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 an extension of a previously approved Office and Management and Budget (OMB) notice, the Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131. OMB approval for the ABN expires on February 28, 2011.

A. Background

The use of written notices to inform Medicare beneficiaries of their liability under specific conditions has been available since the "limitation on liability" provisions in section 1879 of the Social Security Act (the Act) were enacted in 1972 (P.L. 92-603). The standard notice for conveying information on beneficiary liability is the Advanced Beneficiary Notice of Noncoverage (ABN) and has been approved by OMB (collection 0938-0566), consistent with the Paperwork Reduction Act of 1995 (PRA).
The currently approved ABN was revised in 2008 to include: suggestions for changes made by users of the ABN and by beneficiary advocates based on experience with the former notices; 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. Additional changes were made based on suggestions received during the public comment period.

Prior to this revision, PRA approval for collection 0938-0566 was for two versions of the ABN, the General Use ABN (Form CMS-R-131-G) and an ABN specifically for physician-ordered laboratory tests (Form CMS-R-131-L). In 2008, these two notices were combined into a single notice with an identical OMB number which is the currently approved ABN. The revised notice has enabled us to capture the overall improvements incorporated into the ABN while still permitting pre-printing of key laboratory-specific information, such as the denial reasons which were used in the past with the ABN-L.

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

- Section 1879 of 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 determined "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 (DME) 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 know, 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 DME 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 that 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. Sections 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 the most recent CMS statistics published in Tables II.3, II.5, and II.8 of 2009 CMS Statistics, we estimate the number of physicians, providers, practitioners, and suppliers potentially delivering ABNs as approximately 1,326,282.

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.
An ABN may be given, and the beneficiary may subsequently choose not to receive the item or service. An ABN may also be issued because of other applicable statutory requirements other than 1862(a)(1) such as when a beneficiary wants to obtain an item from a supplier who has not met Medicare supplier number requirements, as listed in section 1834(j) (1) of the Act. Since there is no quantifiable data on these occurrences, with our prior PRA submission, we estimated that an ABN was probably delivered in about one third of the situations in which an ABN could be issued. We had invited the public to comment on this approach and the resulting estimate; however, no comments were received on the assumption, and we have never received any alternative estimates. Thus, we will continue to use this methodology with this package submission.

According to claims data from Table V.6 of the 2009 CMS Statistics, approximately 131,177,550 claims were filed for care which could have necessitated ABN delivery. We estimate that 43,725,850, or one third of these encounters, were associated with ABN issuance.

As stated above, there are an estimated 1,326,282 providers or suppliers who could issue an ABN, or on average, each notifier will deliver about 33 ABNs a year.

43,725,850 Estimated ABNs delivered annually	/	1,326,282 Providers and suppliers who might issue the ABN	=	32.9687 ≈ 33 ABNs delivered annually per notifier

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 first 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 about ways to improve the ABN, and we have incorporated these suggestions into the revised notice. The revised ABN was last published in the Federal Register on February 23, 2007 and May 25, 2007 for public comment and received OMB approval on February 1, 2008.

As part of the PRA renewal process, a 60-day Federal Register notice was published in Vol. 75, No. 175, pg 55330, on September 10, 2010. No public comments were received.

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 notifiers (physician, provider, practitioners, and suppliers) and the number of ABNs issued is based on 2009 published data (see #2. above).

With an annual estimate of 43,725,850 ABNs and 7 minutes (0.11662 hours), on average, needed to deliver each notice, we estimate the annual hour burden to be 5,099,309 hours or 3.85 hours per notifier. These estimates are only slightly higher than our previously published burdens of 4,701,959 hours annually and 3.7 hours per notifier.

5,099,309 Annual hour burden	/	1,326,282 Provider and supplier notifiers	=	3.84815 ≈ 3.85 Hourly burden per notifier

The cost per notice is $3.33 based on our expectation that these notices would be prepared by a staff person with professional skills at the 2009 GS-12, step 1 hourly salary of $28.55.

3.85	x	$28.55	=	$109.9175 ≈ $109.92

Hourly burden per notifier		2009 GS-12, step 1 hourly salary		Annual cost per notifier
$109.92 Annual cost per notifier	/	32.968709 Annual notices per notifier	=	$3.33407 ≈ $3.33 Cost per notice

We estimate the annual cost of delivering 43,725,850 ABNs at $3.33 per notice to be $145,607,081.

$3.33 Cost per notice	X	43,725,850 Annual number of responses	=	$145,607,080.50 (≈ $145,607,081) Annual cost burden

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.

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 hourly burden estimate is slightly higher than our currently approved burden amount due to growth in the Medicare program. Since the number of items and services provided annually to Medicare beneficiaries has increased,[1] our calculation of the number of ABNs issued annually is predictably higher. However, because the number of Medicare providers responsible for ABN delivery has also increased, the change in hourly burden per notifier is minimized.

Although our annual hour burden estimate is higher than the currently approved amount, our annual cost burden is $180,648,421 less than the currently approved cost burden of $326,255,502. We determined that this decrease is the result of a clerical error in our last PRA submission. In our 2007 submission, the annual cost burden was given as $326,255,502 instead of $126,255,502. Thus, if we compare the current cost estimate of $145,607,081 with the cost estimate of

[1] Number of claims submitted for items and services that might receive an ABN has increased by more than 10 million annually. From Table V.6 of the 2009 CMS Statistics and Table 52 of the 2006 CMS Statistics.

$126,522,502, there is a $19,351,579 increase in the annual cost burden which is more consistent with the 3,423,344 increase in annual responses and 397,350 increase in annual hour burden that we have projected.

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.