800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

April 25, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: CMS-6058-P, Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule (Vol. 81, No. 40), March 1, 2016.

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 comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on program integrity enhancements to the provider enrollment process. The agency indicates that this proposed rule is part of its ongoing effort to prevent questionable providers and suppliers from entering the Medicare program and enhance its ability to promptly identify and act on instances of improper behavior.

The AHA strongly supports efforts to reduce fraud and abuse in the Medicare program. Hospitals see themselves as key partners with CMS to root out program integrity issues and vulnerabilities. Along these lines, we would like to suggest several recommendations that we believe will improve CMS's proposals while also helping to protect well-meaning providers from inappropriate delays, denials or revocation of enrollment. Specifically, enrollment should not be put at risk for minor administrative errors, and providers should not be held responsible for reporting information that they have no ability to access or verify. In addition, providers should not be required to report information prior to a final resolution of an appeal, nor should they be subject to a substantial new reporting burden for information to which the agency already has access.

DISCLOSURE OF AFFILIATIONS AND DISCLOSABLE EVENTS

In response to concerns that certain providers and suppliers were able to evade federal health care program integrity provisions by changing names or establishing complex entity relationships, Congress incorporated requirements, through the Affordable Care

Act (ACA), for the disclosure of certain information when entities enroll in the Medicare program and when they revalidate their enrollment. These requirements are intended to identify such relationships before federal health care programs potentially enroll and make payments to entities that would not otherwise be eligible for enrollment.

The proposed rule would implement these requirements by requiring providers and suppliers seeking enrollment or revalidation to disclose current or past "affiliations" with individuals and entities that have or have had a "disclosable event," including: (1) any current uncollected debt to Medicare, Medicaid or the Children's Health Insurance Program (CHIP); (2) any prior or current payment suspension under a federal health program; (3) any exclusion from participation in Medicare, Medicaid or CHIP; or (4) any denial, revocation or termination of Medicare, Medicaid or CHIP enrollment. CMS proposes to define "affiliation" to include:

1. A 5 percent or greater direct or indirect ownership interest in another organization;
2. A general or limited partnership interest in an entity, regardless of the ownership interest;
3. The exercise of operational or managerial control, or directly or indirectly conducting the day-to-day operations of another organization;
4. Acting as an officer or director of a corporation; and
5. Any reassignment relationship.

CMS could deny or revoke the provider's or supplier's enrollment if the agency determines that the affiliation poses an undue risk of fraud, waste or abuse.

Reassignment relationships. **The AHA recommends that CMS remove reassignment relationships from the list of affiliations for which disclosable events must be reported.** The first four types of affiliations listed above originate from statute. They specify relationships that exist and must be reported between an enrolling provider and other individuals or entities with an ownership or control interest over the enrolling provider. By contrast, reassignment means that an employed or contracted physician or non-physician practitioner (NPP) reassigns his or her Medicare payments to a provider that handles the billing for their services. Further, physicians and NPPs who are able to reassign their Medicare payments must already be directly enrolled in the Medicare program, a vetting process which itself requires disclosures of information that CMS seeks here. Hospitals and health systems often have hundreds of physicians and NPPs who reassign their billing rights to them.

Look-back period for "disclosable events." CMS proposes that providers and suppliers seeking Medicare enrollment or revalidation must disclose current or past (within the last five years) affiliations with individuals and entities that have had a "disclosable event." Applicants must report the disclosable events for such affiliations regardless of when the events occurred – meaning it is possible that the disclosable event may have

occurred before or after the period during which there was an "affiliation" between the applicant and the affiliated provider or supplier. The AHA is concerned that an enrolling or revalidating provider may have no way to reasonably know about disclosable events that have occurred outside of the period of their affiliation with another provider or supplier. **Therefore, the AHA recommends that disclosable events that occurred only within the period of time during which there was an affiliation be required to be disclosed.**

Reporting "disclosable events" under appeal. CMS also proposes that providers who are enrolling or revalidating their enrollment must report affiliations with individuals and entities that have "disclosable events" under appeal. However, requiring disclosure before an appeal is resolved is premature. It effectively negates the purpose of the appeal, which is to determine whether the agency's action was appropriate. Unless, and until an action is upheld, there legally is no disclosable event. **Therefore, the AHA recommends that CMS not require the reporting of otherwise "disclosable events" while an appeal is pending.**

ADDITIONAL AUTHORITY TO DENY OR REVOKE MEDICARE ENROLLMENT

The proposed rule also expands CMS's authority to deny or revoke a provider's or supplier's Medicare enrollment in certain circumstances.

Failure to report enrollment updates. CMS has authority to revoke the billing privileges of individual or groups of physicians or NPPs who fail to report a change in their practice location or a final adverse action (such as a revocation or suspension of a federal or state license or certification) within 30 days. In the proposed rule, CMS would extend this revocation basis to the failure to report in a timely manner any change in enrollment data. Furthermore, the agency would extend the timely reporting requirements to all other types of providers and suppliers. CMS notes in the preamble discussion, that while it would retain the discretion to revoke a provider's or supplier's enrollment for *any* failure to meet the reporting requirements, its proposal is focused on egregious cases of non-reporting, such as a complete failure to report a new practice location.

CMS proposes a number of factors in the regulatory text that it indicates would be used to determine whether a revocation is appropriate: (1) whether the data in question was reported; (2) if the data was reported, how belatedly; (3) the materiality of the data in question; and (4) any other information that it deems relevant in its determination. While these factors are reasonable considerations, the AHA does not believe that they are adequate to protect against the revocation of a provider's billing privileges for trivial reasons. **As the preamble language states CMS's intent is to focus on "egregious" cases, the AHA recommends that CMS adds to the regulatory text the language from the proposed rule's preamble indicating that a decision to revoke would be focused on "egregious" cases of non-reporting.**

All practice locations included in revocation when billing from non-compliant location. The proposed rule would give CMS authority to revoke a provider's or supplier's Medicare enrollment – including all of the provider's or supplier's practice locations, regardless of whether they are part of the same enrollment – if the provider or supplier billed for items or services furnished in a location that did not comply with the Medicare enrollment requirements. In the proposed regulatory language, CMS includes a number of factors that would be used to determine whether and how many of the provider's or supplier's other locations should be revoked including:

- the reason(s) for and specific facts behind the location's non-compliance;
- the number of additional locations involved;
- whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions;
- the degree of risk that the location's continuance poses to the Medicare Trust Funds;
- the length of time that the noncompliant location was non-compliant;
- the amount that was billed for services performed at or items furnished from the non-compliant location; and
- any other evidence that CMS deems relevant to the determination.

While these factors are reasonable considerations, the AHA is concerned about the possible revocation of many or all of a provider's practice locations for minor technical instances of non-compliance in a single location. **Therefore, the AHA recommends that CMS add to the regulatory text the language from the proposed rule's preamble indicating that this proposal is designed primarily to stop providers and suppliers that knowingly operate fictitious or otherwise non-compliant locations in order to circumvent CMS policies.**

EXPANSION OF ENROLLMENT OR OPT-OUT REQUIREMENT FOR PHYSICIANS ORDERING, CERTIFYING, REFERRING OR PRESCRIBING MEDICARE SERVICES

CMS proposes to expand its current authority to require that in order to order, certify, refer or prescribe any Part A or Part B services, item or drug, a physician or eligible professional must be enrolled in Medicare or have validly opted-out of the Medicare program. Currently, this requirement to enroll or opt-out applies only to imaging services, clinical laboratory services, durable medical equipment items and home health services.

The AHA appreciates that CMS proposes to delay the application of this requirement to calendar year (CY) 2018 in order to give sufficient time for providers and suppliers to complete the enrollment or opt-out process and for stakeholders (including CMS and its contractors) to prepare for, operationalize, and implement these requirements and conduct any necessary education. Based on past experience, we are concerned that one year may not be enough time to undertake and complete all of the needed actions, particularly

educating providers and suppliers about the new requirements and completing the enrollment or opt-out of all providers and suppliers who would need to do so.

Further, despite efforts by CMS, AHA and others to encourage physicians and NPPs to enroll in or validly opt-out of Medicare, many have not yet done so. These likely include physicians who do not usually treat Medicare beneficiaries and, therefore, have never felt it necessary to enroll in the Medicare program, such as physicians in the military, Public Health Service, dentists and pediatricians. However, these physicians may, on occasion, order, refer or certify beneficiaries for Medicare services. **Therefore, we recommend that CMS ensure that it allots adequate time, even if it must delay the policy further; otherwise we are concerned that for these activities, patient access to care may be disrupted.** In addition, we are concerned about CMS's ability to keep its enrollment/opt-out database up-to-date on an ongoing basis. **As such, we also recommend that CMS ensure that the enrollment database is updated in real-time and that regular audits occur to verify that the data in it is correct and easy to access by providers.**

Once again, the AHA appreciates the opportunity to comment on the proposed rule. If you have any questions concerning our comments, please feel free to contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or rschulman@aha.org

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President