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Association®**

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Via electronic mail

January 4, 2016

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide our views regarding the Centers for Medicare & Medicaid Services' (CMS) upcoming rulemaking for the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act. The AHA believes that hospitals and practitioners should communicate clearly with Medicare beneficiaries and their families about their status in the hospital. Accordingly, the NOTICE Act requires that hospitals provide beneficiaries with a timely written notification and a related oral explanation if they receive outpatient observation services for more than 24 hours. The notification must explain their status as an outpatient, as well as the reasons for, and implications of, this status.

The AHA has a number of initial recommendations, detailed below, for issues that should be addressed in NOTICE Act rulemaking.

Implementation Timeline. Hospitals will need an adequate amount of time to develop and operationalize policies and procedures for implementing NOTICE Act requirements, including re-evaluating and changing existing policies and procedures, updating their information systems and providing extensive education to their staff. We believe that allowing hospitals a six-month implementation period after the final rule is issued would provide the time necessary to operationalize this new policy. This implementation period also would have the additional benefit of giving CMS time to issue clear and detailed guidance to hospitals and Medicare contractors.

Enforcement. The NOTICE Act amends the provider agreement provisions of the Social Security Act. It is our understanding that violations of requirements in this section can lead to the termination of a hospital's Medicare provider agreement. As such, the AHA encourages CMS to



describe in its proposed rule how it intends to enforce the Act's provisions and the penalties for noncompliance. However, we believe that defaulting to terminating a hospital's provider agreement in response to a finding of noncompliance with the Act's provisions would be too egregious a penalty to impose. Instead, we encourage CMS to develop a graduated process that begins with notifying and educating the provider about the regulatory requirements. This would allow time for the hospital to develop and carry out a corrective action plan.

Notification Requirements. With regard to what the notification must include, the Act requires that hospitals explain to beneficiaries that they are outpatients receiving observation services, the reasons for their status and the implications of outpatient status for the services they receive, such as the implications for cost-sharing requirements and subsequent eligibility for skilled nursing facility (SNF) coverage under Medicare. However, hospitals often do not have access to specific coverage and cost-sharing information until the beneficiary has been discharged and the claim submitted. This is especially the case for beneficiaries enrolled in Medicare Advantage plans. Therefore, the AHA urges CMS to clarify in its rulemaking that hospitals are permitted to use a standard notification to the beneficiary about applicable Medicare outpatient policies regarding cost-sharing, the prohibition on coverage of self-administered drugs, eligibility requirements for SNF services, and any other relevant Medicare policy. Hospitals will not be able to provide, and CMS should not require, an entirely individualized notification for each beneficiary. Further, we believe that it would be helpful if CMS were to provide optional templates for such a written notification for hospitals' use. These should contain standard, easy-to-understand language that may be adopted or adapted by the hospital for its own notifications.

Timing of the Required Notification. The Act requires that for beneficiaries receiving outpatient observation services for more than 24 hours, the hospital must provide the written notification and oral explanation no later than 36 hours after observation began (or upon discharge). The AHA urges CMS to clarify whether and how notifications would apply to beneficiaries who have received more than 24 hours of observation care and who are subsequently admitted to the hospital as inpatients. Further, CMS should address how the notification requirements would apply to a beneficiary who has been admitted as an inpatient, but is subsequently reverted, via condition code 44, to outpatient status. For example, consider the case of a patient who received fewer than 24 hours of observation services prior to being admitted, but the encounter was subsequently determined not to qualify as an inpatient admission and the patient was reverted to outpatient status. Would the number of hours of observation provided prior to admission count toward the 36-hour deadline for notification or does the clock for notification re-start upon the second course of observation?

Oral Explanation. The AHA also recommends that CMS not limit which hospital staff may provide the oral explanation to the beneficiary. Instead, hospitals should be permitted to determine which staff are best equipped to provide the oral explanation in an appropriate and timely manner.

Beneficiary Signature Requirement. The Act provides that, if a beneficiary refuses to provide a signature, the notification must be signed and dated by the hospital staff member who presented the written notification. The AHA recommends that CMS also apply this process in other situations that are outside of the hospital's control – such as when a beneficiary is unable, due to

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his or her medical or mental condition, to receive and sign the notification and no patient representative is available.

Overlap with Similar State Laws and/or Regulations. A number of states, such as New Jersey, Minnesota and Pennsylvania, have laws and/or regulations that mandate notifications similar to those in the NOTICE Act for outpatients receiving observation services. CMS should clarify in its rulemaking which requirements, state or federal, would take precedence in these cases. Alternatively, CMS should address whether a hospital that complies with substantially equivalent requirements imposed by its state could be considered to also be in compliance with the requirements of the NOTICE Act. We believe that it would be confusing and counter-productive to require hospitals in these states to give patients two somewhat different notifications, potentially provided at different times, informing them about generally the same thing.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Ashley Thompson  
Senior Vice President  
Public Policy Analysis and Development