

## Supporting Statement for the Medicare Outpatient Observation Notice CMS-10611

### A. BACKGROUND

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)). The NOTICE Act requires hospitals and critical access hospitals (CAHs) to provide written and oral notification to individuals receiving observation services as outpatients for more than 24 hours. The statute mandates the Secretary develop a plain language written notice for this purpose. The written notice must be delivered no later than 36 hours after observation services are initiated, must include the reason the individual is receiving observation services, and must explain the implications of receiving outpatient observation services, such as cost sharing, and post-hospitalization eligibility for Medicare coverage of skilled nursing facility (SNF) services. The hospital or CAH must obtain the signature of the individual or an individual acting on behalf of the patient. The statutory effective date of the NOTICE Act is 12 months after the date of the enactment, which is August 6, 2016.

To fulfill these statutory requirements, we are submitting the Medicare Outpatient Observation Notice (MOON) for approval as a new collection. The MOON will serve as the standardized notice used to notify persons entitled to Medicare benefits under Title XVIII of the Act, who receive more than 24 hours of observation services that their hospital stay is outpatient and not inpatient, and the implications of being an outpatient. The MOON contains all of the informational elements listed above as required by statute.

We have added implementing regulations for the NOTICE Act to 42 CFR 489.20 and 405.926.

### B. JUSTIFICATION

#### 1. NEED AND LEGAL BASIS

Section 1866(a)(1) lists conditions for providers of services to participate in the Medicare program. Under this section, the NOTICE Act adds a new subparagraph (Y) containing requirements for hospitals and CAHs to provide notification to individuals entitled to Medicare benefits under Title XVIII of the Act who receive outpatient observation services for more than 24 hours. The notification must be provided as both a written notice and an oral explanation. The MOON will serve as the written notice component of this new mandatory notification process. The standardized content of the MOON will include all informational elements required by statute in language understandable to beneficiaries.

## 2. INFORMATION USERS

Based on CMS statistics for 2014, we estimate the number of hospitals and CAHs delivering the MOON to be 6,142, delivering approximately 1,399,999 notices (sources: CMS Office of Enterprise and Data Analytics and CMS Medicare Plan Payment Group).

MOONs are 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.

## 3. IMPROVED INFORMATION TECHNOLOGY

Hospitals must deliver a hard copy of the MOON to beneficiaries and enrollees. 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 an 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 we are requesting 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 on an as-needed basis as described under 2, above.

## 7. SPECIAL CIRCUMSTANCES

There are no special circumstances.

## 8. FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

We solicited comments on the program and measure requirements through the FY 2017 IPPS/LTCH PPS proposed rule and responded to those comments in the corresponding

final rule. The notice of proposed rulemaking published on August 1, 2016 (XX FR XXXX). Please see attached pages for comment summary.

#### 9. PAYMENT/ GIFT TO RESPONDENT

We will not provide payment or gifts to respondents.

#### 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 ESTIMATE

As explained in section 2, we estimate that 6,142 hospitals and CAHs will deliver 1,399,999 notices, annually.

We estimate that delivery of the 2-page MOON, including the oral explanation, will take approximately 15 minutes (0.25 hour). Based on the 15 minute (0.25 hour) response time and annual frequency of responses, the annual hour burden is estimated to be 350,000 hours (1,399,999 responses x 0.25 hour) or approximately 57 hours per respondent (350,000 annual hour burden / 6,142 hospitals and CAHs).

The cost per response is approximately \$16.78 based on an hourly salary rate of \$67.10 and the 15 minute response estimate. By multiplying the annual responses by \$16.78, the annual cost burden estimate is \$23,491,983 (1,399,999 responses x \$16.78) or approximately \$3,824.81 per hospital (\$23,491,983/6,142 hospitals and CAHs).

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](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.

**Table1: Cost Estimates**

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered nurse	29-1141	\$33.55	\$33.55	\$67.10

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.

### 13. CAPITAL COSTS

There are no capital costs.

### 14. COSTS ASSOCIATED TO FEDERAL GOVERNMENT

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

### 15. PROGRAM OR BURDEN CHANGES

This is a new collection, but there have been burden changes since we put this out for comment with the IPPS NPRM.

We inadvertently did not include outpatient observation service claims for Medicare Advantage (MA) enrollees in the estimated MOON burden in the proposed rule. We have updated our calculations to include MA outpatient observation service claims and our estimate now fully accounts for outpatient services claims for all Medicare Beneficiaries. In addition, we have increased the estimated time for hospitals to prepare and deliver the MOON to 15 minutes. We have done this to account for the addition of a free text field to indicate why a beneficiary is receiving outpatient observation services, in response to public comments suggesting such rationale be included in the MOON.

### 16. PUBLICATION AND 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 any exemption.

### 18. CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

## C. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.