Supporting Statement for the
Advance Beneficiary Notice of Noncoverage (ABN)
Contained in 42 CFR §411.404 and §411.408

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) requests a revision of a previously approved Office and Management and Budget (OMB) notice, formerly titled the Advance Beneficiary Notice (ABN).

A. BACKGROUND

The use of written notices to inform beneficiaries of their liability under specific conditions has been available since the "limitation on liability" provisions in section 1879 of the Social Security Act were enacted in 1972 (P.L. 92-603). The standard advance beneficiary notice (ABN) for conveying information on beneficiary liability is now approved by OMB, consistent with the Paperwork Reduction Act of 1995 (PRA). (Note that although CMS is retaining the commonly used "ABN" acronym, we are changing the official title to "Advance Beneficiary Notice of Noncoverage" in order to convey more clearly the purpose of the notice.)

The revised ABN included in this package incorporates: suggestions for changes made by users of the ABN and by beneficiary advocates based on experience with the current form, refinements made to similar liability notices in the same period through consumer testing and other means, as well as related Medicare policy changes and clarifications occurring in the same interval. We have made additional changes based on suggestions received during the recent public comment period.

Note that previous PRA approval for Collection 0938-0566 was for two versions of the ABN, the General Use ABN, form CMS-R-131-G, and CMS-R-131-L, specifically for physician-ordered laboratory tests. These two notices have now been combined into a single notice. This version of the ABN continues to combine the general ABN (ABN-G) and the laboratory ABN (ABN-L) into a single notice, with an identical OMB form number. As combined, however, the new notice will enable us to capture the overall improvements incorporated into the revised ABN while still permitting pre-printing of key laboratory-specific information, such as the denial reasons used in the current ABN-L.

The ABN has been used to notify Medicare beneficiaries of liability under the following statutory provisions:

- Section 1879 of the Social Security Act ('the Act"), the "limitation on liability" provision, is applicable to all providers, physicians, practitioners and suppliers participating in the Medicare Program, on an assigned or unassigned basis, for items or services denied under section 1862(a)(1). Most commonly, these are denials of items and services as "not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member", and specific denials under section 1879(g)(2), which occur when a hospice patient is found not to be terminally ill;

- Section 1834(a)(18) of the Act is applicable to suppliers of durable medical equipment and medical supplies, for items furnished on an unassigned basis and denied with refund requirements under section 1834(a)(17(B) due to an unsolicited telephone contact, unless: (1) a supplier informs the beneficiary, prior to furnishing the item, that Medicare is unlikely to pay for the item and the beneficiary, after being so informed, agrees to pay out of pocket (i.e., the supplier uses the ABN for advance notification), or (2) a supplier did not known, or could not reasonably have been expected to know, that Medicare would not pay for the item;

- Section 1834(j)(4) of the act is applicable to suppliers of durable medical equipment and other medical supplies for items and services furnished on an unassigned basis and denied with refund requirements when: (1) under section 1834(a)(15), there is failure to obtain an advance coverage determination; or (2) under section 1834(j)(1), there is a lack of a supplier number, or (3) denials under section 1862(a)(1) of the Act ("not reasonable and necessary…"); and

- Section 1842(l) of the Act is applicable to physicians "who do not accept payment on an assignment-related basis", requiring refunds to beneficiaries of any amounts collected for denials with refund requirements under section 1862(a)(1) of the Act. Note refunds are specified as not required in either of two circumstances: (1) when a physician informs the beneficiary, prior to furnishing the service, that Medicare is unlikely to pay for the service and the beneficiary, after being so informed, agrees to pay out of pocket (i.e., the physician uses the ABN for advance notification), or (2) when a physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service.

Implementing regulations are found at 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), which specify written notice requirements. These requirements are fulfilled by the ABN and subject to PRA.

B. JUSTIFICATION

1. NEED AND LEGAL BASIS

Under section 1879 of the Act, a physician, provider, practitioner or supplier of items or services participating in the Medicare Program, or taking a claim on assignment, may bill a Medicare beneficiary for items or services usually covered under Medicare, but denied in an individual case under one of the several statutory exclusions (specified in A above), if they inform the beneficiary, prior to furnishing the service, that Medicare is likely to deny payment. 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), require written notice be provided to inform beneficiaries in advance of potential liability for payment, and thus contain a paperwork burden. Therefore, these requirements comply with all general information collection guidelines in 5 CFR 1320.6.

2. INFORMATION USERS

Based on CMS statistics for 2005, we estimated the number of physicians, providers, practitioners and suppliers potentially delivering ABNs as about 1.3 million (calculated from Tables 17, 19 and 22, 2006 CMS Statistics). No public comments were received disputing or supporting this estimate.

ABNs are not given every time items and services are delivered. Rather, ABNs are given only when a physician, provider, practitioner or supplier anticipates that Medicare will not provide payment in specific cases.

Previously, Medicare estimated that 2.5% of claims were denied for general questions of medical necessity, and assumed all such cases potentially involved delivery of ABNs. However, this estimate only accounted for ABNs delivered when services were received. It did not take into account either those instances when the beneficiary received an ABN and subsequently chose not to receive the items and services, or denials based on applicable statutory requirements other than 1862(a)(1). Although we do not have quantifiable estimates of these two types of situations, we believe they may constitute up to one third of situations where an ABN is delivered. Thus, we revised the ABN volume estimate to reflect ABN delivery in those situations. This approach resulted in an estimate of 40,302,506 ABNs delivered to beneficiaries for 2005.

We invited the public to comment on this approach and the resulting estimate, however, no comments were received on the approach, nor did we receive any alternative estimates.

While a few commenters indicated in general that the overall number of ABNs might have been underestimated, such comments were purely anecdotal and based on individual experience; these commenters also acknowledged that the individual experiences of notifiers would vary. Therefore, the number of ABNs estimated was kept the same. Based on estimated1.3 million notifiers, on average each notifier will deliver about 31.7 ABNs a year.

3. IMPROVED INFORMATION TECHNOLOGY

ABNs are usually given as hard copy notices during in-person patient encounters. In some cases, notification may be done by telephone with a follow-up notice mailed. There is no provision for alternative uses of information technology to deliver ABNs, though incorporation of ABNs into other automated business processes is permitted, and some limited flexibility in formatting the notice in such cases is allowed, as discussed in the form instructions. Notifiers may choose to store the required signed copy of the ABN electronically.

4. DUPLICATION OF SIMILAR INFORMATION

The information we are requesting is unique and does not duplicate any other effort.

5. SMALL BUSINESS

The more relevant information that a beneficiary receives in an ABN, the greater his or her ability is to make an informed decision about receiving the service and assuming responsibility for payment. Thus, a clear and understandable ABN should reduce the burden on small businesses that would otherwise be associated with providing services and pursuing Medicare billing for services for which they potentially would not be reimbursed.

6. LESS FREQUENT COLLECTION

ABNs are given on an as-needed basis as described under 2., above.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances.

8. FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

The ABN was published as a Federal Register Notice and subject to public comment prior to OMB's approval in 2003. Since that time, we have received many suggestions from form users about ways to improve the ABN and, as noted above, we have incorporated these suggestions into the new proposed notice.

Consistent with the PRA approval we published a revised form in the Federal Register on February 23, 2007. The 60-day public comment period ended on April 24, 2007. We received over 40 public comments and have considered them carefully in making further revisions to the notice and the accompanying notice instructions

A few of the comments we received addressed the burden estimate. A number of commenters argued that creating any changes in the ABN or its instructions would increase burden, and that the current burden estimate was too low, but none of these commenters provided specific recommendations for revising the burden estimate. Nevertheless, we did make some changes to the form, such as removing the blank for other insurance that were said to add to burden without necessarily aiding beneficiaries. Some commenters asked that pilot testing or additional review by public committees occur before the notice is finalized. Since the PRA process itself requires two rounds of public comment, we believe that there is already adequate opportunity for public input. Some commenters noted other concurrent CMS initiatives involving physicians, practitioners, providers, and suppliers that require significant operational resources (i.e., the National Provider Identifier (NPI) initiative), and asked for a reasonable period of time in which to transition from the current ABN to the new notice. We agree that a reasonable transition period is necessary and intend to address that issue prior to final approval of the new ABN.

9. PAYMENT/GIFT TO RESPONDENT

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

10. CONFIDENTIALITY

According to the applicable definition of confidentiality, this item does not apply.

11. SENSITIVE QUESTIONS

There are no questions of a sensitive nature associated with this notice.

12. BURDEN ESTIMATE

The number of affected beneficiaries, notifiers (physician, provider, practitioners and suppliers given under 2. above) is based on 2005 data.
With an annual estimate of 40,302,506 ABNs, and 7 minutes on average needed to deliver each notice, we estimated the hourly burden to be 4,701,959 hours or 3.7 hours per notifier. A few commenters stated that the ABN required more than 7 minutes to complete, and suggested that a range of 10-15 minutes would be more appropriate. In most cases however, these commenters included in their time estimates activities such as researching coverage policies that are not solely required by the ABN are not always part of preparing and delivering the notice, and moreover, are general responsibilities of those participating in Medicare. We also received one comment suggesting that the time required to give the ABN had been overestimated, and should be no more than 3 minutes. Therefore, in striking a balance, the time estimate was kept at 7 minutes.

We estimated the annual cost of delivering 40,302,506 ABNs to be $326,255,502. This is a total cost of $69.39 per notifier. The cost per notifier is based on our expectation that these notices would be prepared by a staff person with professional skills at the GS-12 Step 1 hourly salary of $27.65. Three commenters said this salary estimate was too low, but only one offered an actual quantified estimate based on personal experience, and in doing that acknowledged that variation occurs among notifiers. Therefore, we have maintained the cost estimate noted above.

13. CAPITAL COSTS

Since all affected notifiers are expected to already have the capacity to reproduce ABNs based on CMS guidance, there are no capital costs associated with this collection. Note however the cost estimates (in Section 12 above) do account for some per-notice, non-labor indirect costs, such as the reproduction of individual notices.

14. COSTS TO FEDERAL GOVERNMENT

There is no cost to the Federal Government for this collection.

15. PROGRAM OR BURDEN CHANGES

Issuance of the ABN is an existing collection. The burden estimate has increased due to two main factors: (1) growth in the Medicare program, and (2) adjustments in assumptions and methodology. In terms of Medicare’s growth, the number of beneficiaries, providers and

suppliers and claims have all increased since the last ABN burden estimate was completed. In terms of revisions to our assumptions and methodology, increases were made to: (1) allow more time on average to deliver each ABN based on recent public comments on similar liability notices (from 5 to 7 minutes per notice to better account for complex situations and use by first-time and infrequent notifiers), (2) better account for the number of ABNs given (see 2. above), (3) more accurately estimate personnel related costs based on recent public comments on similar liability notices (higher estimated costs of $26.53 instead of $20), and (4) incorporate revised assumptions increasing the number of providers that may have to give ABNs, which in turn increased the total number of claims from which the number of ABNs nationally was estimated.

Based on the above changes CMS will allow a six month transitional period from the date of implementation to begin using the new form.

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.

19. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.