Supporting Statement Medicare Change of Status Notice

(CMS-10868; OMB #0938-1467)

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) requests approval for new collection CMS-10868.

CMS-4204-F "Medicare Program: Appeal Rights for Certain Changes in Patient Status", sets forth new appeals procedures for certain Medicare beneficiaries who are initially admitted as hospital inpatients but are subsequently reclassified as outpatients receiving observation services during their hospital stay and meet other eligibility criteria. We are requiring hospitals to deliver, as soon as possible after certain conditions are met and prior to release from the hospital, a new standardized beneficiary notice, informing eligible beneficiaries of the change in their status, the resulting effect on Medicare coverage of their stay, and their appeal rights if they wish to challenge that change. This new notice is called the Medicare Change of Status Notice (MCSN).

Comments were received on CMS-4204-P related to this notice. Corresponding changes were made to this final version of the notice in response to those comments. Specific edits are noted in the crosswalk accompanying this supporting statement.

This notice underwent consumer testing¹ to ensure the notice is clear and easy to understand. Based on feedback from testing, several revisions were made to the notice, including language and formatting changes to improve clarity and readability for patients who receive this notice. Corresponding changes have been made to the notice instructions. Specific edits are noted in the crosswalk accompanying this supporting statement.

In addition to a Spanish translation, the MCSN is translated into Vietnamese, Chinese, and Korean. This aligns with CMS translations of other beneficiary facing materials. Additionally, these are the only notice language translations available at this time. We will work incrementally to add additional translations as appropriate and available for future renewals of this collection.

A. JUSTIFICATION

1. NEED AND LEGAL BASIS

42 CFR 405.1210, as required by the order from the Federal district court for the District of Connecticut in the case *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020)), *aff'd sub nom.*, *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022).

2. INFORMATION USERS

¹ This testing methodology is set forth and approved in OMB collection 0938-1382 Gen IC #11.

Hospitals must deliver a hard copy of the MCSN to beneficiaries eligible for an appeal.

The beneficiary must be given a paper copy of the signed MCSN to keep, regardless of whether a paper or electronic version is delivered and whether the signature is digitally captured or manually signed.

The MCSN will apprise eligible beneficiaries of their appeal rights and instruct them on how to appeal.

USE OF INFORMATION TECHNOLOGY

The MCSN will generally be delivered as a hard copy during in-person patient encounters. In some cases, notification may be done by telephone with a follow-up notice mailed. Electronic issuance of the MCSN 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 should receive a copy of the MCSN for his/her own records. Hospitals may choose to store the required signed copy of the MCSN electronically.

4. DUPLICATION OF EFFORTS

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

5. SMALL BUSINESSES

These requirements will not adversely affect small businesses.

6. LESS FREQUENT COLLECTION

The MCSN will be given on an as-needed basis, to only those beneficiaries eligible per 42 CFR 405.1212. Should this form not be given when applicable, beneficiaries will not be able to exercise their appeal rights when their status is changed from inpatient to outpatient receiving observation services.

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 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

A 60-day Federal Register notice of the Medicare Program: Appeal Rights for Certain Changes in Patient Status proposed rule (RIN 0938- AV16, CMS- 4204-P) published in the Federal Register on12/27/2023 (88 FR 89506). Comments related to this proposed rule are addressed in 4204-F and were also summarized and provided separately to OMB.

The 30-day Federal Register notice of the Medicare Program: Appeal Rights for Certain Changes in Patient Status Final Rule (0938-AV16, CMS-4204-F) published on 10/15/2024 (89 FR 83240).

9. PAYMENTS/GIFTS TO RESPONDENT

No payments or gifts is provided to respondents for their participation or involvement within the collection of information.

10. CONFIDENTIALITY

Not applicable. Any maintained records will not become part of a federal system of records.

11. SENSITIVE QUESTIONS

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

12. BURDEN ESTIMATES

<u>Wages</u>

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 (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.

We estimate it would take 10 minutes (0.1667 hour) at \$90.84/hour for a registered nurse to complete the two data fields and deliver each notice to the applicable beneficiary.

The 10-minute estimate is same as that for our Important Message from Medicare (CMS-10065/10066; OMB 0938-1019), which the MCSN notice is modeled after.

In 2022 there were approximately 15,655 instances where hospital stays met the criteria for an appeal, With regard to this final rule we estimate that hospitals would be required to give an estimated 15,655 MCSN notices to beneficiaries each year. In aggregate, we estimate an annual hospital burden of 2,610 hours (15,655 notices x 0.1667 hour/notice) at a cost of \$237,092 (2,610 hour x \$90.84/hour).

Note: our data does not permit us to determine whether the observation services occurred prior to the initial inpatient stay or followed the change in status from inpatient to outpatient, as required to qualify for an appeal. As a result, 15,655 MCSN notices likely overstates the number of beneficiaries eligible for an appeal.

	MELL 1: MINONE REQUIREMENTS MID BONDEN LOTIMATES							
Regulation								Ī
Section(s)								
Under Title	OMB Control			Time per	Total	Labor	Total	
42 of the	Number		Total	Response	Time	Cost	Cost	
CFR	(CMS ID Number)	Respondents	Responses	(hours)	(hours)	(\$/hour)	(\$)	
	0938-1467	6,162		0.1667				
§ 405.1210	(CMS-10868)	hospitals	15,655	(10 min)	2610	90.84	237,092	

TABLE 1: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

13. CAPITAL COSTS

There are no capital costs associated with this collection.

14. COST TO FEDERAL GOVERNMENT

The cost to the Federal government is on a triennial basis and is associated with the preparation and release of the MCSN 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 OPM 2023 General Schedule (GS) Locality Pay Tables, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB.pdf. 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 \$1,392.00.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	\$58.00	24	\$1,392.00
			TOTAL: \$1,392.00

The annualized cost to the Federal government is \$464 (\$1,392/3).

15.PROGRAM OR BURDEN CHANGES

This is a new collection.

16.PUBLICATION AND TABULATION DATES

CMS does not intend to publish data related to the notices.

17. EXPIRATION DATE

CMS will display the expiration date and OMB control number at the bottom of all forms and instructions.

18. CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The use of statistical methods does not apply for purposes of this notice.