Supporting Statement for the Home Health Advance Beneficiary Notice (HHABN)
(OMB 0938-0781)

INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS) requests a renewal of the Home Health Advance Beneficiary Notice (HHABN) (CMS-R-296), collection 0938-0781, which was last approved by the Office of Management and Budget (OMB) in 2006 and expires on August 31, 2009.

A. Background

Home health agencies (HHAs) are required to provide written notice to Medicare beneficiaries under various circumstances involving the initiation, reduction, or termination of services. The vehicle used in these situations is the Home Health Advance Beneficiary Notice (HHABN) (CMS-R-296).

The notice is designed to ensure that beneficiaries receive complete and useful information regarding potential financial liability or any changes made to their plan of care (POC) to enable them to make informed consumer decisions. The notice must provide clear and accurate information about the specified services and, when applicable, the cost of services when Medicare denial of payment is expected by the HHA.

In 2006, subsequent to the decision of the US Court of Appeals (2nd Circuit) in the *Lutwin v. Thompson* case, the HHABN underwent format modifications so that the previously approved HHABN, which until that time served solely as a notification of liability notice, could also be used for beneficiary notification of changes of care consistent with HHA conditions of participation (COPs). Interchangeable option boxes were added to the form to support its multiple notification purposes. Option Box 1 addresses liability and Option Boxes 2 and 3 address change of care notifications.

Consistent with the PRA process, CMS obtained public comments on the HHABN during a comment period that ended May 23, 2006. Appropriate changes in the form, instructions, and burden estimates were made at that time in consideration of these comments.

We have updated the HHABN form and instructions for this renewal package. We made minor changes on the form to assure accessibility in compliance with Section 508 of the Rehabilitation Act of 1973, as amended in 1998. In addition, the requirement for beneficiaries to list their health insurance claim number (HICN) on the form has been removed and telephone contact information for Medicare is pre-printed within the form text rather than left as blanks for HHAs to complete. No further substantive changes have been made.

B. Justification

1. Need and Legal Basis

The HHABN is used to address both liability and COP requirements depending on the circumstances.
The HHABN notifies Medicare beneficiaries of liability under the following statutory provisions:

- 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 Original 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, as all speak to the potential liability mentioned above;

- Under section 1879 of the Social Security Act, a physician, provider, practitioner or supplier of items or services participating in the Original Medicare Program may bill a Medicare beneficiary for items or services usually covered under Medicare, but denied in an individual case under certain statutory exclusions. Notifiers must inform the beneficiary, prior to furnishing the service, that Medicare is likely to deny payment, consistent with 42 CFR § 411.404(b) and (c), and § 411.408(d)(2) and (f).

The following provisions of the Social Security Act (the Act) would necessitate delivery of the HHABN by the HHA:

- 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 home health COP requirements are set forth in §1891 of the Social Security Act [42 USC 1395bbb]. The applicable regulations under 42 CFR §484.10(c) specify that Medicare patients receiving HHA services have the following rights:

> "(c) Standard: Right to be informed and to participate in planning care and treatment. (1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.
> (i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.
> (ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made."

2. <u>Information Users</u>

Based on CMS statistics for 2007, we estimate the number of HHAs potentially delivering the HHABN as about 9,024 (Source: Table II.5 in 2008 CMS Statistics, U.S. Department of Health and Human Services, CMS Pub. No. 03490).

HHABNs are not given every time items and services are delivered. Rather, as detailed above, HHABNs are given only 1.) for liability purposes, when the HHA anticipates that Medicare will not pay for a service or 2.) as required under the home health COPs, when the HHA becomes aware of a change in a beneficiary's plan of care. Option Box 1 is used on the HHABN to give beneficiaries notice of liability. Option Box 2 or Option Box 3 is used to notify beneficiaries of care changes due to doctor/ordering provider orders or HHA-specific limitations.

CMS reports 5,803,471 episodes of home health care in 2007 (Source: CMS, Chronic Care Policy Group data). Based on CMS estimates and industry comments, we believe that HHABN use associated with each episode of care is as follows:

- Option Box 1: 8.0 percent of 5,803,471 episodes equals 464,278 HHABNs issued annually
- Option Box 2: 4.8 percent of 5,803,471 episodes equals 278,567 HHABNs issued annually
- Option Box 3: 200 percent of 5,803,471 episodes equals 11,606,942 HHABNs issued annually (that is, there are approximately 2 HHABNs issued using Option Box 3 for each episode of care).

The 200% estimated use of Option Box 3 during annual 60-day episodes of care reflects the high number of care changes that occur due to doctor/provider orders. Adding the three figures above, the total number of HHABNs issued annually is 12,349,787.

When Option Box 1 is used, based on information collected on this notice, the HHA may submit a bill to a Medicare Regional Home Health Intermediary (RHHI). An RHHI will make an initial determination on all claims that are sent by an HHA. RHHIs and other federally authorized parties may request a copy of the HHABN when developing the related claim or investigating a pertinent complaint. Surveyors may review this notice when at a home health agency as part of assuring compliance with the HHA COPs.

3. Use of Information Technology

HHABNs will usually be 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 HHABNs, though incorporation of HHABNs 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 store the signed copy of the HHABN electronically.

4. Duplication of Efforts

The information we are requesting is unique and does not duplicate any other effort.

5. Small Business

All HHAs will be expected to give the HHABNs in relevant situations. The requirement does not impose any greater burden on small businesses than on large businesses, since there is no difference in the information collected.

6. Less Frequent Collection

The HHABN is given on an as-needed basis in all relevant situations.

7. Special Circumstances

The HHABN utilizes an interchangeable "options box" approach that remains unchanged from the current OMB approved HHABN. In situations involving Medicare coverage issues, HHAs will insert the Option Box 1 information. In situations where HHAs decide to stop providing services of their own accord, HHAs will insert the Option Box 2 information. Most frequently, in situations involving reduction of care based on physician's orders, HHAs will use Option Box 3. This informs the Medicare beneficiary that the HHA will no longer deliver certain services because there is no physician's order for those services.

8. Federal Register Notices/Outside Consultation

A 60 day *Federal Register* notice was published on May 15, 2009.

The HHABN was published several times as a *Federal Register* notice and was previously published for comment on March 24, 2006. Interested parties will have an opportunity to comment. Public comments will be considered carefully in making any necessary revisions to the notice and accompanying instructions.

9. Payments/Gifts to Respondents

No gift is made to the respondent.

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 HHAs is given under 2. above based on 2007 data.

CMS received industry comments in 2006 requesting increased time estimates for HHABN delivery. Based on these comments, delivery of the HHABN with Option Box 1 was estimated to be 18 minutes and those with Option Boxes 2 or 3 was estimated to take 4 minutes each. Since there have been no significant changes to the form or its content, these time estimates remain unchanged in calculating burden.

To determine the HHABN response time per notice, we first multiplied the minutes per response associated with each option box by the number of HHABNs issued using each option box (see 2. above). This gives the minutes required annually to complete HHABNs with each option box.

Option Box 1: 18 minutes x 464, 278 HHABNs = 8,357,004 minutes
Option Box 2: 4 minutes x 278,567 HHABNs = 1,114,268 minutes
Option Box 3: 4 minutes x 11,606,942 HHABNs = 46,427,768 minutes

The sum of the minutes required annually to complete HHABNs calculated above is 55,899,040 minutes, and we divided this number by the number of HHABNs delivered annually (12,349,787) to calculate the HHABN response time of 4.53 minutes per notice, which we rounded up to 5 minutes.

The total annual hour burden (all option boxes) is 1,028,737 hours. On average, 9024 respondents will deliver approximately 1369 HHABNs annually for a total annual hour burden of 114 hours per respondent. A total annual cost of $3,075.72 per respondent is calculated based on our expectation that these notices will be prepared by a staff person with professional skills at the GS-12- Step 1 hourly salary of $26.98 (Office of Personnel Management (OPM); www.opm.gov). The average cost per response is calculated to be $2.25 by obtaining the ratio of the annual cost per respondent to the annual notices per respondent. The estimated cost of delivering 12,349,787 HHABNs at a rate of $2.25 is $27,787,020.

13. Capital Costs

There are no capital costs. All affected notifiers are expected to already have the capacity to reproduce HHABNs.

14. Cost to Federal Government

There is no cost to the Federal Government for collection.

15. Changes to Burden

The HHABN is an existing collection. The total annual hour burden has increased due to an increase in the number of respondents and increased episodes of care. However, the total annual cost burden has decreased due to the recalculation of the estimates using more reliable and current CMS data related to home health episodes and home health providers, as well as current federal salary schedules published by OPM.

16. Publication/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. Collections of Information Employing Statistical Methods

There are no statistical methods associated with this collection.