

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 have been no changes made to the ABN form itself; however, there have been minor language and grammar edits made to the ABN form instructions to improve provider/supplier readability and comprehension. Also, in accordance with Title 18 of the Act, guidelines for dual eligible beneficiaries and the Qualified Medicare Beneficiary (QMB) Program have been added to the ABN form instructions.

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.

Below you will see a calculation for comparison using the same [CMS Statistics](#) (calendar year (CY) 2014) used in the last submission to include the Part B claims. This data was not included on the last submission because it did not include the Part B claims; this is strictly for comparison to show what the data should have looked like.

According to claims data from Table V.6 of the [2015 CMS Statistics](#) approximately 1,121,194,700 claims (990,400,000 (Part B) + 115,369,800 (Outpatient Hospital) + 15,424,900 (HHAs)) were filed for care which could have necessitated ABN delivery by physicians, providers, practitioners and suppliers. We estimated that 369,994,251 (1,121,194,700 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 (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 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 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 both large and small businesses alike 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. 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 associated with this collection.

8. FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

The 60-day notice published in the Federal Register on 08/20/2019 (84 FR 43135). We received 5 comments. The reconciliation of the comments may be

found in the CMS Response to Public comment supplemental documents. We made minor edits to the ABN form instructions page in response to those comments. The ABN form required no edits.

The 30-day notice published in the Federal Register on 12/18/2019 (84 FR 69380). We received 3 comments. The reconciliation of the comments may be found in the CMS Response to Public comment supplemental documents. We made no changes to the ABN form or the form instructions.

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, 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 2018 Claims statistics (source: CMS, Center for Medicare), approximately 1,158,231,470 claims (1,008,616,249 (Part B) + 135,567,890 (Outpatient Hospital) + 14,047,331 (HHAs)) were filed

for care in total. Using our methodology that 1/3 of those would require delivery of the ABN, we estimate that 382,216,385 (1,158,231,470 x .33) were associated with ABN issuance.

Based on CMS statistics for CY 2017, we estimate the number of physicians, providers, practitioners and suppliers potentially delivering ABNs as about 1,589,060 (Source: [CMS Program Statistics: Medicare Providers Section](#)). On average, each notifier will deliver about 241 ABNs a year (382,216,385 ABNs/1,589,060 providers issuing the ABN).

Wages

To derive average costs, we used data from the [U.S. Bureau of Labor Statistics' May 2018 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	32.01	32.01	64.02

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 382,216,385 ABNs, and 7 minutes (0.11667 hours) on average needed to deliver each notice, we estimate the hourly burden to be 44,593,186 hours (382,216,385 responses x 0.11667 hours/response) or 28.1 hours per notifier (44,593,186 hours / 1,589,060

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 382,216,385 ABNs to be \$2,855,156,396 (382,216,385 responses x \$7.47 cost per response (\$64.02 x 0.11667 hours)). This is a cost of \$1,797 per notifier (\$2,855,156,396 annual cost / 1,589,060 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	1,589,060	382,216,385	7 min (0.11667 hr)	44,593,186	64.02	2,855,156,396

For comparison, the below table is based on CY 2014 CMS Statistics:

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	1,597,409	369,994,251	7 min (0.11667 hr)	43,167,229	59.44	2,567,760,102

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 several nonsubstantive changes. We have also adjusted our burden estimates based on an overall increase in respondents and Medicare claims filed by the respondents.

Non-substantive Changes

There were no changes to the form.

This iteration adds language to the ABN form instructions to help providers/suppliers provide proper delivery of the ABN form to Dual Eligible beneficiaries and those in the QMB Program, in accordance with Title 18 of the Social Security Act. This change is not expected to cause a change in burden estimates because we believe these beneficiaries were already receiving the ABN.

Additionally, minor formatting edits to the form instructions were 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.

After the 60-day public comment period, minor edits were made for clarity in response to the comments received.

The changes are set out in the following supplemental documents:

- ABN (Instructions) – Crosswalk

Adjusted Burden Estimates

In terms of Medicare's general growth, the number of participating providers and suppliers has decreased since the last PRA submission from 1,597,409 to 1,589,060. The number of claims submitted that might receive an ABN have increased from 1,121,194,700 to 1,158,231,470 claims; from 369,994,251 to 382,216,385 claims associated with an ABN issuance. Please keep in mind that we are using the same data that was used for the last PRA submission, however, we are including the Part B claims that should have been included for a more viable comparison. If we did not include the Part B claims and only used the data from last year, we would have to estimate that the burden increased from 63,601,300 claims to 382,216,385 claims or a difference of 318,615,085 claims.

The estimated number of annual responses has increased by 12,222,134 (from 369,994,251 to 382,216,385 claims associated with an ABN issuance) with a corresponding annual hour burden increase of 1,425,957 hours (from 43,167,229 hours to 44,593,186 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 \$59.44/hr. In this submission, we are continuing to use BLS data with fringe benefits of \$64.02/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.