Supporting Statement for the
Expedited Review Notices and Supporting Regulations
Contained in 42 CFR §§405.1200 and 405.1202

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) requests a revision of two previously approved Office of Management and Budget (OMB) notices, the Notice of Provider Non-Coverage (Generic Expedited Review Notice) and the Detailed Explanation of Provider Non-Coverage. This information collection is associated with CMS-4004-FC, [Medicare Program; Expedited Determination Procedures for Provider Service Terminations], which was published on November 26, 2004 (Vol. 69 No. 227). The rule provided for an expedited appeal when a Medicare beneficiary receives notice from a provider of services that his or her Medicare covered services will be terminated. The rule allows beneficiaries to request an expedited determination by a Quality Improvement Organization (QIO) on whether such services should continue. Providers affected by the rule include skilled nursing facilities (SNFs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and hospices.

A. Background

The final rule sets forth regulations for implementing the expedited review process required by Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000(BIPA). 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 an individual and a physician certifies that failure to continue services is likely to place the individual's health at significant risk; or (2) discharge the individual from the provider of services.

Under these requirements, HHAs, CORFS, and hospices must deliver standardized notices to all beneficiaries no later than 2 days in advance of their discharges or termination of their services. This notice is titled "Notice of Medicare Provider Non-Coverage." If the beneficiary disputes the discharge or termination, the beneficiary is entitled to an expedited determination by a QIO about whether the provider's coverage decision is correct. If the beneficiary requests such a determination, the provider must send the beneficiary a detailed explanation of why the services should end. This additional notice, titled the "Detailed Explanation of Provider Non-Coverage" is the second notice included in this package.

The regulation and associated notices are modeled closely on the parallel Medicare Advantage (MA) procedures and notices. The MA regulations were set forth in our April 4, 2003 final rule and the standardized notices (CMS-10095 A and B) were approved by OMB in March, 2004. Comments received on the MA notices through the rulemaking and Paperwork Reduction Act (PRA) process were taken into account when developing the notices contained in this publication.

The revised Notice of Provider Non-Coverage and Detailed Explanation of Provider Non-Coverage will no longer require use of the beneficiary's Medicare number as a patient identifier. Instead, providers may use a number that helps to link the notice with a related claim when applicable. This field is now optional and choosing not to enter a number will not invalidate the notice.

B. JUSTIFICATION

1. NEED AND LEGAL BASIS

Section 521 of BIPA, Pub.L.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 an individual may obtain an expedited determination and reconsideration with respect to the termination of provider services. Based on notice and comment rulemaking, we are implementing this process through a 2-stage notice process.

- §405.1200(b) – Prior to any termination of covered service, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services.

- §405.1202(f) – When an QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed termination notice to the beneficiary by close of business of the day of the QIO's notification.

2. INFORMATION USERS

According to the 2006 Data Compendium published by CMS, there are 8,618 HHAs, 524 CORFs, and 2,275 hospices participating in Medicare that potentially would need to issue the notices. Based on 2005 CMS Customer Information System (HCIS) data, we estimate that approximately 3.1 million beneficiaries annually will receive the Notice of Medicare Provider Non-Coverage from HHAs, CORFs , and hospices.

3. USE OF INFORMATION TECHNOLOGY

HHAs, CORFs, and hospices generally must deliver hard-copies of the required advance notice to beneficiaries. Providers must also deliver detailed written notices whenever those beneficiaries request appeals. There is no provision for alternative uses of information technology for the advanced or detailed notices. The beneficiary requests are done via telephone.

4. DUPLICATION OF SIMILAR EFFORTS

The forms CMS-10123 and 10124 do not duplicate an existing information collection.

5. SMALL BUSINESSES

The new requirements have been designed to impose as little burden as possible on these providers while still ensuring the accuracy and efficiency of the expedited review process required by BIPA. The timing and general nature of the advance notice requirement allows for flexibility for facilities in that the notice must be delivered no later than 2 days in advance. Facilities that can reliably project the service termination date further in advance of 2 days may deliver the required notice earlier and we encourage them to do so. When the end-date of the service is known upon admission, for example, as in a one day home health visit for follow-up of minor surgery, the advance termination notice can be delivered upon admission. The detailed notice is delivered to beneficiaries only when they appeal the termination decision. We anticipate that delivery of this notice for providers represents a very small (no more than 1-2 percent) fraction of the total number of notices delivered. The rule will not have a significant impact on small rural hospitals.

6. LESS FREQUENT COLLECTION

Consumer research supports providing information when the individual needs to make a decision. In this context, that would entail giving notice of the end of Medicare coverage as close as possible to the planned service termination date. At the same time though, issuing

the notice as early as practical minimizes a beneficiary's potential liability by facilitating conduct of the review process while covered services continue. We believe that we have balanced these goals in requiring that the notice be provided no later than 2 days in advance of coverage ending. Providing advance notices to less than 100% of individuals that receive the services would not afford equal protection to all beneficiaries about their rights. Additionally, in these provider settings, there is no reliable method of discerning whether a beneficiary is dissatisfied with the impending termination of services other than to provide notice of his or her appeal rights. The distribution of the Notice of Medicare Provider Non-Coverage is similar to the Important Message from Medicare, which is delivered to all Medicare beneficiaries receiving in-patient hospital services upon admission, or shortly thereafter. The Detailed Explanation of Provider Non-Coverage is similar to the Detailed Notice of Discharge (CMS-10066), which is a notice given to beneficiaries who object to being discharged from an in-patient hospital setting.

7. SPECIAL CIRCUMSTANCES

The regulation at §405.1202(b) requires that the notices be validly delivered to either beneficiaries or their representatives in circumstances where a beneficiary is unable to understand the notice.

8. FEDERAL REGISTER /OUTSIDE CONSULTATION

A 60-day Federal Register notice was published on February 29, 2008.

Information about the notices and corresponding information was published in the Federal Register in November of 2004. There has been no current outside consultation regarding these notices.

9. PAYMENTS/GIFTS TO RESPONDENT

We do not plan to provide any payment or gifts to respondents.

10. CONFIDENTIALITY

We are not collecting information. The provider and QIO will maintain records of notices and decisions, but those records do not become part of a federal system of records. Therefore, this item is not applicable.

11. SENSITIVE QUESTIONS

We do not require beneficiaries to answer any sensitive questions, and note that the revised Notice of Provider Non-Coverage and Detailed Explanation of Provider Non-Coverage will no longer require use of the

beneficiary's Medicare number as a patient identifier. Instead, when applicable, providers may use a number that helps to link the notice with a related claim.

12. BURDEN ESTIMATE

§405.1200 Notifying beneficiaries of provider service terminations.

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.

Based on out experience with this notices and similar notices, such as the Important Message from Medicare (CMS-R-193) and the Notice of Medicare Non-Coverage (CMS-10095), we estimate that it will take providers (HHAs, CORFs, and Hospices) 10 minutes to prepare and furnish each notice. In 2005, 3.1 million beneficiaries received services from home health agencies. Thus, we estimate that providers delivered 3.1 million notices to beneficiaries. The total annual burden associated with this requirement is 516,666 hours. (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, but the number is considered to be an extremely small percentage of the total number of annual hospice patients. Accordingly, our analysis is necessarily limited to HHA services.)

§405.1202—Expedited determination procedures

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 was not available to Medicare beneficiaries prior to 2000. Therefore, we derived our initial estimate of the proportion of beneficiaries likely to request QIO reviews of HHA/CORF/hospice service terminations by extrapolating from existing MA data on HHA appeals. Since implementation of the final rule in 2004, CMS has tracked the number of FFS expedited appeal requests filed with QIOs. Based on this data, the number of detailed notices delivered to fee-for-service beneficiaries in 2007 is much lower than

the estimate we developed using the 2002 MA data. Using annualized data on the number of expedited appeals requested during the first half of FY07, we estimate the annual number of fee-for-service reviews at no more than 15,637. We also estimate that it will take the 15,637 beneficiaries 15 minutes (on average)to file an appeal. The total annual burden associated with this requirement is 3,909 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 15,637 beneficiaries who file appeals will also submit additional evidence. We also estimate that it will take each of the 1,563 beneficiaries 60 minutes to submit their additional 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 1,563 hours.

13. CAPITAL COSTS

There are no capital costs associated with this collection.

14. COSTS TO FEDERAL GOVERNMENT

There is no cost to the Federal Government for this collection, although the Federal Government will entail costs in establishing costs with the notices.

15. CHANGES TO BURDEN

The right to an expedited review of the termination of HHA/CORF/hospice services was not available to Medicare beneficiaries prior to 2000. Therefore, we derived our initial estimate of the proportion of beneficiaries likely to request QIO reviews of HHA/CORF/hospice service terminations by extrapolating from existing MA data on HHA appeals. Since implementation of the final rule in 2004, CMS has tracked the number of FFS expedited appeal requests filed with QIOs. Based on this data, the number of notices delivered to fee-for-services beneficiaries in 2007 is much lower than the estimate we developed using the 2002 MA data.

The increase in the total annual burden estimate is the result of an increase, from 5 minutes to 10 minutes, in the amount of time required to issue the notice. Based on feedback received from the provider community and our experience with this and other standardized

notices, we believe that 10 minutes is a more accurate approximation of the time required to issue the notice.

16. PUBLICATION AND TABULATION DATES

These notices will be published on the Internet; however, no aggregate or individual data will be tabulated from them.

17. EXPIRATION DATE

We are not requesting exemption.

18. CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

C. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.