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CMS DELAYS IMPLEMENTATION OF NOTICE ACT IN FINAL RULE

On August 2, 2016, the Centers for Medicare & Medicaid Services ("CMS") released its Hospital Inpatient Prospective Payment System and Long-Term Acute Care Hospital Final Rule Issues for Fiscal Year 2017, which are set to be published on August 22, 2016 and effective October 1, 2016. CMS included the final rule for Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services to implement the Notice of Observation Treatment and Implication for Care Eligibility ("NOTICE") Act. The NOTICE Act was enacted on August 6, 2015 and requires certain Medicare patients to be informed of their observation status and related implications.

The final rule: (i) requires hospitals and critical access hospitals ("CAHs") to utilize a standard Medicare Outpatient Observation Notice ("MOON") to provide written notice in accordance with the NOTICE Act; (ii) delays implementation of the NOTICE Act's requirements until the MOON is finalized; and (iii) provides other slight modifications and clarifications regarding implementation of the NOTICE Act. Once finalized, hospitals and CAHs must present the MOON to Medicare patients who are placed in outpatient observation status for longer than 24 hours, verbally discuss its contents with such patients and obtain appropriate signatures on the MOON. The full text of the final rule can be found here.

IMPLEMENTATION DELAY

The NOTICE Act's requirements were originally set to take effect on August 6, 2016; however, CMS has indicated that the final rule will not be effective until October 1, 2016. The MOON is subject to the Paperwork Reduction Act approval process and must undergo a 30-day public review and comment period beginning on August 22, 2016. CMS believes that the finalization of the MOON by the Office of Management and Budget ("OMB") will likely coincide closely with the effective date of the final rule in October. After the MOON has been finalized, hospitals and CAHs will have 90 calendar days to fully implement use of the MOON. The implementation period will be announced sometime after the effective date of the final rule on the CMS Beneficiary Notices Initiative website located here.

SUMMARY OF ADDITIONAL MODIFICATIONS AND CLARIFICATIONS IN FINAL RULE

In the final rule, CMS implements the NOTICE Act by revising the Medicare Conditions of Participation to specify a process for hospitals and CAHs to notify certain individuals, verbally and in writing, regarding their observation status and the implications of receiving such services. The rule requires hospitals and CAHs to provide the standardized MOON to patients entitled to Medicare benefits if the patient receives more than 24 hours of outpatient observation services. The MOON must be provided no later than 36 hours after observation services are initiated or sooner if the individual is transferred, discharged or admitted as an inpatient and must be accompanied by a verbal explanation of its contents. The MOON must be signed by: (i) the patient; (ii) the patient's representative; or (iii) if the patient/patient representative refuses to sign, the staff member who presented the MOON along with additional required information regarding the signature refusal. A copy of the signed MOON must be retained by the hospital or CAH, but it may be kept electronically.

CMS adopts the proposed rule with little modification. The only noted modification in the final rule concerns the timing for delivery of the MOON. CMS clarifies that the final rule requires the MOON be provided after the outpatient observation services have been initiated and should not be provided at an earlier time, such as during an annual visit. CMS modified its proposed rule to clarify that CMS will consider a MOON that is provided to a patient prior to the patient receiving outpatient observation services for more than 24 hours to be in compliance with the written delivery requirements of the NOTICE Act. CMS cautions, however, that hospitals and CAHs should not routinely provide the MOON to patients at the initiation of outpatient observation services.

In response to received comments, CMS clarifies a number of other items related to implementing the NOTICE Act's requirements, including the following.

- The MOON must be provided to patients entitled to Medicare benefits regardless of whether the outpatient observation services furnished are payable under Medicare and to patients with a Medicare Advantage or other Medicare health plan. This includes situations where Medicare or a Medicare Advantage or other Medicare health plan is a secondary payer and where a patient is enrolled in Part A but not Part B.
- CMS is not prescribing what level of staff member must deliver the MOON to a patient but is instead leaving such determination to the

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hospitals and CAHs. However, the staff member must be able to explain the contents of the MOON and assist in answering the patient's questions in compliance with the requirements of the NOTICE Act.

- The 24-hour period of outpatient observation services refers to elapsed time from the initiation of such services pursuant to a physician order and not billable time. The term "physician order" encompasses those orders by residents and other non-physician practitioners authorized by state law and hospital staff bylaws to order observation services. Where observation services have been ordered but not yet initiated, the 24-hour period runs from the time the services are initiated. Observation time ends when all medically necessary observation services are completed.
- The NOTICE Act's requirements do not impact or change the current requirements and guidance related to the two-midnight policy previously issued by CMS.
- No appeal rights will be afforded to beneficiaries regarding receipt of the MOON. CMS states that regulations will be modified to reflect that the issuance of the MOON is not an initial determination triggering appeal rights.

UPDATES TO MEDICARE OUTPATIENT OBSERVATION NOTICE

An English language version of the MOON has been presented to the OMB. That document may be viewed here. Once approved, a Spanish language version will also be made available.

CMS has significantly revised the originally proposed MOON based on the comments received in response to the proposed rule. Sections have been removed, including fields for physician name, date and time observation services were initiated, hospital name and QIO contact information. Hospitals and CAHs will be permitted to preprint the MOON to include their name and logo at the top. A field has been added for specific information as to why the patient has been placed in outpatient observation as opposed to inpatient status. There have also been significant formatting and language changes to enhance clarity and comprehension. CMS anticipates periodic updates to the MOON based on continued experience.

The final rule notes a number of items that hospitals and CAHs are required or recommended to include in the "Additional Information" section of the MOON or include as part of the verbal explanation. For example, if an individual receives more than 24 hours of observation services as an outpatient and is admitted as an inpatient prior to the delivery of the MOON, the hospital should explain in the "Additional Information" section of the MOON that, as an inpatient, the individual may have Part A cost-sharing responsibilities. The MOON must also be annotated with the date and time of the inpatient admission. CMS notes that further guidance on information that may or must be included in the "Additional Information" section will be forthcoming in Medicare manual provisions, along with guidance on the verbal explanation and signature requirements.

PRACTICAL TAKEAWAYS

Facilities and other interested parties impacted by the NOTICE Act should consider providing comments to OMB on the revised MOON during the 30-day comment period following publication of the final rule. Additionally, hospitals and CAHs that have not already done so should consider updating policies and procedures to address the NOTICE Act's requirements and plan educational opportunities for personnel delivering the MOON to explain its contents and the process of obtaining the requisite signature(s).

Additionally, a handful of states already require similar notifications, and facilities should ensure compliance with the new NOTICE Act requirements in addition to applicable state law. To date, CMS is not aware of any state law in direct conflict with or contradictory to the final rule. CMS notes the MOON may already comply with certain state laws. Alternatively, CMS indicates in its final rule that hospitals and CAHs may craft an "Additional Information" statement or separate attachment to be included with the MOON to align the MOON with state law requirements, if possible. However, where state law and the NOTICE Act do not align, hospitals and CAHs may be required to provide duplicate notices at different times. Facilities should consider the state-imposed legal obligations in this regard and determine the most efficient way to comply with both the NOTICE Act and applicable state law in a way that will ensure proper understanding by patients.

If you have any questions, need assistance formulating comments or would like additional information about this topic, please contact:

- Stephane P. Fabus at (414) 721-0904 or sfabus@hallrender.com; or
- Your regular Hall Render attorney.

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