Supporting Statement Medicare Outpatient Observation Notice (MOON) (CMS-10611; OMB 0938-1308)

A. BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) requests the extension of the Office of Management and Budget (OMB) currently approved Medicare notice, the Medicare Outpatient Observation Notice (MOON).

The MOON is a standardized notice delivered to people entitled to Medicare benefits under Title XVIII of the Act who receive more than 24 hours of observation services, informing them that their hospital stay is outpatient and not inpatient, and the implications of being an outpatient.

This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans.

For purposes of these provisions:

- The term "Medicare health plans" includes Medicare Advantage plans and cost plans, and
- "Beneficiaries" refers to Medicare beneficiaries in Original Medicare and "enrollees" refers to Medicare beneficiaries enrolled in Medicare health plans.
- "Hospitals" refers to hospitals and Critical Access Hospitals (CAHs).

We are not making any changes to this package's requirements or any information collection/reporting instruments or instructions.

We are proposing several changes that have no impact on our requirements or burden estimates.

The CMS Office of Communications (OC) streamlined all sections of the form, updating the layout and wording using plain language to comport with research and current practices. These changes do not impact or change the information being collected, or the currently approved per response estimates, but the total burden estimates have been updated with more recent annual response data. Our currently approved per response estimates are unchanged. The changes made to this form were completed by the CMS OC to promote plain language in order to increase accessibility and reduce health disparities. OC supplied the following information on how their design and language decisions used in this form are research-based:

The Office of Communications recommendations are soundly based on research-based best practices in plain language and information design. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. We've been conducting consumer research with 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 and easy to use. Consumer testing is ongoing,

and we iteratively refine language and design standards as our audiences and their information needs evolve. We work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

B. JUSTIFICATION

1. NEED AND LEGAL BASIS

On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE

Act requires hospitals and CAHs to provide written notification and oral explanation to individuals who receive observation services as outpatients for more than 24 hours. The process for delivery of this notice was addressed in rulemaking, including a final rule, CMS1655-F (81 FR 56761, 57037 through 57052, August 22, 2016), effective October 1, 2016. The resulting regulations are located at 42 CFR Part 489.20(y).

The Medicare Outpatient Observation Notice (MOON) serves as the written notice component of this mandatory notification process. The standardized content of the MOON includes all informational elements required by statute, in language understandable to beneficiaries, and fulfils the regulatory requirements at 42 CFR Part 489.20(y).

2. INFORMATION USERS

The MOON is used to inform Medicare beneficiaries (including Medicare Advantage health plan enrollees) that they are outpatients receiving observation services and are not inpatients of a hospital or CAH.

The MOON is not given every time items and services are furnished in a hospital or CAH. Rather, hospitals are only required to deliver the MOON to individuals receiving observation services as outpatients for more than 24 hours.

Based on CMS statistics for 2023, we estimate the number of hospitals and CAHs delivering the MOON to be 5,817, delivering approximately 2,073,991 notices (source: CMS Office of Enterprise and Data Analytics Information Policy & Analytics Group).

3. IMPROVED INFORMATION TECHNOLOGY

Hospitals must deliver a hard copy of the MOON to beneficiaries and enrollees or their representatives. Hospitals must retain a copy of the signed MOON and may store the MOON electronically if electronic medical records are maintained.

If a hospital elects to issue a MOON that is viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper rather than electronic issuance if that is what the beneficiary prefers. Regardless of whether a

paper or electronic version is issued, and whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the signed MOON.

In cases where the beneficiary has a representative who is not physically present, hospitals are permitted to give the MOON by telephone as long as a hard copy is delivered to the representative.

4. DUPLICATION OF SIMILAR INFORMATION

The information given to Medicare patients in this notice is unique and does not duplicate any other effort.

5. SMALL BUSINESS

All hospitals are expected to give the MOON 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 MOON is given as often as required by law, described under item number 2, above. If this information is provided less frequently or not provided at all, Medicare beneficiaries won't be informed that their hospital stay is outpatient and not inpatient and the implications of being an outpatient.

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 secrets, 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 9/24/2025 (90 FR 45939). CMS received one comment during the 60-day public comment period. No substantiative changes were made to the form or the form instructions.

The 30-day notice published in the Federal Register on 12/08/2025 (90 FR 56763).

9. PAYMENT/ GIFT TO RESPONDENT

No payment or gifts are provided to the respondents for their participation. The MOON is used to inform Medicare beneficiaries (including Medicare Advantage health plan enrollees) that they are outpatients receiving observation services and are not inpatients of a hospital or CAH.

10. CONFIDENTIALITY

We do not pledge confidentiality, as we are not collecting information. The provider will maintain records of notices and decisions, but those records do not become part of a federal system of records.

11. SENSITIVE QUESTIONS

We do not require beneficiaries to answer any sensitive questions.

12.BURDEN ESTIMATES

Hourly Burden

We estimate that delivery of the 2-page MOON, including the oral explanation, will take approximately 15 minutes. Based on the 15 minute (0.25 hour) response time and annual frequency of responses, the annual hour burden is estimated to be 518,498 hours (2,073,991 responses x 0.25 hour) or approximately 89 hours per respondent (518,498 annual hour burden/5,817 hospitals and CAHs).

<u>Wages</u>

To derive average costs, we used data from the <u>U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates</u> for all salary estimates. In this regard, the following table

presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: Cost Estimates

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered nurse	29-1141	\$45.00	\$45.00	\$90.00

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.

As stated in section 2, we estimate that 5,817 hospitals and CAHs will deliver 2,073,991 notices, annually.

The cost per response is approximately \$22.50 based on an adjusted hourly salary rate of \$90.00 and the 15-minute response estimate (\$90.00 Adjusted Hourly Wage x 0.25 hour). By multiplying the annual responses by \$22.50, the annual cost burden estimate is \$46,664,798 (2,073,991 responses x \$22.50) or approximately \$8,022 per hospital (\$46,664,798/5,817 hospitals and CAHs).

Table 2: Burden Summary

	Respondent s	Responses	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr.)	Total Cost (\$)
Total	5,817	2,073,991	2,887,866	0.25 hr (15 min)	518,498	90.00	\$46,664,798

13. CAPITAL COSTS

There are no capital costs.

14. COSTS ASSOCIATED TO THE FEDERAL GOVERNMENT

The cost to the Federal government is on a triennial basis and is associated with the preparation and release of the MOON and 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 <u>OPM 2025 General Schedule (GS) Locality Pay</u> 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 \$1,572.00. The annualized cost to the Federal government is \$524 (\$1,572/3).

Table 3. Cost Estimates

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	\$65.42	24	\$1,572.00
			TOTAL: \$1,572.00

15. PROGRAM OR BURDEN CHANGES

We estimate that 5,817 hospitals and CAHs will deliver 2,073,991 notices, annually. This represents an increase of 1,390,769 from our last collection. This is due to our recent capacity to capture Medicare Advantage data in addition to Original Medicare. There are no associated policy changes, but solely the ability to fully account for the existing burden. Hourly burden has increased from 170,806 to 518,498 due to the growth in hospitals/CAHs and notices submitted.

The cost per response is now \$22.50 based on an adjusted hourly salary rate of \$90.00. Previously, it was \$19.89 based on an hourly salary rate of \$79.56. This is due to updated wage index numbers.

16. PUBLICATION AND TABULATION DATES

The notice will be published online at https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative However, no aggregate or individual data will be tabulated from the notice.

17.EXPIRATION DATE

We are not requesting any exemption. Expiration and OMB control number will be displayed on all forms and instruction documents.

18. CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

19. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.