Supporting Statement for the Extension of the
Advance Beneficiary Notice of Noncoverage (ABN)
Contained in 42 CFR 411.404 and 411.408
CMS-R-131, OMB 0938-0566

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 (the Act) were enacted in 1972 (P.L. 92-603).

A. 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 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 the Background 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 320.6.

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 home health agencies (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:

- 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

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.

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

An ABN may also be issued when a beneficiary wants to obtain an item from a supplier who has not met Medicare supplier number requirements or when statutory requirements for issuance specific to HHAs are applicable.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

The 60-day notice published in the Federal Register on November 9, 2015 (80 FR 69227). We did not receive any comments.

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

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 2015 CMS Statistics (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/2015.html), approximately 190,803,900 claims were filed for care which could have necessitated ABN delivery by physicians, providers, practitioners and suppliers. We estimate that **63,601,300** or one third of these encounters, were associated with ABN issuance.

Based on CMS statistics for 2015, we estimate the number of physicians, providers, practitioners and suppliers potentially delivering ABNs as about **1,540,850** (calculated from Tables II.5, II.8, and 11.9 2015 CMS Statistics). On average, each notifier will deliver about **41 ABNs a year** (63,601,300 ABNs/year / 1,540,850 providers issuing the ABN).

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe

benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Other Healthcare Practitioners and Technical Occupations	29-9000	29.72	29.72	59.44

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

With an annual estimate of **63,601,300 ABNs**, and **7 minutes** (0.11667 hours) on average needed to deliver each notice, we estimate the hourly burden to be **7,420,364 hours** (63,601,300 responses x 0.11667 hours/response) or **4.82 hours per notifier** (7,420,364 hours / 1,540,850 providers and suppliers who might issue an ABN). The 7 minute/response estimate is unchanged from this collection's current approval.

We estimate the annual cost of delivering 63,601,300 ABNs to be **$440,757,009** (63,601,300 responses x $6.93 cost per response ($59.44 x 0.11667 hours)). This is a cost of **$286.05 per notifier** ($440,757,009 annual cost / 1,540,850 respondents).

Annual Burden Summary

Regulation Section(s) in Title 42 of the CFR	**Frequency**	**Respondents**	**Total Responses**	**Burden per Response**	**Total Annual Burden (hours)**	**Total Labor Cost of Reporting ($/hr)**	**Total Cost ($)**
411.404(b) and (c), and 411.408(d)(2) and (f)	Occasionally	1,540,850	63,601,300	7 min (0.11667 hr)	7,420,364	59.44	440,757,009

Information Collection Instruments and Associated Materials

- Advanced Beneficiary Notice of Noncoverage (English)
- Form Instructions: Advanced Beneficiary Notice of Noncoverage (English)
- Advanced Beneficiary Notice of Noncoverage (Spanish, “Notificación previa de NO-cobertura al beneficiario (ABN)”)

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

As described in more detail below, this iteration contains several nonsubstantive changes. We have also adjusted our burden estimates based on an overall increase in respondents and Medicare claims filed by the respondents.

Nonsubstantive Changes

The non-substantive changes to the form and the form instructions will have little effect on burden for all users. There are no substantive changes to the form or to the instructions.

This iteration adds language to the ABN to inform beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (Section 504) by alerting the beneficiary to CMS’s nondiscrimination practices and the availability of alternate forms of this notice if needed.

The Section 504 requirement was in effect with the prior notice, and including standard CMS language to advise the beneficiary of CMS’s nondiscrimination policies and availability of alternate forms of this notice is not expected to change respondent burden associated with the ABN.

Minor edits to the form instruction are made to provide clarity and assist providers/suppliers with proper ABN delivery which should slightly ease the burden of form completion but is not expected to cause a dramatic change in burden estimates for the ABN. Minor language and grammatical edits have been made to the ABN Form Instructions to improve provider/supplier comprehension and decrease

the probability of errors in completing the ABN. An incorrect reference to §50.14.3 in the form instructions was changed to §50.7.1(b), the correct reference.

The changes are set out in the following supplemental documents:

- Crosswalk
- ABN (English) – Track Changes
- ABN (Spanish) – Track Changes
- ABN (Instructions) – Track Changes

Adjusted Burden Estimates

In terms of Medicare's general growth, the number of participating providers and suppliers has increased since the 2013 PRA submission from 1,288,837 to **1,540,850**. The number of claims submitted that might receive an ABN have increased from 158,903,312 to **190,803,900 claims; from 52,967,771 to 63,601,300** claims associated with an ABN issuance.

Thus, the estimated number of annual responses has increased by **10,633,529 responses** with a corresponding annual hour burden increase of **1,243,262 hours** (from 6,177,101 hours in 2013 to 7,420,364 with this PRA submission).

The 7 minute/response estimate is unchanged from this collection's current approval.

The 2013 PRA package's cost calculations used OPM's GS-12, Step 1 salary of $28.88/hr. In this 2016 iteration, we are using BLS data and adjusting their mean hourly wage to include fringe benefits. The cost in this iteration is using a revised wage of **$59.44/hr**.

16. PUBLICATION AND TABULATION DATES

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

17. EXPIRATION DATE

We are not requesting this exemption.

18. CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.