

November 4, 2019

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

Re: CMS–6058–FC, Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process (Vol. 84, No. 175), September 10, 2019.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) final rule with comment period on program integrity enhancements to the provider enrollment process. The agency indicates that this final rule is part of its ongoing effort to protect the Medicare program from 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. Unfortunately, CMS's final rule includes overly burdensome and unworkable provisions that set providers up for failure and possible enforcement actions. The rule is completely at odds with the agency's signature Patients Over Paperwork initiative insofar as it imposes reporting requirements that would be difficult, if not impossible, for providers to comply with and fails to protect well-meaning providers from inappropriate delays, denials or revocation of their enrollment. 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.



The AHA previously raised these and other concerns in our April 25, 2016 comment [letter](#). Although CMS made some minor timing modifications, we are disappointed that the agency did not adopt our substantive recommendations or similar recommendations voiced by many other provider and supplier stakeholders. For example, although CMS did adopt a phased-in approach for the new affiliation disclosure requirements, this does not lessen, in any way, the ultimate burden that the final rule places on those providers that will still have to begin collecting the required information before the requirements go into effect more broadly. **As such, we strongly urge CMS to postpone the effective date of this final rule until the agency reassesses the feasibility of the rule's requirements and the ability of providers and suppliers to comply. As we discuss below, we recommend that CMS give particular reconsideration to several of the policies in this final rule and implement a more reasonable and less burdensome approach to enhance program integrity.**

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 final rule implements these requirements by requiring providers and suppliers seeking enrollment or revalidation to disclose any and all current or past affiliations that they, or their owning or managing employees or organizations, have, or within the past five years have had, with a currently or formerly enrolled provider or supplier that has a disclosable event. Disclosable events include:

1. Any uncollected debt to Medicare, Medicaid or the Children's Health Insurance Program (CHIP) regardless of the amount of the debt or whether the debt is currently being repaid or appealed;
2. Any prior or current payment suspension under a federal health program, regardless of when the payment suspension accrued or was imposed;
3. Any exclusion from participation in Medicare, Medicaid or CHIP, regardless of when the exclusion occurred or whether the exclusion is currently being appealed; or
4. Any denial, revocation or termination of Medicare, Medicaid or CHIP enrollment, regardless of the reason, whether it is currently being appealed or when it occurred.

CMS defines “affiliation” to include any of the following:

- A 5% or greater direct or indirect ownership interest that an individual or entity has in another organization;
- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization;
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization, either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization;
- An interest in which an individual is acting as an officer or director of a corporation; and
- Any reassignment relationship.

CMS will be able to 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.

As noted above, in response to concerns raised by commenters, including AHA, regarding the significant burden this rule could place on providers and suppliers, CMS adopted a phased-in approach under which it will, for now, require disclosure of affiliations only from those providers and suppliers that have one or more affiliations, as determined by CMS, that will trigger a disclosure. Such providers and suppliers will be required to report all their disclosable affiliations, upon request from CMS. This requirement will become effective after CMS has revised the provider enrollment forms to accommodate the required disclosures. However, CMS notes that eventually it will require every provider and supplier to disclose affiliations upon initial enrollment and revalidation.

Reassignment relationships. **The AHA continues to recommend 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, though a vetting process which itself requires disclosures of most information that CMS seeks here, including any final adverse legal actions such as exclusions, revocations or suspensions. Including reassignment relationships as part of the definition of affiliation dramatically, and needlessly, increases the burden that the final rule imposes on hospitals and health systems, which often have hundreds of

physicians and NPPs who reassign their billing rights to them. **A phase-in period does not, in any way, reduce this tremendous burden on providers.**

Look-back period for disclosable events. CMS will require that providers and suppliers seeking Medicare enrollment or revalidation 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. **Enrolling or revalidating providers 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.** Further, CMS does not consider circumstances where it or a Medicare contractor has made an error resulting in a disclosable event, such as a temporary payment suspension or notice of an uncollected debt to the provider. Yet, as written, the final rule will capture these CMS or contractor mistakes as required disclosable events and hold providers accountable for their reporting. **We are disappointed that CMS failed to substantially acknowledge and heed the concerns of the majority of commenters who expressed grave concerns about the burden of researching, obtaining, tracking and disclosing information that providers have no reasonable way of accessing.** Neither CMS's cursory recognition of the burden involved in this requirement nor the phasing-in of the reporting requirements adequately addresses the fact that providers will not be able to comply. Notably, such efforts will need to begin without certainty of critical definitions and components of the final rule. **Therefore, the AHA continues to strongly recommend that only disclosable events that occurred within the period of time during which there was an affiliation be required to be disclosed.**

Reporting disclosable events under appeal. CMS also will require that providers who are enrolling or revalidating their enrollment report affiliations with individuals and entities that have disclosable events under appeal. However, requiring disclosure before an appeal is resolved 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 again 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 rule also greatly 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 currently 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 final rule, CMS extends this revocation basis to the failure to report in a timely manner *any change* in enrollment data. Furthermore, the agency extends the timely reporting requirements to all other types of providers and suppliers. CMS notes in the preamble discussion, that while it retains the discretion to revoke a provider's or supplier's enrollment for any failure to meet the reporting requirements, it is focused on egregious cases of non-reporting, such as a complete failure to report a new practice location.

CMS includes a number of factors in the regulatory text that it indicates will 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, they are not adequate to protect against the revocation of a provider's billing privileges for trivial reasons. **In the preamble to the proposed rule, CMS stated its intent to focus on "egregious" cases and in the final rule it refers to "significant" cases. The AHA continues to urge CMS to add to the regulatory text this language indicating that a decision to revoke would be focused on egregious/significant cases of non-reporting.** Given the serious consequences of this vastly expanded denial and revocation of enrollment authority, we respectfully disagree with CMS's assertion that the language regarding "egregious" non-reporting is inappropriate for regulatory text.

All practice locations included in revocation when billing from a non-compliant location.

The final rule gives 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 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 non-compliant location was noncompliant;
- 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 once again recommends that CMS add to the regulatory text the language from the rule's preamble indicating that this provision is designed primarily to stop providers and suppliers that "knowingly operate fictitious or otherwise non-compliant locations in order to circumvent CMS policies."** Considering the significant consequences in play, we respectfully disagree with the agency's explanation for declining the AHA's request; that "[l]anguage that outlines the underlying purpose of (or rationale for) a particular regulatory provision is generally not included in regulatory text."

Reliance on possible subregulatory guidance for defining and clarifying regulatory requirements. **In addition, we are concerned about CMS's inappropriate deferral to possible future subregulatory guidance regarding a number of critical clarifications that are essential to a proper understanding of and compliance with the final rule's requirements.** This includes, among other things, further defining and/or clarifying:

- the definition of "affiliation;"
- the impact of reporting voluntary terminations;
- the affiliation disclosure process;
- the agency's expectations regarding the level of effort providers and suppliers must expend when researching affiliations;
- the "knew or should reasonably have known" standard;
- the process by which "undue risk" determinations will be made;
- how states are to inform Medicaid-only and CHIP-only about the form and manner of their affiliation disclosure requirements and other state Medicaid and CHIP requirements; and
- the process by which CMS and/or its contractors will apply the factors outlined in the final rule to take deny or revoke enrollment actions.

Such additional clarity on these issues is critical and must be subject to notice-and-comment rulemaking; the effective date of a regulation should not fall before such clarifications are issued. Indeed, we are concerned that, in the preamble, the agency states that, “CMS will issue accompanying sub-regulatory guidance regarding the affiliation disclosure process, *though this may or may not be issued before CMS’ begins sending affiliation disclosure requests to providers and suppliers.*” (Emphasis added). It is improper for requests for affiliation disclosure to occur before providers and suppliers completely understand what they are required to report.

The AHA appreciates the opportunity to comment on this final rule with comment period. 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/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development