Supporting Statement for the Revision of 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) request a revision of the Advance Beneficiary Notice of Noncoverage (ABN), CMS-R-131, Collection 0938-0566, which was re-approved by the Office of Management and Budget (OMB) in 2011. The ABN is being revised to include its use in the home health setting.

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 ABN for conveying information on beneficiary liability has been approved by OMB, consistent with the Paperwork Reduction Act of 1995 (PRA).

This package incorporates expanded use of the ABN by home health agencies (HHAs) as reflected in the revised instructions. No substantive changes have been made to the form. There are no changes that will affect existing ABN users.

Historically, HHAs have used the Home Health Advanced Beneficiary Notice of Noncoverage (HHABN), CMS-R-296, OMB No. 0938-0781, to give liability notice to beneficiaries. The HHABN, last approved under PRA in 2009, has been used as a change of care notice in addition to serving as a notice of liability. In an effort to streamline and simplify beneficiary notices, the liability notice portion of the HHABN, known as "Option Box 1" will now be replaced by use of the ABN. The change of care notification portion of the HHABN will be replaced by the new Home Health Change of Care Notice (HHCCN) (CMS-10280) which is the subject of a separate PRA package. Accordingly, the HHABN will be discontinued from use.

While the ABN may be new to some HHAs, those operating combined HHA and hospice facilities will already be familiar with the ABN since hospices presently use this notice.

B. JUSTIFICATION

1. NEED AND LEGAL BASIS

The ABN has been used to notify Medicare beneficiaries of liability under the following statutory provisions. The first two items listed below apply to all users of the ABN:

- 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;

- 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.

In addition, the following provisions of the Social Security Act (the Act) are specific to home health care and would necessitate delivery of the ABN by HHAs:

- The patient does not need intermittent skilled nursing care - §1814(a)(2)(C) [Part A] or §1835(a)(2)(A) [Part B] of the Social Security Act.
- The patient is not confined to the home - §1814(a)(2)(C) [Part A] or §1835(a)(2)(A) [Part B] of the Act.
- The service may be denied as "not reasonable and necessary" ("medical necessity") - §1862(a)(1) of the Act.
- The service may be denied as "custodial care" - §1862(a)(9) of the Act.

The following three provisions apply to some but not all ABN users and are <u>not</u> applicable uses of the ABN for HHAs.

- 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.

2. INFORMATION USERS

Based on CMS statistics for 2010, we estimated the number of physicians, providers, practitioners and suppliers (not including HHAs) potentially delivering ABNs as about 1,025,323 (calculated from Tables II.5 and II.8 2011 CMS Statistics). The addition of 10,914 HHAs brings the total estimated ABN issuers to 1,288,837.

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 or when statutory requirements for issuance specific to HHAs are applicable. Since there is no quantifiable data on these occurrences, with our prior ABN 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 2011 CMS Statistics, approximately 158,887,600 claims were filed for care which could have necessitated ABN delivery by physicians, providers, practitioners and suppliers excluding HHAs. We estimate that 52,962,533 or one third of these encounters, were associated with ABN issuance.

As stated above, there are an estimated 1,277,923 non-HHA providers or suppliers who could issue an ABN, or on average, each notifier will deliver about 41 ABNs a year.

Standard ABN Calculation excluding HHAs:

52,962,533	/	1,277,923	=	41.44 ≈ 41
Estimated ABNs delivered annually		Providers and suppliers who might issue the ABN		ABNs delivered annually per notifier excluding HHAs

Using the aforementioned methodology, 15,712 HHA claims filed in 2010 can be added to the 158,887,600 provider and supplier claims to equal 158,903,312 total claims with 52,967,770.66 or approximately 52,967,771 claims associated with ABN issuance. Adding 10,914 HHAs to the other 1,277,923 providers and suppliers equals a total of 1,288,837 notifiers. If 52,967,771 ABNs are delivered by 1,277,923 providers and suppliers), each notifier will deliver about 41 ABNs per year.

Standard ABN Calculation including HHAs:

52,967,771	/	1,288,837	=	41.10 ≈ 41
Estimated ABNs delivered annually		Providers and suppliers who might issue the ABN		ABNs delivered annually per notifier including HHAs

However, we should note that past PRA package calculations for HHABN Option Box 1 use (the home health substantive equivalent of the ABN) were estimated based on episodes of care rather than claims data. The formulas for calculating HHABN Option Box 1, 2, and 3 issuance were developed in 2006 by CMS with HHA industry assistance and issuance of HHABN Option Box 2 and 3 could be estimated more accurately by using episode of care data. It was estimated that 8% of home care episodes would be associated with Option Box 1 use, 8% would be associated with Option Box 2 use, and 200% of episodes would be associated with Option Box 3 use.

Using the HHABN computation, we calculated the number of ABNs associated with episodes of home care. Per the CMS Chronic Care Policy Group, there were 6,897,670 episodes of home health care in 2010. 8% of home health episodes equates to 551,814 episodes associated with ABN use.

The episode data was extrapolated to determine the number of claims that would be associated with ABN use. In 2011, HHAs submitted 15,712 claims for 6,897,670 episodes of care; thus, an average of 439 episodes occurs per claim. If there are approximately 439 episodes associated with each claim, 551,814 episodes associated with ABN use are associated with approximately 1257 claims.

Using the HHABN calculation and converting episodes of HHA care associated with ABNs to HHA claims associated with ABNs, the following estimate was obtained:

(52,962,533 + 1257)=				
52,962,533	/	1,288,837	=	41.09 ≈ 41
Estimated ABNs delivered annually		Providers and suppliers who might issue the ABN		ABNs delivered annually per notifier

Since the two different PRA submission methodologies for calculating ABNs delivered annually per notifier produced approximately the same numerical estimate, this and future ABN PRA estimates will be done using claims data only (as outlined earlier in this section), and we will not rely on episodes of care for calculations.

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. Electronic issuance of ABNs is permitted as long as the beneficiary is offered the option to receive a paper copy of the notice if this is preferred. Regardless of the mode of delivery, the beneficiary must receive a copy of the signed ABN for his/her own records. 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 several times as a *Federal Register* notice and subject to public comment prior to OMB's approval. It was last re-approved in 2011. The ABN is now being amended to include use by HHAs.

A 60 day Federal Register notice will be published on [date]. Interested parties will have an opportunity to comment. If we receive public comments in response, we will consider them carefully in making revisions to the notice and the accompanying notice instructions.

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 2010 data. With an annual estimate of 52,967,771 ABNs, and 7 minutes on average needed to deliver each notice, we estimate the hourly burden to be 6,177,101.45 hours or 4.79 hours per notifier. The 7 minute time estimate is unchanged from this collections prior PRA approval.

We estimate the annual cost of delivering 52,967,771 ABNs to be $178,501,388. This is a total cost of $138.34 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 $28.88 See: Office of Personnel Management (OPM) website at www.opm.gov/oca/12tables/pdf/gs-h.pdf) . Using these calculations, the cost per response is estimated to be $3.37.

13. CAPITAL COSTS

Since all affected notifiers are expected to already have the capacity to reproduce ABNs or HHABNs 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, even with the incorporation of HHABN liability notices, is an existing collection. The overall burden estimate with the new HHA uses has increased due to two main factors: (1) general growth and

increase in claims submissions to the Medicare program, and (2) methodology revisions to include HHA users.

In terms of Medicare's general growth, although the number of participating providers and suppliers has decreased slightly since the 2011 PRA submission, the number of claims submitted that might receive an ABN have increased from 131,177,550 to 158,887,600 claims exclusive of HHA claims. Adding HHA claims that might be associated with an ABN brings the total claim submission to 158,903,312. The annual respondents included in the cost burden decreased from 1,326,282 to 1,277,923 excluding HHAs. Adding HHAs to the respondents bring the total number of respondents to 1,288,837. The 2011 PRA package calculations were done using a lower GS-12, Step 1 salary of $28.55 per hour; so, the salary increase also contributes to the increased cost per notice from $3.22 to $3.34. Therefore, the annual cost burden for this notice is minimally increased from $145,606,931 to $178,501,388.

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.