reconsideration process that differs slightly from that imposed under section 1869(c)(3)(C)(iii).)

C. Special Rules for Inpatient Hospital Discharges (Proposed §§ 405.1204 and 405.1206)

[If you choose to comment on issues in this section, please include the caption "Inpatient Hospital Discharges" at the beginning of your comments.]

The proposed regulations for these sections essentially mirrored the longstanding existing procedures under which QIOs conduct reviews of disputed discharges from inpatient hospitals. We believe it is appropriate and convenient to consolidate the procedures for expedited reviews of all provider service terminations and discharges in one location in the regulations. The proposed provisions were drawn from the following sources: section 1154(e) of the Act, § 412.42(c) and (g), Chapter 414 of the Medicare hospital manual and section 7000 *et seq.* of the QIO manual. In proposing to consolidate these provisions, we made no changes to the substance of existing rules for expedited initial determinations. We did, however, propose that when a beneficiary remains an inpatient in the hospital, the expedited reconsideration process

would parallel the process for other types of provider discharges. See proposed 42 CFR 405.1204(g)(1). This was in keeping with section 1869(c)(3)(C)(iii), which would now require the QIC to conduct the reconsideration of hospital discharge determinations. We recognize that section 1155 of the Act continues to require QIO reconsiderations of QIO initial determinations. However, Congress's passage of 1869(c)(3)(C)(iii) supersedes that provision, as the provisions are inconsistent, and later-enacted provisions are generally viewed as taking precedence over earlier-enacted provisions. We do not believe it would be possible for both QIOs and QICs to simultaneously provide reconsiderations of hospital discharge determinations. Moreover, section 1869(c)(2) defines a QIC as an organization "independent of any organization under contract with the Secretary that makes initial determinations [under section 1869(a)(1)]." We therefore believe Congress intended to provide that reconsiderations of hospital discharges be performed in a similar manner to other provider discharges, that is by the QIC.

III. Analysis of and Responses to Public Comments on the November 15, 2002 Proposed Rule

[If you choose to comment on issues in this section, please include the caption "Analysis and Response to Public Comments" at the beginning of your comments.]

We received 39 timely comments on the November 15, 2002 proposed rule, 6 of which addressed the expedited determination procedures. These commenters included representatives of provider organizations and beneficiary advocacy groups. These comments and our responses are discussed below.

A. Comments on the Expedited Determination Procedures Required by Section 1869 of the Act

Comment: Several commenters questioned whether ABNs were the appropriate vehicle for notifying beneficiaries of their statutory right to an expedited determination. They stated that we would need to carefully review the existing ABNs to ensure that they provide clear, adequate notice of this right. One commenter recommended that the regulations include a specific requirement for providers to provide a written discharge or termination notice to beneficiaries before services end. This commenter also noted that a beneficiary should be entitled to an expedited determination even if he or she does not

receive such a discharge notice. Another commenter noted that there are significant potential liability implications associated with tying the expedited determination process to the delivery of the ABN; they pointed out that shielding beneficiaries from liability during the review process would require that the ABN be issued up to 5 days before the scheduled termination of service.

Response: We have carefully reexamined the proposed provisions in light of these comments, particularly with respect to whether existing ABNs are the appropriate vehicle for notifying beneficiaries of the right to an expedited determination when their services are about to end. As commenters suggested, we have conducted a thorough review of the existing ABNs that are used in the provider settings and how they would need to be revised to accommodate the statutory expedited determination requirements. In addition, we have taken into account the procedures set forth in our April 4, 2003 (67 FR 16652) final rule that established a similar expedited review process for Medicare Advantage (MA) enrollees whose provider services are about to end. The provisions of the April 4, 2003 final rule were the product of extended litigation, followed by notice and comment rulemaking, and produced a largely parallel expedited review process that went into effect for MA enrollees on January 1, 2004.

Based on this review, we determined that extensive revisions to several different ABNs, and to the timing of ABN delivery, would be required if ABNs were to serve as the notice contemplated by the statute for initiating the expedited determination process. The primary purpose of all existing provider ABNs is to enable beneficiaries to make informed decisions as to whether they wish to receive continuing medical services when a provider believes that the services are unlikely to be covered by Medicare. Providers may deliver ABNs at any time before the planned termination of covered services. A beneficiary who chooses to continue receiving provider services following delivery of an ABN acknowledges that he or she may be financially liable for the services. If a beneficiary chooses to accept this potential liability and continue receiving the services in question, the provider submits a "demand bill" to its Medicare claims contractor. Contractors then process demand bill claims in the same manner that they would process other manual claims. Also, currently ABNs are not required in every termination situation

where a beneficiary may request an expedited determination (for example, a service termination that is in accordance with an approved plan of care); conversely, the existing ABN is designed to be delivered in some situations where expedited determinations are not available (such as at the outset of services). Thus, we believe that it would not serve the best interests of either beneficiaries or providers to attempt to adapt the ABN to meet both its existing purpose and the purposes of the expedited review process.

Instead, we concluded that that using ABNs to implement the expedited determinations for original Medicare beneficiaries is impractical, and that, as a result, several changes are needed to the proposed regulations. The primary change involves the establishment of a requirement for a simple, standardized, largely generic notice to each beneficiary before a discharge or service termination. We believe that this termination notice will ensure that all beneficiaries know that Medicare coverage of their provider services is about to end and are aware of their associated appeal rights. In situations where a beneficiary chooses to exercise the right to an expedited determination, a detailed notice similar to the existing ABN will still be furnished before the termination of services. The detailed notice will explain how Medicare coverage rules apply in individual situations, address liability issues, and facilitate the expedited review process by providing the patient-specific information needed by both a beneficiary and the QIO conducting the process. Consistent with the MA program requirements, this two-step notification process should best meet the needs of the large majority of beneficiaries who need to know only when coverage of their services will end and what their appeal rights are, as well as the small minority of beneficiaries who want more specific information about why their services are ending.

We believe that this approach will alleviate potential beneficiary and provider confusion and ensure that providers are not faced with unnecessary administrative burdens. All beneficiaries will receive a clear, simple notice of the impending end of Medicare coverage of their provider services and their right to an expedited review of this decision. Then, as under the existing ABN process, any beneficiary who objects to the service termination will receive a detailed notice of the reason for this decision before being deprived of the services in question. Beneficiaries will receive a

binding expedited initial determination on the coverage of their services no later than 1 day after the date the services were scheduled to end. This will reduce the beneficiary's potential liability for any services that are denied on appeal.

Section 405.1200(b) establishes the requirement for an advance written notice of termination of Medicare coverage of services in an HHA, SNF, CORF, or hospice. This section also addresses the timing of the notice, the required content, and the financial liability implications. Like in the MA context, providers will be required under § 405.1200(b)(1) to deliver the termination notice no later than 2 days before the proposed end of covered services. If, in a non-residential setting, the span of time between services exceeds 2 days, the provider must notify the beneficiary no later than the next to last time services are delivered. Also consistent with the parallel MA regulations, we are including a cross-reference to this notification requirement in § 489.27(b), the section of the Medicare provider agreement regulations that sets forth provider notification requirements.

As a commenter pointed out, the only way to fully ameliorate financial liability concerns associated with the expedited determination would be to require a termination notice as much as 5 days before services were to end, and then conduct the review process during the time span between the notice and the service termination. However, as we learned in the process of establishing the parallel MA process, requiring providers to furnish termination notices that far in advance generally is not practical from a medical decision-making standpoint. On the other hand, employing the existing ABN process, which permits ABN delivery at any time before service termination, would mean that the expedited determination procedures generally would not even begin until after services had ended. Thus, as discussed in detail in our April 4, 2003 final rule on expedited determinations under the MA program (68 FR 16655), we believe that the 2-day advance notice requirement strikes an appropriate balance between the realities of medical decision-making practices and the need to ensure that a beneficiary has an opportunity to an expedited determination while minimizing financial exposure for either the individual or the provider.

Section 405.1200(b)(2) describes the required content of the notice. Unlike an ABN, the initial discharge notice will not include detailed information about Medicare coverage policies or how they relate to the individual's particular

health needs or conditions. We recognize that in the vast majority of cases, beneficiaries are in agreement with their care providers' determinations that Medicare-covered services should end and that the service termination is consistent with the plan of care; thus, a more detailed explanation of the underlying reasons for the termination would serve no purpose and impose an unnecessary burden on providers. Instead, the only patient-specific elements of the termination notice will be the beneficiary's name and the date that coverage of services will end. Other required elements of the notice, such as a description of the beneficiary's right to an expedited determination and how to exercise that right, will constitute entirely standardized information. When a beneficiary does not object to the termination decision, no further notice is required. Again, however, if a beneficiary disputes the discharge or termination of services, the subsequent detailed notice will provide the critical, patient-specific information relevant to the individual coverage termination decision. We will develop both of these pre-termination notices through the Office of Management and Budget's Paperwork Reduction Act Process.

Section 405.1200(c) establishes that valid delivery of a termination notice requires that a beneficiary sign the notice. This requirement codifies longstanding policy for valid ABN delivery and is consistent with § 422.624(c) of the parallel MA regulations. We note that the associated provider manual provisions for ABNs and the MA program permit exceptions to this rule in situations where a beneficiary refuses to sign a properly delivered notice, and we incorporate a similar policy into 405.1200(b)(4). As explained in the April 4, 2003 final rule with comment period (68 FR 16658), if a beneficiary refuses to sign the notice, the provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

Section 405.1200(d) explains that a provider is financially liable for continued services until 2 days after valid delivery of the termination notice or until the service termination date specified on the notice, whichever is later. This provision serves two purposes. First, it ensures that a beneficiary has at least 2 days after receiving a notice before he or she can be liable for additional services, thus limiting beneficiary liability as the expedited determination process plays out. In addition, it accommodates situations where a provider is able to

identify the service termination date and deliver notice more than 2 days in advance. Under those circumstances, it is possible that the expedited determination process (and a subsequent discharge, if applicable) could take place entirely during the period between notification and the planned service termination date, permitting a beneficiary to incur no additional liability despite an unfavorable decision from a QIO.

As noted above, the new process will still rely on a detailed notice similar to the existing ABN, but only in those instances where a beneficiary requests an expedited determination. The circumstances in which this more detailed notice will be required, and the contents of that notice, are set forth under § 405.1202(f), "Responsibilities of Providers." The content requirements are very similar to those of the existing ABN, including a specific and detailed explanation of why services are no longer considered reasonable and necessary or otherwise covered by Medicare, a description of applicable Medicare coverage rules, and any applicable beneficiary-specific information that is relevant to the coverage determination. As under the MA expedited review process, this notice will be furnished to both the QIO and the beneficiary who requested the expedited review since the QIO will need the information to make its determination and the beneficiary will need it in order to make an informed decision on whether to introduce any evidence into the expedited proceedings.

Finally, as explained in the November 15, 2002 proposed rule (67 FR 69337), we agree that if a provider fails to deliver a notice to a beneficiary, a beneficiary retains the right to an expedited determination with respect to the discharge. We have made minor changes to the regulation text that addresses the beneficiary's right to an expedited determination, to ensure that the right to a determination is not premised strictly on the delivery of a termination notice, although we anticipate that this will be the situation in most cases.

As noted at the beginning of this final rule, the effective date for these new provisions is July 1, 2005. In the interim, we will obtain public comment on the new provider notices and work closely with the provider community to make sure that they are aware of their notice delivery obligations. We also intend to review CMS beneficiary education materials and conduct beneficiary outreach to inform Medicare beneficiaries of the right to a review.

Finally, we are reviewing both CMS surveying protocols and QIO review protocols to identify changes that may be needed to facilitate effective implementation, monitoring, and enforcement of these requirements.

Comment: Commenters indicated that the organization of the proposed provisions was confusing and asked for further clarification in the provisions describing notification to beneficiaries, the procedure for requesting a determination, and the responsibilities of providers under the new process.

Response: As explained in the previous response, we have revised the proposed regulations to incorporate a requirement that providers routinely notify beneficiaries before discharging them or terminating covered services. This change necessitated several structural changes to the proposed provisions, and results in a process that is in most ways the same as that set forth in the April 4, 2003 final rule on expedited reviews of provider service terminations (68 FR 16652). Given these similarities, as well as the comments concerning the lack of clarity in the proposed rules, we have reorganized the proposed regulations to address these concerns. We have clarified that the rules in 405.1200 through 405.1204 apply only to non-hospital providers, since hospitals have their own special set of rules that apply to them through the application of section 1869(c)(3)(C)(iii)(III) of the Act, as well as section 1154(e). Wherever possible, we have adopted the wording and structure of the parallel MA regulations that describe the expedited review procedures (§§ 422.624 and 422.626), unless there is a substantive reason to vary from those regulations.

Thus, § 405.1200 describes how and when beneficiaries must be notified of impending service terminations. Section 405.1202 then details a beneficiary's right to an expedited determination (paragraph (a)), how to request a determination (paragraph (b)), rules on when coverage of provider services ends (paragraph (c)), and on the "burden of proof" for an expedited determination (paragraph (d)), the procedures a QIO follows (paragraph (e)), a provider's responsibilities during the review process (paragraph (f)), and the billing limitation during the review process (paragraph (g)). We believe that this organizational approach, in combination with the substantive changes explained above, will produce a clear understanding of the procedural requirements associated with these provisions.

We note that § 405.1202(d), concerning the "burden of proof"

during an expedited determination largely consolidates proposed requirements regarding the information a QIO considers in making its determination. For example, this section restates the proposed requirement (previously under proposed § 405.1200(d)(2)) that a provider must supply the information a QIO needs to make its determination, and explicitly acknowledges a beneficiary's potential role in the process. It is also intended to clarify that it is the responsibility of a provider, who has an obligation to be familiar with Medicare coverage rules, to explain its decision that Medicare coverage is no longer warranted. This is a necessary procedural rule that reflects the reality that a provider who intends to discharge a beneficiary or terminate a beneficiary's services must be able to establish for the record the reasoning behind the discharge or termination decision. The QIO will then make its determination on the basis of this record. This provision is not intended to limit the QIO's discretion in making its determination, nor does it materially change the provider's role. The provision does not impact the substantive standards for QIO review and does not imply a working assumption by a QIO that coverage of care must continue.

In concert with this clarification of the QIO review process, we have also specified under § 405.1202(e) that the deadline for the QIO's expedited determination is 72 hours from the receipt of the request for a review, rather than from the "receipt of the request for an expedited determination and the requested information." This change lends a greater degree of certainty to the timing of the process and thus benefits both providers and beneficiaries. A QIO may delay its decision if it has not yet received necessary information, but the provider may be held financially liable for continued services resulting from the delay. Again, these refinements parallel the requirements for expedited reviews under the MA program.

Comment: One commenter suggested that the "timely manner" requirement (that is, the provision at proposed § 405.1200(b)(2) that prohibited use of the expedited review process absent a timely request for review) for beneficiary appeals be more specific. The commenter also recommended that additional time be available in special circumstances.

Response: We agree that the provision in question (under proposed § 405.1200(b)(2)) was unclear. As part of the changes in the organization of the regulation, we have eliminated the proposed "timely manner" reference

and simply specified under § 405.1202(b)(1) that a beneficiary must request an expedited determination by noon of the calendar day following receipt of the discharge notice. We believe that this deadline allows a beneficiary adequate time to request an expedited determination, given that a beneficiary need only make a telephone call to initiate the review process, and there are no financial or documentation obligations on the part of the beneficiary. The notice requirements set forth at § 405.1200(b)(2) will ensure that each beneficiary will receive a simple discharge notice that will contain clear, consistent information on their rights and how they may contact the QIO to request an expedited determination.

We have added a provision to § 405.1202(b)(1) specifying that if for some reason a QIO is unavailable to receive a beneficiary's request for an expedited determination, he or she has until noon of the next day the QIO is available to accept the request to submit the request for a review. In other situations where a beneficiary fails to meet the noon deadline for requesting an expedited determination, we will instruct QIOs, consistent with § 405.1202(b)(4), to accept the request and notify the beneficiary and the provider of its determination as soon as possible following receipt of the request. This is similar to the process now in effect for untimely requests for a hospital review. However, note that the financial liability protections of § 405.1202(g) (prohibiting billing during the expedited appeal process) would not apply. Finally, beneficiaries will retain the option of receiving services after their scheduled discharge date, and then accessing the standard claims appeal process for billed services.

Comment: One commenter questioned whether providers would still be required to submit bills for appealed services. The commenter noted the example of a demand bill.

Response: In general, these regulations do not affect a provider's responsibility to submit bills for beneficiary services, and the usual requirements for claim submission would continue to apply. However, a QIO's expedited determination constitutes a binding Medicare determination as to whether an individual's provider services are covered. Medicare contractors will be informed of the expedited QIO determinations in all these situations, and contractors' payment determinations will reflect the results of the QIO's review, absent very unusual circumstances (such as an eligibility

error). An individual would retain the right to appeal the contractor's payment determination through the claims appeal process.

In addition, the "demand bill" process will continue to be available for determinations that are not subject to these procedures, such as when a provider informs an individual before initiating services (through an ABN) that the provider does not believe the services are covered by Medicare.

Comment: Commenters questioned which discharge situations would provide a beneficiary the right to appeal. Specifically, the commenter asked if beneficiaries could appeal if their rehabilitation was discontinued, even as their Part A coverage continued. Another commenter recommended that we clarify whether reductions in service are subject to the expedited determination process.

Response: Section 1869(b)(1)(F) of the Act specifies that the right to expedited proceedings applies to individuals whose services are terminated by a provider or who are discharged from a provider of services. We believe it was the intent of Congress to apply these rights to the traditional provider service settings of SNFs, CORFs, HHAs, and hospice, rather than to apply these rights more broadly, such as to stand-alone rehabilitation services furnished by an outpatient department of a hospital. We note that the proposed rule erroneously included hospitals in the definition of the providers for which these expedited determination procedures would apply, although inpatient hospitals continue to be subject to the existing expedited review procedures established under section 1154(e) of the Act (and incorporated into BIPA under the "Special Rule for Hospitals" at section 1869(c)(3)(C)(iii)(III) of the Act), as discussed in the next section of this preamble.

To clarify these points, we have revised § 405.1200(a) regarding applicability of the expedited determination procedures to specify that the new notice and appeal provision apply only to SNFs, HHAs, CORFs, and hospices, and that they do not include reductions in services, as discussed below. If a beneficiary continues to receive Part A services in a skilled nursing facility provider, but some Part B services have been discontinued, we will consider this to be a reduction and not a termination of services.

As discussed in the proposed rule, the BIPA requirements concerning provider notice and expedited determination procedures are not applicable to reductions in service. The statute

specifically refers only to service termination and discharges, and we do not believe the authority exists to extend these provisions further. In most settings, care reductions are a continuing, expected, and generally positive part of the care delivery continuum. We believe that providing an expedited appeal right for service reductions would be unwieldy and inappropriate. However, in no way does this final rule reduce a beneficiary's existing appeal rights for reduction in care situations. For example, home health agencies will continue to provide ABNs for reductions in services that are not consistent with the original plan of care, and these types of situations will still be subject to the existing notice and appeal procedures.

Comment: One commenter pointed out an inconsistency between the summary section of the proposed rule and the proposed regulation text. Specifically, the commenter noted that hospice providers were not included in the discussion of those providers affected by the expedited appeal provisions, but were included in the text of the proposed rule.

Response: In this final rule, we have corrected the inconsistency regarding hospice providers. Thus, we have continued to specify under § 405.1200(a) that hospices are considered providers for purposes of the expedited proceedings provisions. Although we expect situations where beneficiaries object to their discharge from a hospice to be rare, these individuals may exercise the right to an expedited determination. We have also clarified under § 405.1202(a) that, like beneficiaries who request an expedited determination for discharges from residential providers, beneficiaries who request an expedited determination for hospice coverage terminations are not required to obtain a physician certification that failure to continue provision of the services will place the individual's health at significant risk. We believe that the all-inclusive nature of hospice care is generally akin to a residential setting.

Comment: Two commenters raised questions regarding what triggers a beneficiary's right to an expedited determination in response to a provider termination or discharge. They asked for additional clarification in situations where services are being terminated because there are no physician's orders or appropriate certifications to continue care. One commenter suggested that "technical" requirements, such as certification of homebound status for home health patients, be established before the right to an expedited

determination can be exercised. The commenter noted that although a strict reading of the proposed regulations would permit an expedited determination without these requirements being met, allowing an expedited review under these circumstances raises important questions about the provider's authority to continue to deliver care and to be reimbursed for that care by the Medicare program. Another commenter recommended that a beneficiary be able to appeal a denied request for an expedited review.

Response: These comments raise two key issues with respect to both the availability of the statutory right to an expedited determination and the appropriate remedy available to a beneficiary who exercises that right. Section 1869(b)(1)(F) of the Act provides only limited direction on these issues, specifying that the Secretary must provide an expedited determination at a beneficiary's written or oral request, providing that an individual may request an expedited determination when he or she has received notice that a provider plans: (1) To terminate services provided to an individual, and a physician certifies that failure to continue provision of such services is likely to place the individual's health at significant risk; or (2) to discharge the individual from the provider of services. Given this construction, we do not believe it was the intent of Congress to prohibit a beneficiary from requesting an expedited determination in situations where Medicare coverage requirements are not met. Thus, § 405.1202(a) of this final rule essentially establishes that any individual whose Medicare-covered provider services are being terminated may request an expedited determination.

We generally do not intend to place restrictions on a beneficiary's right to request an expedited review when coverage of their provider services is about to end. In all termination situations where Medicare coverage requirements are at issue, beneficiaries must receive notice of the provider's decision to terminate Medicare-covered services and have an opportunity to dispute the decision if they so choose. The QIO will then have an obligation to deal with these requests in an appropriate manner.

A provider cannot be reimbursed for Medicare services unless the customary Medicare-required elements are in place. These include both technical requirements (such as the existence of a physician's order for the services or the requirement that an HHA patient be

homebound), as well as the medical necessity requirement that the services in question be reasonable and necessary for the given beneficiary under the given set of circumstances. Even under the existing claims appeals process a beneficiary typically has the right to appeal a determination by a contractor that the technical requirements are not in place, and the beneficiary may prevail in this appeal if he or she can demonstrate that these requirements were in fact met.

Similarly, we believe that Congress intended that the expedited determination process offer beneficiaries an opportunity for an independent review of the provider's decision on the impending coverage termination. The absence of a physician's order for additional services, or of a plan of care establishing that a patient is confined to the home, cannot be used to prove that a patient does not need care. Instead, the provider must explain to the QIO the reasoning behind the lack of the Medicare-required elements.

The QIO will consider this and other relevant information in making its determination, including, where applicable, the physician certification that failure to continue providing services may place the individual's health at significant risk. The QIO will be fully aware of the necessary "technical" requirements for coverage and will have the authority to make a determination both for these threshold coverage requirements and for whether continued services are reasonable and necessary for the individual. When a QIO determines that coverage of care should continue, a provider may rely on the QIO's determination as dispositive evidence that all needed elements of Medicare coverage are met and that the care will be reimbursed appropriately by Medicare. No matter what a QIO's decision on a case, however, an individual will have an opportunity to request an expedited reconsideration from a QIC.

Comment: One commenter expressed concern about the use of "calendar days" in establishing the deadline for a beneficiary to request an expedited determination. (see proposed § 405.1202(b)(1)). The commenter noted that beneficiaries informed of a service termination on a Friday or Saturday could encounter difficulties and would have little access to assistance to make their request. They asserted that using a next "working day" requirement would be more realistic for the use of QIO resources.

Response: Our experience with deadlines tied to "working days" is that

they are often interpreted differently by different entities involved in the appeals process and consequently tend to add ambiguity and uncertainty to the process. Our general regulatory approach in recent years has been to eliminate deadlines based on "working days" whenever possible and instead rely on a "calendar day" approach. We believe this measure provides greater clarity and reduces delays and potential additional liability risks generally associated with extending deadlines to accommodate the working day approach.

At the same time though, we recognize that there are also problems associated with the use of calendar days. Although QIOs are expected to be available to receive requests, notify providers of the requests, and conduct reviews on a daily basis, providers may have difficulty in furnishing the necessary records on weekends. Thus, we agree that this is a valid concern: This is why we have tried to build as much flexibility as possible into these regulations to help ameliorate potential problems. For example, these regulations give providers the flexibility to notify beneficiaries of a planned termination more than 2 days in advance, which can serve both to avoid the need for weekend notifications and to ensure that the ensuing parts of the expedited review process (such as providing documentation to QIOs) can be accomplished during normal working hours. We intend to work with provider and consumer organization representatives and with the QIOs to identify ways to reduce the need for a beneficiary to be given notice on a weekend, as well as to develop uniform procedures to deal with those relatively infrequent situations where this is unavoidable.

We use "working days" in the context of inpatient hospital discharges because this standard is required by section 1154(e) of the Act. This section specifically uses the phrase "working days" when establishing deadlines for parties involved in expedited appeals of hospital discharges.

Comment: One commenter expressed concern with the provider requirements for submitting medical records during an expedited appeal. The commenter asked whether the timeframe was realistic, and questioned how weekends would affect the timeframe.

Response: Under § 405.1202(f)(2), providers are required to submit records to the QIO by close of business of the day they are informed by the QIO of the beneficiary's request for an expedited review. Although we recognize that this is a rigorous standard, we believe that

this deadline for provider submission of necessary information is necessary to carry out Congressional intent for an expedited determination process without subjecting beneficiaries to unneeded liability. Therefore, in both our April 4, 2003 final rule and this regulation, we have revised the appeals process (by adjusting the time frame for records to be sent to the QIO) to ensure that the process is completed within 3 days of the notice of termination. The effect of these changes is that a Medicare beneficiary should face a maximum of 1 day of financial liability if a QIO rules that the disputed discharge date is appropriate.

We strongly encourage providers to distribute termination notices as early as possible (that is, as soon as the service termination date is known) to ameliorate difficulties associated with the need to furnish records promptly. Similarly, QIOs need to exercise discretion and good judgment in obtaining needed documentation from providers, and, as made explicit in the regulations, we anticipate that in some circumstances QIOs will rely on telephone evidence that can be followed up with written confirmation. Because we recognize that weekend discharges may cause difficulties in meeting the record submission deadlines, we intend to issue further guidance on this issue. Finally, we note that this documentation deadline is the same as the one established by section 1154(e) of the Act for QIO reviews of hospital discharges, and as the deadline established by regulation for expedited proceedings under the MA program (§ 422.626(e)).

Comment: One commenter questioned the consequences of a provider not submitting requested documentation on time. The commenter questioned who would be responsible for payment in these instances.

Response: As discussed above, a provider is responsible for submitting needed documentation to support the termination decision by close of business of the day following the day it is notified by the QIO of the request for an expedited determination. If the QIO does not receive the information needed to sustain a provider's decision to terminate services, it may make its determination based on the evidence available, or it may defer a decision until it receives the necessary information. If a provider does not fulfill this obligation, it may be liable for any excess continued Medicare coverage of the individual's provider services due to the provider's delay, as determined by the QIO. To address this issue, we have set forth these principles in

§ 405.1202(e)(7), under the procedures the QIO follows in making its determination.

Comment: One commenter raised the issue of beneficiaries' access to their own case information. The commenter recommended that the QIO and provider be required to ensure that all necessary medical and social service information be available to beneficiaries.

Response: In this final rule, under § 405.1202(f), if a beneficiary requests an appeal, a provider must present a beneficiary with a detailed notice that will include an explanation of why services are no longer needed. This detailed notice will include the specific information from the beneficiary's situation used to make the discharge decision. Section 405.1202(f)(3) explicitly establishes that a beneficiary has the right to request a copy of the information sent by the provider to the QIO and that the information should be made available by no later than close of business of the day after the material is requested. We do not believe this final rule is the appropriate vehicle to address the availability of social service information to beneficiaries; these requirements are traditionally included in the discharge planning conditions of participation for the appropriate provider.

Comment: Two commenters expressed concern about when beneficiary liability begins and how beneficiaries will be informed of their financial liability. They questioned whether QIO notification marks the beginning of beneficiary liability. They also suggested that beneficiaries be informed of financial liability through the "initial determination".

Response: Although we are somewhat unclear as to the commenter's reference to an "initial determination" in this context, we fully agree that a beneficiary must be informed of potential liability as soon as possible. Therefore, we have required under § 405.1200(b) that each beneficiary receive a standardized termination notice that specifies the date on which beneficiary liability begins. This notice also will inform beneficiaries that financial liability for noncovered care will exist in unsuccessful expedited review requests. Also, under § 405.1202(e)(8), the QIO's notice of its determination decision must inform beneficiaries of the consequences of the QIO decision, such as the potential liability if they continue services after their discharge date. We believe these provisions will ensure that all beneficiaries are fully apprised of their potential financial liability before

and during the expedited determination process.

Comment: One commenter raised issue with the reimbursement rates for providers whose beneficiaries appeal discharges. The commenter was concerned that providers were at financial risk because they would be unable to bill beneficiaries until the expedited QIO determination was completed. The commenter was also concerned about providers incurring bad debts from unsuccessful appeals. The commenter suggested that payment rates to providers with bad debts resulting from unfavorable QIO decisions be adjusted.

Response: Under § 405.1202(g) and § 405.1204(f), providers are precluded from billing beneficiaries for disputed services only during the brief expedited process. Even for expedited proceedings that include an expedited reconsideration, the entire decision making process will encompass less than one week from the originally scheduled discharge. Thus, we do not believe that this final rule will have a significant effect on providers' financial risk. If providers can furnish evidence of a pattern of beneficiary failure to pay money due after an unsuccessful expedited determination request, we will assess such evidence and related information to determine the appropriateness of proposing policy changes consistent with existing statutory authority or seeking legislative changes.

We note that the preclusion on billing pending the expedited determination is consistent with current procedures for SNFs, under *Sarrassat v. Sullivan*, 1989 WL 208444 (N.D. Cal. 1989), *aff'd* 961 F.2d 217 (9th Cir. 1992). In *Sarrassat*, the plaintiffs asserted that SNF beneficiaries were not adequately notified that the SNF believed Medicare would not cover care, and that beneficiaries were not permitted to appeal the SNF's assertion to the fiscal intermediary. The court affirmed a settlement agreement providing that SNFs would be unable to bill beneficiaries until their initial determination was complete, a process that is much longer than the expedited proceedings established under this final rule. Thus, we believe that building this type of temporary protection from billing into the new expedited appeals process is an appropriate step, particularly given the short time periods involved.

Comment: One commenter questioned whether QIO appeal rights would be included on the Notice of Discharges required by Nursing Home Reform Law. The commenter also questioned

whether QIO review is a mandatory or permissive alternative to State review.

Response: Information about an individual's expedited review rights will be part of the standardized portion of the provider termination notice required under this final rule. Although this information may be furnished through other vehicles as well, we will not deem the inclusion of the appeal right information on any other notice to satisfy this regulatory requirement. The QIO expedited review process implements a Medicare statutory requirement, and we cannot determine whether States will consider this process an acceptable alternative to an existing State review requirement.

Comment: One commenter stated that the proposed rule was not clear with regard to whether particular QIO initial determinations are subject to redeterminations. They questioned whether the new expedited determinations were subject to the redetermination rights set forth in § 405.940 of the proposed rule of November 15, 2002.

Response: QIO expedited determinations are not subject to the redetermination rights set forth under BIPA and addressed at proposed § 405.940 of our November 15, 2002 proposed rule. (We note that section 1869(a)(3)(A) of the Act states that redeterminations must exist for fiscal intermediary and carrier initial determinations, but does not discuss QIO initial determinations.) Instead, a beneficiary may request an expedited reconsideration of that expedited determination. A beneficiary who misses the deadline for an expedited reconsideration would retain access to the standard claims appeal procedures.

Comment: One commenter raised concerns with a cost to the Medicare program not discussed in the proposed rule. The commenter suggested that there would be a necessary cost of educating beneficiaries and providers about their rights and obligations. In particular, the commenter stated that beneficiaries would need education regarding the use of ABNs as a part of the appeals system.

Response: We agree that these expedited provisions, as well as all other aspects of the implementation of BIPA, will require extensive provider and beneficiary education. We will work to achieve that end. In addition, as discussed in detail above, a new notice will be used instead of ABNs to inform beneficiaries of their expedited appeal rights. We believe that the use of a distinct and standardized notice will simplify the notification process and promote understanding by beneficiaries.

Comment: One commenter requested clarification regarding beneficiary costs for access to medical and other information. They wanted copying and associated charges to reflect actual expenses.

Response: We agree with the commenter that clarification of beneficiary charges for documentation is needed and have changed the regulation text accordingly. Section 405.1202(f)(3) states that a provider may charge the beneficiary a reasonable amount to cover the costs of duplicating such documentation or delivering it to the beneficiary. We note that this requirement is consistent with our policy for managed care enrollees as contained in our April 4, 2003 final rule (68 FR 16660).

B. Comments on Procedures for Expedited Reviews of Inpatient Hospital Discharges

As noted above, the proposed rule did not include substantive changes to the procedures used by QIOs to conduct expedited initial determinations of disputed hospital discharges, although it did specify that reconsiderations will be performed by QICs, rather than QIOs. We continue to believe that incorporating the relevant procedures into the same regulatory subpart that will contain the expedited determination procedures for other providers (as well as the new appeals procedures required under BIPA when they are made final) will prove convenient for all parties. As a result of the organizational changes to the requirements for other provider services terminations, the hospital-related requirements are now set forth at §§ 405.1206 and 405.1208. Section 405.1206 sets forth the expedited review procedures for beneficiary-initiated appeals, and § 405.1208 covers hospital-initiated appeals. We note that, in keeping with our current policies, QIO determinations are binding on hospitals, without further appeal, but beneficiaries may request reconsiderations of unfavorable QIO decisions. Under our current policies, and consistent with section 1155 of the Act, QIOs, rather than QICs, conduct reconsiderations of expedited determinations concerning inpatient hospital discharges. As stated above, we recognize that section 1869(c)(3)(C)(iii)(III) requires QICs to now perform expedited reconsiderations of expedited determinations, and we expect that QICs will be fully established by the date of implementation. However, in the event QICs have not yet been established at the implementation date, our plan is to have the QIOs continue to perform the

reconsiderations. Since section 1155 already authorizes QIOs to perform reconsiderations, but does not otherwise govern the process for such reconsiderations, we believe we will have the authority, until QICs are operational, to allow QIOs to hear the reconsiderations in accordance with the QIC procedures.

In §§ 405.1206 and 405.1208 we continue to cross-reference the expedited reconsideration process for non-hospital providers. We believe that Congress' intent in incorporating section 1154(e)(2) through (4) into section 1869(c)(3)(C)(iii)(III) was to ensure that statutory time frames and financial liability protections applicable to QIO reviews of hospital discharges continue to apply. Therefore, we have continued to apply those financial protections and time frames to the QIO initial determinations, while creating a uniform process at the QIC reconsideration stage.

We also recognize that the new QIC reconsideration process for hospital discharges may now conflict with some of the provisions governing reconsiderations under 42 CFR part 478. For example, 42 CFR 478.40 requires a \$200 amount in controversy for an ALJ hearing, whereas the QIC reconsideration procedures would require only a \$100 amount in controversy. We plan to issue conforming amendments to part 478 in the future to take into account the changes made by BIPA. However, to the extent there is a direct inconsistency between the part 478 regulations and either the statute or the regulations announced in this final rule, the statute and the regulations announced by the final rule would govern.

Only one commenter addressed these provisions.

Comment: One commenter suggested that the hospital discharge review provisions at proposed § 405.1204(a) define "inpatient hospital discharge", as it applies to these reviews. The commenter asked for a reference to the Code of Federal Regulation (CFR) or statutory provision for the definition. The commenter also questioned how physician concurrence is to be documented and included in the patient record.

Response: Consistent with § 412.4(a) of the regulations concerning the inpatient hospital prospective payment system, a hospital inpatient is considered to be discharged when the patient is formally released from the hospital. For expedited review purposes, a discharge does not include a death or a transfer to another hospital. Hospitals must continue to comply with

the relevant Medicare conditions of participation under part 482 of the CFR concerning documentation requirements. We view physician concurrence as a routine element of the hospital discharge process, and do not believe any change to the medical records and discharge planning procedures are warranted.

Comment: The commenter requested specification of how beneficiaries would receive the notice of non-coverage required under proposed § 405.1204(a). The commenter expressed concern that beneficiaries in hospitals may be unable to exercise their right to appeal due to their health condition. The commenter recommended that the regulations regarding hospital discharge appeals reflect this concern.

Response: The requirements for providing beneficiaries with the Hospital Issued Notice of Non-coverage (HINN) continue long-standing practice under the original Medicare program, as discussed in detail in our April 4, 2003 final rule (68 FR 16660). In brief, hospitals must issue the "Important Message from Medicare" upon admission to all Medicare inpatients. Hospitals issue HINNs to any beneficiary that expresses dissatisfaction with an impending discharge, and a hospital may not bill the beneficiary or his/her representative without issuance of the HINN. We have added under § 405.1206(b) the requirement that delivery of a notice of non-coverage is valid only if a beneficiary has signed and dated the notice to indicate that he or she both received the notice and understood its contents. This policy is consistent with our other CMS requirements governing the delivery of similar notices, such as those set forth in CMS program memoranda A-99-52 and A-99-54 for advanced beneficiary notices under original Medicare. We have no indication that this standard has proven problematic. Note that this requirement for successful delivery does not permit a beneficiary to extend coverage indefinitely by refusing to sign a notice of termination. If a beneficiary refuses to sign a notice, the provider can annotate its copy of the notice to indicate the refusal, and the date of the refusal will be considered the date of receipt of the notice. This standard has already been articulated in our hospital manual provisions at section 414.5.

By the time that termination notices are issued, providers will have already needed to assess a beneficiary's ability to accept delivery of a notice, based on typical admission assessments, care planning evaluations and discharge planning activities that have taken place

during the course of treatment. In the event a provider believes that a beneficiary is not capable to receive the notice, providers must be well acquainted enough with the beneficiary's particular situation to make alternative arrangements, if necessary, to deliver a valid notice. For example, an incapacitated beneficiary is not able to act on his or her rights and, therefore, cannot validly receive the notice. This situation can be remedied through the use of an authorized representative under Federal or State law. This issue is also discussed in section 414.5 of the Hospital Manual.

Comment: The commenter raised several issues regarding coverage during review. In particular, the commenter expressed concern with coverage with the use of calendar days as the standard, and wanted more specificity for when the beneficiary failed to file timely and continued their hospital stay.

Response: The provisions at § 405.1206(f), which specify that a beneficiary is responsible for services furnished after noon of the calendar day after the beneficiary receives the QIO determination, are consistent with section 1154(e)(4) of the Act regarding expedited reviews of inpatient hospital stays. Although the statute refers to "working days" for most aspects of this process, it does not use that terminology in establishing liability; therefore, we believe it is reasonable to conclude that the calendar days, and not working days, should be used.

We believe that § 405.1206(e)(3) clearly explains that if a beneficiary does not make a timely request for an expedited review, the beneficiary may bear financial liability. That is, the beneficiary may be responsible for charges beyond the date on the hospital issued notice of non-coverage (HINN). Again, beneficiaries generally receive a HINN only when they express dissatisfaction with a hospital's decision to discharge them from inpatient care.

Comment: The commenter asked whether beneficiaries could face charges from hospitals for providing medical record data, and what documentation procedures are associated with notice requirements.

Response: We agree, particularly where notification takes place by telephone. Hospitals may charge beneficiaries a reasonable amount for providing them with copies of their medical records. Hospitals may not, however, charge beneficiaries for providing the medical records to the QIO or QIC.

IV. Provisions of this Final Rule With Comment Period

A. Summary of Provisions

For the convenience of the reader, listed below are the major elements of the regulations concerning the new expedited proceedings that are set forth in this final rule with comment period. This listing is intended solely as a reference aid rather than as a comprehensive statement of the policies set forth in the regulation text.

Section 405.1200 describes the applicability of the expedited determination and reconsideration provisions and establishes an advance notification requirement for all provider service terminations and discharges. Section 405.1200(a) specifies that for purposes of these provisions in 405.1200 through 405.1204, the term provider includes the non-hospital providers of SNFs, HHAs, CORFs, and hospices. Hospitals have their own special rules that apply by virtue of section 1154(e) of the Act, which was incorporated into section 1869(c)(3)(C)(iii)(III) of the Act.

Section 405.1200(b) sets forth the notification requirement that applies when a beneficiary's SNF, HHA, CORF, or hospice services are being terminated. These procedures require that the provider deliver, generally no later than 2 days before the termination of services, a standardized notice that informs the beneficiary of the date of discharge and how to file an appeal.

Section 405.1202(a) describes a beneficiary's right to an expedited determination of a non-hospital provider's decision to terminate services.

Section 405.1202(b) explains how a beneficiary must request an expedited determination: A beneficiary must make a request to the QIO by no later than noon of the next calendar day following receipt of the notice of termination. The beneficiary must be available to answer questions by the QIO and may submit evidence to be used in the decision-making process.

Section 405.1202(c) and (d) sets forth the coverage rules associated with the expedited determination process and the procedural burden of proof rules.

Section 405.1202(e) describes the procedures a QIO must follow from the time it receives a beneficiary's request for an expedited determination through the issuance of its decision. These include immediately informing a provider of a beneficiary's request for an expedited determination, assessing the validity of the discharge notice, examining pertinent medical records, offering the beneficiary, provider, and

physician an opportunity to present their views, and reaching a decision and informing the appropriate parties of its decision. All of these activities must be carried out within 72 hours of the beneficiary's request for an expedited determination.

Section 405.1202(f) and (g) detail the responsibilities of providers. Upon learning that a beneficiary has requested an expedited determination, the provider, by close of business of the day of the QIO's notification, must send a detailed notice to the beneficiary containing the reasons why the services are no longer covered and applicable Medicare coverage rules or policy. Providers may not bill a beneficiary who has requested an expedited determination for any disputed services until the expedited appeals process is complete (including an expedited reconsideration, if applicable).

Section 405.1204 sets forth a beneficiary's right to an expedited reconsideration by a QIC regarding a QIO expedited determination. This right is established under § 405.1204(a), and the procedures to be followed by beneficiaries, the QIC, the QIO, and the provider are described in the following sections. We believe that QICs will be operational at the time we implement the reconsiderations established in this final rule. However, in the event the QICs are not yet operational at the time of implementation, QIOs will perform expedited reconsiderations. We believe it would be contrary to the public interest to delay implementation of these expedited review procedures until the QICs have been fully established. QIOs are well suited to administer expedited reconsiderations and currently perform this function for expedited appeals of inpatient hospital discharges. In addition, we believe that even had BIPA not been passed, we would have had the administrative authority to create a procedural rule establishing a pretermination review process, to be conducted by the QIOs under sections 1102 and 1154(a) of the Act. If QIOs do perform the expedited reconsiderations until QICs are established, they will use the same procedures to be used by QICs, although we would formally view the process as a process separate from the process fully implementing BIPA expedited reviews using QICs to process reconsiderations.

Section 405.1206 outlines longstanding procedures regarding a beneficiary's right to an expedited determination in response to an inpatient hospital discharge. Consistent with § 1154(e)(4) of the Act, if a beneficiary files a timely request for such a determination, the beneficiary is

not financially responsible for inpatient hospital services before noon of the calendar day after receiving the written expedited QIO determination. Consistent with the statute, we note that 412.42(c)(3) specifies that a hospital cannot charge a beneficiary until and unless the hospital provides the beneficiary with a notice of noncoverage.

Section 405.1208 outlines longstanding rules concerning the right of a hospital to request an expedited QIO review. In short, a hospital may request QIO review if it believes the beneficiary does not need further inpatient care but is unable to obtain physician agreement.

B. Decision To Issue a Final Rule With Comment Period

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

As discussed above, the new expedited review process set forth in this final rule is closely modeled on the process now in effect for MA enrollees under our April 4, 2003 final rule. Some commenters on the November 15 proposed rule recognized the close relationship between the two processes, and thus, they recommended changes to the proposed rule notice and appeal procedures that would make the procedures largely parallel. We strongly agree that making the notice and appeal procedures available to MA enrollees and original Medicare beneficiaries as similar as possible is prudent public policy, and will minimize confusion among beneficiaries and providers as we implement the new expedited appeal rights for provider service terminations. However, although the provisions implemented here are clearly a logical outgrowth of the proposed provisions and the comments on them, some of the changes are fairly significant, such as the introduction of a standard coverage termination notice, rather than use of the existing ABN. Moreover, the public's familiarity with the issues involved here has now been informed both by this final rule and our April 4, 2003 final rule on the MA process, as

well as with actual experience with the MA process (which began on January 1, 2004). Thus we believe it would be in the public interest to welcome further comments on the changes set forth in this final rule. If these comments warrant changes to these requirements, we will carry out further rulemaking.

V. Response to Comments

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

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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.

The PRA exempts the majority of the information collection activities referenced in this Final Rule with Comment, including collections associated with SNFs. In addition, 5 CFR 1320.4 excludes collection activities during the conduct of redeterminations, reconsiderations, appeals, and other administrative actions. However, the information collection requirement associated with the initial request to seek an expedited determination, in a non-SNF setting, is subject to the PRA.

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

Section 405.1200 Notifying Beneficiaries of Provider Service Terminations

[If you choose to comment on issues in this section, please include the caption "Notifying Beneficiaries of Provider Service Terminations" at the beginning of your comments.]

For any termination of Medicare-covered services, the provider of the service must notify the beneficiary in writing of its decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the requirements and procedures set forth in this section.

Given that CMS has developed standardized formats for these notices, and notices will be disseminated during the normal course of related business activities, we estimate that it will take providers (HHAs, CORFs, and Hospices) 5 minutes to deliver each notice. In 2002, there were approximately 4.2 million Medicare HHA discharges. (Note that the amount of Medicare business with CORFs is so small that Medicare statistical summaries do not include a separate line item for patient encounters with these facilities. Similarly, while we do not have precise estimates of hospice discharges, the number is considered to be an extremely small percentage of the 0.5 million number of annual hospice patients. Thus, our analysis is necessarily limited to HHA services.) We estimate that HHA providers will be required to give an estimated 4.2 million notices to beneficiaries. The total annual burden associated with this requirement is 350,000 hours.

If you wish to view the proposed standardized notices and the supporting documentation, you can download a copy from the CMS Web site at <http://www.cms.hhs.gov/regulations/pr/>.

Section 405.1202 Expedited Determination Procedures

[If you choose to comment on issues in this section, please include the caption "Expedited Determination Procedures" at the beginning of your comments.]

A beneficiary who desires an expedited determination must submit a request for an appeal to the QIO, in writing or by telephone, by no later than noon of the effective date of the written termination notice. If, due to an emergency the QIO is closed on the day the beneficiary requests an expedited determination, the beneficiary must file a request by noon of the next day that the QIO is open for business.

The right to an expedited review of the termination of HHA/CORF/hospice

services has never been available to Medicare beneficiaries. Consistent with our estimate of the proportion of MA enrollees who are likely to request QIO reviews of HHA/CORF/hospice services, we are estimating that approximately 1–2 percent of Medicare fee-for-service beneficiaries who receive termination notices will request an expedited review. We believe this is a reasonable estimate of the maximum number of HHA/CORF/hospice enrollees who are likely to file appeals with the IRE. Thus, we estimate the annual number of fee-for-service reviews at no more than 2 percent of the approximately 4.2 million HHA/CORF/hospice discharges (FY 2002 data), meaning that the maximum number of beneficiaries that are likely to request an expedited determination by the QIO is about 84,000 annually. It is estimated that it will take 84,000 beneficiaries 15 minutes to file an appeal on an annual basis. The total annual burden associated with this requirement is 21,000 hours.

The beneficiary may submit evidence to be considered by the QIO in making its decision and may be required by the QIO to authorize access to his or her medical records in order to pursue the appeal. It is likely that no more than 10 percent of the 84,000 beneficiaries who file appeals will also submit additional evidence. It is estimated that it will take 8,400 beneficiaries 60 minutes to submit evidence on an annual basis. That is, since beneficiaries may not be functioning at their maximum capacity, they may need to contact family members, friends, or their personal physicians who might provide assistance in gathering additional evidence. The total annual burden associated with this requirement is 8,400 hours.

It should be noted that requirements are currently captured and accounted for in currently approved information collection under OMB numbers 0938–0045 "Requirements for Reconsideration for Part A Health Insurance Benefits".

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 and Issuances Group, Attn: Dawn Willingham, CMS–4004–FC, Room C5–14–03, 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.: Christopher Martin, CMS Desk Officer.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: Christopher.Martin@omb.eop.gov; or faxed to OMB at (202) 395–6974.

VII. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption "Regulatory Impact Statement" at the beginning of your comments.]

A. Introduction

We have examined the impact of this rule under the criteria of Executive Order 12866 (September 1993, Regulatory Planning and Review), section 1102(b) of the Social Security Act, the Regulatory Flexibility Act (RFA), Public Law No. 96–354, the Unfunded Mandates Reform Act of 1995, Public Law 104–4, and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). This rule would not meet the \$100 million threshold and therefore is not a major rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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

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

Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals, since as we explain in C., below, we estimate a cost of about \$200 a provider. Although a regulatory impact analysis is not mandatory for this final rule, we believe it is appropriate to discuss the possible impacts of the new appeals procedures on beneficiaries and providers, regardless of the monetary threshold of that impact. Therefore, a brief voluntary discussion of the anticipated impact of this rule is presented below.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule would not have such an effect on State, local, or tribal governments, or on the private sector.

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

B. Overview of the Changes

This final rule implements the requirement under section 1869(b)(1)(F) of the Act that a beneficiary has a right to an expedited determination upon notification by a provider of the provider's decision to discharge the beneficiary or to terminate services. This rule specifies that providers (that is, SNFs, HHAs, CORFs and hospices) must issue a standardized termination notice before all discharges or service terminations to inform beneficiaries of these new appeal rights. In general, we believe that these changes will enhance the rights of Medicare beneficiaries, without imposing any significant financial burden on these individuals. Most notably, the new requirements will significantly reduce a beneficiary's potential liability in situations where disputed provider services are denied on appeal.

C. Expedited Determination and Reconsideration Procedures for Provider Terminations (§ 405.1200 Through § 405.1204)

We project that providers will be responsible for delivering short standardized termination notices to approximately 5.3 million beneficiaries a year. This includes about 1.1 million SNF discharges and 4.2 million HHA discharges. The required termination notices will be largely standardized, requiring only the insertion of the beneficiary's name and discharge date. We estimate that it will 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 5.3 million notices annually, we estimate the aggregate cost of delivering these notices to be roughly \$13 million. Given that there are roughly 24,000 affected providers, the average costs associated with this provision will be less than \$600 per provider.

At most, we believe that 2 percent of affected individuals (that is, 106,000 beneficiaries) will request an expedited determination. For these 106,000 cases, providers will be required under this final rule to deliver a detailed termination 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 will take providers 60 to 90 minutes to prepare the detailed termination notice and to prepare a case file for the QIO. At an estimated cost of \$30 per hour, we project an aggregate cost of \$3.2 million to \$4.8 million to approximately 24,000 providers, or about \$200 per provider.

Thus, we believe that the total financial impact of the new notice and expedited determination requirements is less than \$20 million annually. We do not anticipate that the provisions of this final rule will have a significant financial impact on individual providers. We note that both the advance termination notice and the detailed termination notice will be developed through OMB's Paperwork Reduction Act process and thus will be the subject of further opportunity for public comment. The only other significant costs associated with this provision will result from the Secretary's commitment to contract with QIOs and QICs to conduct these expedited reviews. We are projecting first year costs, including training and start costs for QIOs, to the Medicare

Trust Fund of about \$32 million to carry out this function.

List of Subjects in 42 CFR Parts 405 and 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 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), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Add a new subpart J to read as follows:

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

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services. The provider must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A provider must notify the beneficiary of the decision to terminate covered services no later than

2 days before the proposed end of the services. If the beneficiary's services are expected to be fewer than 2 days in duration, the provider must notify the beneficiary at the time of admission to the provider. If, in a non-residential setting, the span of time between services exceeds 2 days, the notice must be given no later than the next to last time services are furnished.

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

(i) The date that coverage of services ends;

(ii) The date that the beneficiary's financial liability for continued services begins;

(iii) A description of the beneficiary's right to an expedited determination under § 405.1202, including information about how to request an expedited determination and about a beneficiary's right to submit evidence showing that services must continue;

(iv) A beneficiary's right to receive the detailed information specified under § 405.1202(f); and

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the termination notice is valid if—

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

(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 provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(5) *Financial liability for failure to deliver valid notice.* A provider is financially liable for continued services until 2 days after the beneficiary receives valid notice as specified under paragraph (b)(3) of this section, or until the service termination date specified on the notice, whichever is later. A beneficiary may waive continuation of services if he or she agrees with being discharged sooner than the planned service termination date.

§ 405.1202 Expedited determination procedures.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to an expedited determination by a QIO under the following circumstances:

(1) For services furnished by a non-residential provider, the beneficiary disagrees with the provider of those services that services should be terminated, and a physician certifies that failure to continue the provision of the service(s) may place the beneficiary's health at significant risk.

(2) For services furnished by a residential provider or a hospice, the beneficiary disagrees with the provider's decision to discharge the beneficiary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request for a determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone, by no later than noon of the calendar day following receipt of the provider's notice of termination. If the QIO is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIO is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or to supply information that the QIO may request to conduct its review.

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

(4) If a beneficiary makes an untimely request for an expedited determination by a QIO, the QIO will accept the request and make a determination as soon as possible, but the 72-hour time frame under paragraph (e)(6) and the financial liability protection under paragraph (g) of this section do not apply.

(c) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the QIO reverses the provider's service termination decision. If the QIO's decision is delayed because the provider did not timely supply necessary information or records, the provider may be liable for the costs of any additional coverage, as determined by the QIO in accordance with paragraph (e)(7) of this section. If the QIO finds that the beneficiary did not receive valid notice, coverage of provider services continues until at least 2 days after valid notice has been received. Continuation of coverage is not required if the QIO determines that coverage could pose a threat to the beneficiary's health or safety.

(d) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of

proof rests with the provider to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) In order for the QIO to determine whether the provider has met the burden of proof, the provider should supply any and all information that a QIO requires to sustain the provider's termination decision, consistent with paragraph (f) of this section.

(2) The beneficiary may submit evidence to be considered by a QIO in making its decision.

(e) *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 provider of those services that a request for an expedited determination has been made.

(2) The QIO determines whether the provider delivered valid notice of the termination decision consistent with § 405.1200(b) and paragraph (f) of this section.

(3) The QIO examines the medical and other records that pertain to the services in dispute. If applicable, the QIO determines whether a physician has certified that failure to continue the provision of services may place the beneficiary's health at significant risk.

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

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) No later than 72 hours after receipt of the request for an expedited determination, the QIO must notify the beneficiary, beneficiary's physician, and the provider of services of its determination whether termination of Medicare coverage is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

(7) If the QIO does not receive the information needed to sustain a provider's decision to terminate services, 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 provider services, the provider may be held financially liable for these services, as determined by the QIO.

(8) The QIO's initial notification may be by telephone, followed by a written notice including the following information:

(i) The rationale for the determination;

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

(iii) Information about the beneficiary's right to a reconsideration of the QIO's determination, including how to request a reconsideration and the time period for doing so.

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

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

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or 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; and

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the provider must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required under § 405.1200(b) and under paragraph (f)(1) of this section. The provider must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the provider of the request for an expedited determination. At the discretion of the QIO, the provider may 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 provider must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO including records of any information provided by telephone. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The provider must accommodate such a request by no later

than close of business of the first day after the material is requested.

(g) *Coverage during QIO review.* When a beneficiary requests an expedited determination in accordance with the procedures required by this section, the provider may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

§ 405.1204 Expedited reconsiderations.

(a) *Beneficiary's right to an expedited reconsideration.* A beneficiary who is dissatisfied with a QIO's expedited determination may request an expedited reconsideration by the appropriate QIC.

(b) *Requesting an expedited reconsideration.* (1) A beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIC, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) receipt of the QIO's determination. If the QIC is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIC is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or supply information that the QIC may request to conduct its reconsideration.

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

(4) A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a reconsideration under the standard claims appeal process, but the coverage protections described in paragraph (f) of this section would not extend through this reconsideration, nor would the timeframes or the escalation process described in paragraphs (c)(3) and (c)(5) of this section, respectively.

(c) *Procedures the QIC must follow.*

(1) On the day the QIC receives the request for an expedited determination under paragraph (b) of this section, the QIC must immediately notify the QIO that made the expedited determination and the provider of services of the request for an expedited reconsideration.

(2) The QIC must offer the beneficiary and the provider an opportunity to provide further information.

(3) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, no later than 72 hours after receipt of the request for an

expedited reconsideration, and any medical or other records needed for such reconsideration, the QIC must notify the QIO, the beneficiary, the beneficiary's physician, and the provider of services, of its decision on the reconsideration request.

(4) The QIC's initial notification may be done by telephone, followed by a written notice including:

(i) The rationale for the reconsideration decision;

(ii) An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability; and

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to the ALJ hearing level if the amount remaining in controversy after the QIO determination is \$100 or more.

(6) A beneficiary requesting an expedited reconsideration under this section may request (either in writing or orally) that the QIC grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines in paragraph (c)(3) of this section do not apply.

(d) *Responsibilities of the QIO.* (1)

When a QIC notifies a QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.

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

(e) *Responsibilities of the provider.* A provider may, but is not required to, submit evidence to be considered by a QIC in making its decision. If a provider fails to comply with a QIC's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIC makes

its reconsideration decision based on the information available.

(f) *Coverage during QIC reconsideration process.* When a beneficiary requests an expedited reconsideration in accordance with the deadline specified in (b)(1) of this section, the provider may not bill the beneficiary for any disputed services until the QIC makes its determination.

§ 405.1206 Expedited determinations for inpatient hospital discharges.

(a) *Beneficiary's right to an expedited determination for an inpatient hospital discharge.* A beneficiary who has received a notice of noncoverage under section 1154(e)(1) of the Act and 42 CFR 412.42(c)(3) may 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. A beneficiary who timely requests an expedited QIO review in accordance with paragraph (d)(1) of this section and who meets the conditions of section 1879(a)(2) of the Social Security Act (that is, the individual did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under part A or part B) may remain in the hospital with no additional financial liability until the QIO makes its determination.

(b) *When delivery of the notice is valid.* (1) Except as provided in paragraph (b)(2) of this section, valid delivery of the notice of non-coverage requires that the beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents.

(2) If a beneficiary refuses to sign the notice, the provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Beneficiary's right to other review.* (1) A beneficiary who fails to request an expedited determination in accordance with paragraph (d)(1) of this section, and remains in the hospital, may request an expedited review at any time during the course of his or her inpatient hospital stay. The QIO will issue a decision in accordance with paragraph (e)(5)(ii) of this section. The escalation procedures described in § 405.1204(c)(5) and the financial liability rules of paragraph (f)(2) of this section do not apply.

(2) A beneficiary who fails to request an expedited determination in accordance with paragraph (d)(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 notice of noncoverage as provided under section 1154(e)(1) or at any time for good cause. The QIO will issue a decision in accordance with paragraph (e)(5)(iii) of this section. The escalation procedures described in § 405.1204(c)(5) and the financial liability rules of paragraph (f)(2) of this section do not apply.

(d) *Procedures the beneficiary must follow.* For the expedited appeal process, the following rules apply:

(1) The beneficiary must submit the request for an expedited determination—

(i) To the QIO that has an agreement with the hospital under part 475 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the hospital has determined that the hospital stay is no longer necessary.

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

(e) *Procedures the QIO must follow.* On the date that the QIO receives the beneficiary's request:

(1) The QIO must notify the hospital that the beneficiary has filed a request for immediate review.

(2) The hospital must supply any information, including medical records, 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 first full working day after the day the beneficiary receives notice of the planned discharge.

(3) The QIO must examine the pertinent records pertaining to the services.

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

(5)(i) When the beneficiary requests an expedited determination in accordance with paragraph (d)(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 working day after it receives all requested pertinent information.

(ii) When the beneficiary does not request an expedited determination in accordance with paragraph (d)(1) 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 working days following receipt of the request and pertinent information.

(iii) When the beneficiary does not request an expedited initial determination in accordance with paragraph (d)(1) 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.

(f) *Coverage during QIO expedited review.* (1) In general, if the beneficiary remains in the hospital after receiving the hospital issued notice of noncoverage, and the hospital, the physician who concurred in the hospital's determination on which the advanced written notice of termination 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 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.

(2) *Timely filing and limitation on liability.* If a beneficiary both files a request for an expedited determination by the QIO in accordance with paragraph (d)(1) of this section, and meets the conditions of section 1879(a)(2) of the Social Security Act (that is, the individual did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under part A or part B), the beneficiary is not financially responsible for inpatient hospital services 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.* When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (d)(1) of this section, that beneficiary may be responsible for charges that extend beyond the date specified on the hospital's advance written notice of termination 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) *Notice of an expedited determination.* (1) When a QIO issues an expedited determination in accordance with paragraph (e)(5) of this section, the

QIO must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited determination must contain the following:

- (i) The basis for the determination;
- (ii) A detailed rationale for the determination;
- (iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any;
- (iv) A statement informing the beneficiary of his or her subsequent appeal rights, and the timeframe for requesting a reconsideration by the QIC.

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

(1) *When 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. If the beneficiary does not make a request in accordance with paragraph (d)(1) of this section, the timeframes described in § 405.1204(c)(3), the escalation procedures described in § 405.1204(c)(5), and the coverage rule described in § 405.1204(f) will not apply.

(2) *When 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 Hospital requests expedited QIO review.

(a) *General rule.* If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(b) *Procedures hospital must follow.* (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his

or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow.*

(1) The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received all pertinent records.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of the hospital's request and receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination.* (1) When a QIO issues an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited initial determination must contain the following:

- (i) The basis for the determination;
- (ii) A detailed rationale for the determination;
- (iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any; and
- (iv) A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

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

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

section. If the beneficiary does not make a request in accordance with paragraph (d)(1) of this section, the timeframes described in § 405.1204(c)(3), the escalation procedures described in § 405.1204(c)(5), and the coverage rule described in § 405.1204(f) will not apply.

(2) *When a 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, this determination is subject to the general claims appeal process.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ Part 489 is amended as set forth below:

■ 1. The authority citation for part 489 is revised 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, 1395ff, and 1395hh).

■ 2. Section 489.27(b) is revised as follows:

§ 489.27 Beneficiary notice of discharge rights.

* * * * *

(b) *Notification by other providers.* Other providers that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable CMS notices in advance of the termination of Medicare services, including the notices required under §§ 405.1202 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: December 23, 2003.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 12, 2004.

Tommy G. Thompson,
Secretary.

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