

## Submitted Electronically

August 30, 2016

Howard Shelanski  
Administrator, Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17th Street, NW  
Washington, D.C. 20503

Subject: OMB Comments on the CMS Medicare Outpatient Observation Notice (MOON) per the Paperwork Reduction Act (CMS-10611)

Dear Administrator Shelanski:

On behalf of our more than 200 member hospitals and health systems, the Florida Hospital Association (FHA) appreciates the opportunity to provide input to the Office of Budget and Management (OMB) request for comments on the Centers for Medicare & Medicaid Services' (CMS) proposed Medicare Outpatient Observation Notice (MOON) per the Paperwork Reduction Act (PRA). FHA supported the passage of the NOTICE Act and agrees it is important to provide all patients with information about their outpatient status and the implications it may have on cost-sharing and post-acute services. Following several member meetings and discussion, we offer the following detailed comments regarding the revisions to the MOON released in August.

FHA appreciates the careful consideration by CMS to address a number of important issues outlined in our extensive comments to the federal fiscal year (FY) 2017 inpatient prospective payment system proposed rule. Further, we are grateful for this second opportunity to comment before implementation. We appreciate that OMB must evaluate the MOON against four criteria in order to fairly evaluate whether the information should be collected and approved. The PRA requires comment and evaluation of the following criteria:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection and burden;
- The quality, utility and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In reviewing the revised MOON and its instructions with our member hospitals, FHA has identified serious concerns that, absent significant revisions, would result in the MOON not meeting the OMB criteria for approval. We urge CMS and OMB to make the following critically important revisions:

1. Eliminate the statement "You are not an inpatient because" and remove completely the free text box. CMS and OMB should return to the previous two bullet points

noted in the April version of the MOON. The previous MOON clearly stated that “you are a hospital outpatient receiving hospital observation services.” It stated “you are not an inpatient” and went on to provide additional information about what observation services are. FHA supports the standardization of the previously released text noted in the April version of the MOON, with the exception of the third bullet “usually lasts 48 hours or less.”

The NOTICE Act (H.R. 876 of the 114th Congress) added a new subparagraph (Y) to section 1866(a)(1) of the Social Security Act. Section 1886(a)(1)(Y) requires hospitals and critical access hospitals to notify Medicare beneficiaries receiving observation services for more than 24 hours of their status as an outpatient under observation and not as an inpatient. Further, the notice must explain the reasons for the individual’s status as an outpatient and the implications of that outpatient status on cost-sharing and on coverage with respect to skilled nursing facility services.

With respect to the field in the MOON that indicates that the Medicare beneficiary is a hospital outpatient receiving observation services, we believe that the revised language in the field is inconsistent with the law as evidenced from a plain reading of the law and from the legislative history of the NOTICE Act. The law requires an explanation of the reason(s) why the patient is in outpatient status and the implication of that outpatient status on cost-sharing and eligibility for payment for subsequent skilled nursing facility services. By contrast, the revised MOON requires hospitals to respond to the statement “You are not an inpatient because.” The revised field requires the hospital to explain a negative (i.e., the reason that the patient is not in inpatient status) rather than explain the reason for the beneficiary’s status as an outpatient receiving observation services.

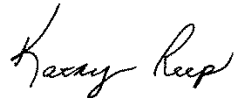
If the revised MOON is finalized as is, CMS must allow hospitals to develop standardized text to be used for all patients that notes, at the time observation services were ordered, the patient did not meet the clinical criteria to warrant an inpatient admission. Further, hospitals may consider pulling standardized language from 42 CFR 412.3 – Admissions for purposes of populating this field. Standardized language may include but not be limited to the following:

- The patient does not meet clinical criteria for inpatient admission at this time.
  - The patient is not expected to receive observation services longer than two midnights.
  - By definition (as specified in the Medicare Benefits Policy Manual, Pub.100-02), the reason for ordering observation services will always be the result of a physician’s decision that the individual does not currently require inpatient services and observation services are needed for the physician to make a decision regarding whether the individual needs further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital.
2. Delay implementation and/or enforcement timeline to ensure all of the following:
- i. Hospitals have adequate time to properly train staff, update admitting procedures and integrate this notice into their electronic medical records as appropriate.

- ii. CMS provides additional guidance to state survey agencies regarding appropriate oversight and implementation of the MOON.
  - iii. Hospitals may complete additional translations of a final MOON for all patients in the community.
3. Create a signature line for staff to sign to document that the information was provided but at the time of notification the beneficiary was unable to sign due to his or her medical condition and there was not a patient representative available. Also include checkboxes for acknowledgement/documentation that oral notification was provided and, if applicable, when an interpreter was used.
4. Change the patient name and identification number on the MOON to be consistent with the Important Message from Medicare (IMM) form, and include the Department of Health & Human Services, CMS logo and OMB approval number on the top right hand corner so the forms look consistent.
5. Provide additional guidance regarding implementation of the MOON as soon as possible, but at least 60 days before the MOON is implemented.

FHA urges OMB to carefully consider our detailed comments and suggestions and to make the necessary changes to the MOON and accompanying instructions to ensure beneficiary understanding and to decrease the administrative and data collection burden. If you have any questions, please feel free to contact me at [kathyr@fha.org](mailto:kathyr@fha.org).

Sincerely,



Kathy Reep  
Vice President/Financial Services