Supporting Statement Part A
Home Health Change of Care Notice
Contained in 42 U.S.C. 1395(bbb) and 42 CFR 484.10(c)
(CMS-10280, OMB 0938-1196)

BACKGROUND

The purpose of the Home Health Change of Care Notice (HHCCN) is to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Consistent with the Medicare Conditions of Participation (COPs) for home health agencies (HHAs) and the decision of the US Court of Appeals 2nd Circuit decision in Lutwin v. Thompson, HHAs must provide the HHCCN to a beneficiary whenever they reduce or terminate that beneficiary's home health services due to physician/provider orders or limitation of the HHA in providing the specific service. Notification is required for covered and non-covered services listed in the plan of care (POC).
Implementing regulations are found at 42 CFR 484.10(c). These requirements are fulfilled by the HHCCN.

There were no substantive changes made to the HHCCN form or the form instructions. We did make plain language and information design changes to the form and form instructions according to our Office of Communications (OC) recommendations. OC's recommendations in plain language and information design are research-based best practices. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. The OC has been conducting consumer research with the patients, caregivers, providers and partners who interact with CMS programs for more than 20 years, and we use feedback from this research to make sure our information and products are clear, easy to use and understand. Consumer testing is ongoing, and we iteratively refine language and design standards as our audiences and their information needs evolve. The OC work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

There was an increase in home health care episodes as well as an increase in home health agencies which led to an increase in the number of notices issued annually. There was also an increase in the annual cost burden which was most likely caused by an increase in the mean hourly wage.

A. JUSTIFICATION

1. NEED AND LEGAL BASIS

The US Court of Appeals 2nd Circuit decision in Lutwin v. Thompson held that the Medicare statute requires HHAs to provide written notice to beneficiaries before reducing or terminating services, not only based on the HHAs adverse Medicare coverage determinations, as the District Court held, but also for any other reason.

The home health COP requirements are set forth in §1891[42 U.S.C. 1395bbb] of the Social Security Act (the Act). The implementing 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. INFORMATION USERS

Home health agencies (HHAs) are required to provide written notice to Original Medicare beneficiaries under various circumstances involving the reduction or termination of items and/or services consistent with Home Health Agencies Conditions of Participation (COPs). The beneficiary will use the information provided to decide whether or not to pursue alternative options to continue receiving the care noted on the HHCCN.

3. IMPROVED INFORMATION TECHNOLOGY

HHCCNs 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 or transmitted via secure fax. In person, electronic issuance of the notice is permitted as long as the beneficiary consents to electronic delivery and a copy is provided to the beneficiary. Incorporation of HHCCNs into other automated business processes is permitted, and some limited flexibility in formatting the notice is allowed as discussed in the form instructions. HHAs may choose to store the required signed copy of the HHCCN electronically.

The HHCCN form and form instructions will be posted online at:

https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative/ffs-hhccn

4. DUPLICATION OF SIMILAR INFORMATION

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 HHCCN 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 HHCCN is only delivered in the circumstances in which the law requires it to be delivered, therefore less frequent collection is not possible, as it is only given when needed.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances (see below). More specifically, this information collection does not do any of the following:

-Require respondents to report information to the agency more often than quarterly;

-Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

-Require respondents to submit more than an original and two copies of any document;

-Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

-Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

-Require the use of a statistical data classification that has not been reviewed and approved by OMB;

-Includes a pledge of confidentiality that is not supported by authority established in statue 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

-Require respondents to 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 Federal Register notice has published to the Federal Register TBD (88 FR).

9. PAYMENT/GIFT TO RESPONDENT

No gifts or payments made to respondents. Providing the HHCCN will afford Medicare beneficiaries the information they need in order to make and be informed about the care they are being provided.

10. CONFIDENTIALITY

CMS pledges to maintain privacy to the extent provided by law.

11. SENSITIVE QUESTIONS

There are no questions of a sensitive nature associated with this notice.

12. BURDEN ESTIMATE

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (See: 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	32.84	32.84	65.68

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.

Annual Burden Estimates

HHCCNs are given on an as-needed basis. HHCCNs are not given every time items and services are delivered. Rather, HHCCNs are given only when the HHA becomes aware of a change in a beneficiary's plan of care (POC) due to physician/ordering provider orders or HHA specific limitations.

Based on CMS statistics for 2021, there were 11,353 HHAs, all of which could potentially deliver the HHCCN (See: 2021 CMS Program Statistics-Medicare Providers).

CMS reports 9,279,712 episodes of home health care in 2021 (Source: 2021 CMS Program Statistics-Home Health Agency Based on CMS estimates and industry comments on frequency of notice issuance, we believe that HHCCN use associated with each episode of care is as follows:

- HHCCN change of care for agency reasons: 4.8 percent of 9,279,712 episodes equals 445,426 HHCCNs issued annually.

- HHCCN change of care due to provider orders: 200 percent of 9,279,712 episodes equals 18,559,424 HHCCNs issued annually. We estimate that an average of 2 HHCCNs are issued per 60-day episode of care due to provider orders.

Based on the above estimates, HHAs will deliver about 19,004,850 (445,426 + 18,559,424) HHCCNs annually.

When CMS introduced the HHCCN in 2013, delivery of the HHCCN was estimated to be 4 minutes (0.0666 hours) based on prior industry comments. Thus, we estimate that it will take 4 minutes (0.0666 hours) to complete the HHCCN, for a total annual burden estimate of 1,265,723 hours (19,004,850 responses x 0.0666 hours). The annual burden estimate per respondent is 111 hours (1,265,723 hours / 11,353 respondents).

We estimate the annual cost of delivering 19,004,850 HHCCNs to be $83,051,195 (19,004,850 responses x $4.37 per response). This is based on our expectation that the HHCCN notices will be prepared by a staff person with an adjusted hourly salary of $65.63. Based on this hourly salary, the cost per response is $4.37 ($65.63 x 0.0666 hours).

We estimate that each of the 11,353 respondents will deliver approximately 1,674 (19,004,850 HHCCNs issued annually / 11,353 respondents) HHCCNs annually for a total annual cost per respondent of $7,284.93 (111 hours x $65.63).

13. CAPITAL COSTS

Since all affected notifiers are expected to already have the capacity to reproduce HHCCNs based on CMS guidance, there are no capital costs associated with this collection.

14. COSTS TO FEDERAL GOVERNMENT

The cost to the Federal government is on a triennial basis and is associated with the preparation and release of the updated notice and supplemental documents (e.g., form instructions and alternate versions). This includes the time it takes the employee to complete the PRA process, another employee to create a translated version, and posting the documents to CMS.gov.

The analysis and preparation of the PRA package and the subsequent release of documents is performed by CMS employees. The average salary of the employees who would be completing this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, is listed in the table below. See OPM 2024 General Schedule (GS) Locality Pay Tables

We estimate that on average it takes a CMS employee 24 hours to perform these activities and the triennial cost to the Federal government to be $1,537.44.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	$64.06	24	$1,537.44

			TOTAL: $1,537.44

15. PROGRAM OR BURDEN CHANGES

Using 2021 claim statistics, the number of HHCCNs delivered annually is estimated to be 19,004,850. The number of HHCCNs delivered annually in the prior PRA submission was 12,385,108, which **increased by 6,619,742 HHCCNs**.

The annual hour burden associated with this collection is estimated to be 1,265,723 hours. The annual hour burden associated in the prior PRA submission for this collection was 824,848 hours which **increases the annual hour burden by 440,875**.

The **increase** in the burden estimates is likely due to an increase in the annual number of home health episodes (from 6,047,416 to 9,279,712) which would cause an increase in the number of HHCCNs issued annually per respondent (from 12,385,108 to 19,004,850).

The annual cost burden **increased by $35,987,785** (current annual cost burden estimate of $83,051,195minus annual cost burden estimate in prior PRA submission of $47,063,410). This increase is likely due to an increase in the adjusted hourly wage (from $57.00 to $65.63) as the basis of calculation from the prior PRA submission.

16. PUBLICATION AND TABULATION DATES

These notices will be published on the CMS.gov website (See section 3); however, no aggregate or individual data will be tabulated from them.

17. EXPIRATION DATE

We are not requesting exemption. We will display the expiration date and OMB control number on the HHCCN.

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.