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 have been no changes to the HHCCN form or the form instructions. There was a decrease in home health care episodes as well as a decrease in home health agencies which led to a decrease in the number of notices issued annually. There was also a decrease in the annual cost burden which was caused by a decrease 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 INFORMATIONTECHNOLOGY

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.

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

Providing the HHCCN less frequently would not afford Medicare beneficiaries the right and autonomy to be updated and make informed decisions about their plan of care.

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/OUTSIDECONSULTATION

The 60-day Federal Register notice has published to the Federal Register 08/20/2021 (86 FR 46854). Following the 60-day Federal Register notice, CMS received one comment. This can be located in the response to comment attachment.

The 30-day Federal Register notice has published to the Federal Register 11/08/2021 (86 FR 61767).

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

According to The American Heritage® Stedman's Medical Dictionary, confidentiality means, “the ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient, unless the patient gives consent permitting disclosure.” Therefore, using the applicable definition of confidentiality, we assume that this form does apply.

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 2020 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	28.50	28.50	57.00

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 2019, there were 11,157 HHAs, all of which could potentially deliver the HHCCN (See: 2019 CMS Program Statistics).

CMS reports 6,047,416 episodes of home health care in 2019 (Source: 2019 CMS Program Statistics, Medicare Utilization and Payment). 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 6,047,416 episodes equals 290,276 HHCCNs issued annually.

- HHCCN change of care due to provider orders: 200 percent of 6,047,416 episodes equals 12,094,832 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 12,385,108 (290,276 + 12,094,832) 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 824,848 hours (12,385,108 responses x 0.0666 hours). The annual burden estimate per respondent is 74 hours (824,848 hours / 11,157 respondents).

We estimate the annual cost of delivering 12,385,108 HHCCNs to be $47,063,410 (12,385,108 responses x $3.80 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

We estimate that each of the 11,157 respondents will deliver approximately 1,110 (12,385,108 HHCCNs issued annually / 11,157 respondents) HHCCNs annually for a total annual cost per respondent of $4,218 (74 hours x $57.00).

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

There is no cost to the Federal Government for this collection.

15. PROGRAM OR BURDEN CHANGES

There are no burden or program changes resulting from the 60-day Federal Register notice. However, CMS received one comment which resulted in changing language to include all provider types who can certify the need for home health services and order services. These changes are in response to an interim final rule that was published May 8, 2020.

Using 2019 claim statistics, the number of HHCCNs delivered annually is estimated to be 12,385,108. The number of HHCCNs delivered annually in the prior PRA submission was 13,640,524, which **decreased by 1,255,416 HHCCNs**.

The annual hour burden associated with this collection is estimated to be 824,848 hours. The annual hour burden associated in the prior PRA submission for this collection was 908,459 hours which **decreases the annual hour burden by 83,611**.

The **decrease** in the burden estimates is likely due to a decrease in the annual number of home health episodes (from 6,660,412 to 6,047,416) which would cause a decrease in the number of HHCCNs issued annually per respondent (from 13,640,524 to 12,385,108).

The annual cost burden **decreases by $9,544,765** (current annual cost burden estimate of $47,063,410 minus annual cost burden estimate in prior PRA submission of $56,608,175). This decrease is likely due to a decrease in the adjusted hourly wage (from $62.38 to $57.00) as the basis of calculation from the prior PRA submission.

16. PUBLICATION AND TABULATIONDATES

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. 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 STATISTICALMETHODS

There are no statistical methods associated with this collection.