

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

BACKGROUND

The use of the written Advance Beneficiary Notice of Non-coverage (ABN) is to inform Medicare beneficiaries of their liability under specific conditions. This 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).

There has been a minor change made to the ABN form itself to update the non-discriminatory language.

We anticipate the burden of this package to increase compared to the data submitted with the last submission as well as an increase in overall claim submissions data. Past submissions used only select Part A claim data and did not include Part B claims data. The ABN, Form CMS-R-13 was designed to inform Medicare beneficiaries of their potential financial liability from these types of entities:

- Providers and suppliers furnishing Medicare Part B items and services;
- Hospice and Religious Non-medical HealthCare Institute (RNHCI) providing Medicare Part A items and services; and
- HHAs for Part A and Part B items and services.

Therefore, the burden estimate will include claims data from those entities, not just Part A data. Inpatient hospital claims are not included because they use other forms for a notice of non-coverage (i.e. Preadmission/Admission Hospital-Issued Notice of Non-coverage (HINN 1)) instead of the ABN. We believe this data does not describe a new population of beneficiaries receiving the ABN but a more accurate estimate of beneficiaries whom actually receive the ABN.

According to claims data from CY 2020 Claims statistics (source: [Chronic Conditions Data Warehouse](#)) approximately 981,659,485 claims (819,876,407 (Part B) + 152,444,421 (Outpatient Hospital) + 9,338,657 (HHAs)) were filed for care which could have necessitated ABN delivery by physicians, providers, practitioners and suppliers. We estimated that 323,947,630 (981,659,485 x

.33) or one third of these encounters, were associated with ABN issuance. For further calculations, please see sections 12 and 15 in this document.

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 (e.g. not medically reasonable and necessary as defined under §1862(a)(1) of the Act), 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 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 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 should 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 issuance of an ABN is statutorily required in certain situations, as outlined in Section 2 above. There is no exception in the Statute that exempts small businesses from this requirement. However, we believe a beneficiary who receives an ABN will be better informed to make timely decisions about their health care services, which may eliminate some burden on large and small businesses alike.

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. Should this form not be given when applicable, the physician, provider, practitioner, or supplier would not be able to transfer potential financial liability to the beneficiary resulting in the physician, provider, practitioner, or supplier being held responsible for payment.

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 TBD (87 FR)

9. PAYMENT/GIFT TO RESPONDENT

We do not plan to provide any payment or gifts to respondents. The ABN provides valuable information to the beneficiary to greater his or her ability to make an informed decision about receiving an item and/or service and assuming responsibility for payment.

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, as 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 CY 2020 Claims statistics (source: [Chronic Conditions Data Warehouse](#)) approximately 981,659,485 claims (819,876,407 (Part B) + 152,444,421 (Outpatient Hospital) + 9,338,657 (HHAs)) were filed for care in total. Using our methodology that 1/3 of those would require delivery of the ABN, we estimate that 323,947,630 (981,659,485 x .33) were associated with ABN issuance.

Based on CMS statistics for CY 2020, we estimate the number of physicians, providers, practitioners and suppliers potentially delivering ABNs as about 1,701,558 (Source: [CMS Program Statistics: Medicare Providers Section](#)). On average, each notifier will deliver about 190 ABNs a year (323,947,630 ABNs/1,701,558 providers issuing the ABN).

Wages

To derive average costs, we used data from the [U.S. Bureau of Labor Statistics' \(BLS\) May 2021 National Occupational Employment and Wage Estimates](#) for all salary estimates. 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	29.55	29.55	59.10

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 323,947,630 ABNs, and 7 minutes (0.11667 hours) on average needed to deliver each notice, we estimate the hourly

burden to be 37,794,970 hours (323,947,630 responses x 0.11667 hours/response) or 22.2 hours per notifier (37,794,970 hours / 1,701,558 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 323,947,630 ABNs to be \$2,235,238,647 (323,947,630 responses x \$6.90 cost per response (\$59.10 x 0.11667 hours)). This is a cost of \$1,314 per notifier (\$2,235,238,647 annual cost / 1,701,558 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	1,701,558	323,947,630	7 min (0.11667 hr)	37,794,970	59.10	2,235,238,647

Information Collection Instruments and Associated Materials

- Advanced Beneficiary Notice of Non-coverage (English)
- Form Instructions: Advanced Beneficiary Notice of Non-coverage (English)
- Advanced Beneficiary Notice of Non-coverage (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 a minor change to the form. We have also adjusted our burden estimates based on an overall increase in respondents and decrease in Medicare claims filed by the respondents. The BLS adjusted hourly wage has also decreased.

Non-substantive Changes

There has been a minor change made to the ABN form itself to update the non-discriminatory language.

Adjusted Burden Estimates

In terms of Medicare's general growth, the number of participating providers and suppliers has increased since the last PRA submission from 1,589,060 to 1,701,558. The number of claims submitted that might receive an ABN has decreased from 1,158,231,470 to 981,659,485 claims; from 382,216,385 to 323,947,630 claims associated with an ABN issuance.

The estimated number of annual responses has decreased by 58,268,755 (from 382,216,385 to 323,947,630 claims associated with an ABN issuance) with a corresponding annual hour burden decrease of 6,798,216 hours (from 44,593,186 to 37,794,970 with this PRA submission).

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

The prior PRA package's cost calculations used the BLS data with fringe benefits of \$64.02/hr. In this submission, we are continuing to use BLS data with fringe benefits of \$59.10/hr.

16. PUBLICATION AND TABULATION DATES

The notices will be posted in the download section of the ABN website at <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

No aggregate or individual data will be tabulated from them.

17. EXPIRATION DATE

We are not requesting this exemption, we plan to display the expiration date and OMB control number on all ABN forms.

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.