June 27, 2013

American Clinical Laboratory Association

Filed Electronically

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1454-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: Proposed Rule: Requirements for the Medicare Incentive Reward Program and Provider Enrollment, CMS-6045-P

Dear Ms. Tavenner:

The American Clinical Laboratory Association ("ACLA") is pleased to have the opportunity to submit comments on the Centers for Medicare and Medicaid Services' ("CMS's") proposed rule entitled "Requirements for the Medicare Incentive Reward Program and Provider Enrollment" ("the Proposed Rule"). [1] ACLA represents clinical laboratories throughout the United States, including local, regional and national laboratories. ACLA members provide services to Medicare beneficiaries across the country, and as a result, will be directly affected by the Proposed Rule.

The Proposed Rule makes a variety of technical changes to the Medicare enrollment process and expands the Medicare Incentive Reward Program, which rewards those who provide information that leads to the collection of Medicare overpayments. We are particularly concerned about the proposed new provisions at Section 424.535(a)(8) which establish new grounds under which Medicare can revoke the enrollment of a provider or supplier. As discussed below, ACLA believes the new provision is vague and should include a requirement that the provider or supplier acted with a bad intent before the privileges can be revoked.

Proposed Section 424.535(a)(8)(i)(B) – Out of State Physicians and Beneficiaries

This provision authorizes CMS to revoke an entity's billing privileges when the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service, including where the "directing physician or beneficiary is not in the state or country when services were furnished." We recognize that the Proposed Rule does not for the first time introduce this language, but we wish to take the opportunity to comment on its lack of clarity. It appears to suggest that abuse of billing privileges includes billing for a service when it would have been impossible to actually provide the services, such as when the physician performing the service was not available to furnish the service or the patient was not available to

[1] 78 Fed. Reg. 25013 (Apr. 29, 2013).

receive the service because he or she was out of the state or country. However, that interpretation is not wholly clear based on the language of the regulation. ACLA has particular concerns about that lack of clarity because a laboratory often is not in the same state where the physician who ordered the service is located.[2] Therefore, the fact that a physician or beneficiary is not in the same state where the laboratory performed the services does not mean that the service could not have been furnished to that beneficiary on that date of service. CMS should clarify that such a circumstance is outside of the realm of that which is contemplated by this rule.

Proposed Section 424.535(a)(8)(ii) – Pattern or Practice of Submitting Claims That Fail to Meet Medicare Requirements

Under this new provision, CMS would be able to revoke an entity's billing privileges if it determines that a provider or supplier has "a pattern or practice of submitting claims for services that fail to meet Medicare requirements." ACLA is concerned that the proposed provision is very vague and without clear standards; as a result, it could be easily misapplied or misused.

First, Medicare billing requirements are extraordinarily complex. It would not be difficult for a laboratory or other provider inadvertently to submit a claim that failed to meet some Medicare requirement. There are also many instances in which the particular requirement may be unclear; thus, a provider might submit what it considered in good faith to be a correct claim but which Medicare might view as incorrect. Moreover, because laboratories bill electronically and submit millions of claims a year, a single inadvertent error could easily be repeated on numerous claims. ACLA is concerned that CMS could take the position that such errors when repeated could constitute a pattern or practice of submitting claims that fail to meet Medicare requirements. While CMS states that this provision is not meant to be used to revoke enrollment for isolated and sporadic claim denials or for innocent errors in billing, the provision itself, as proposed, does not make that intent clear.

CMS suggests that failure to meet medical necessity requirements also could constitute a violation under this provision. In many instances, providers including laboratories will submit claims that a particular contractor may believe do not meet medical necessity requirements. The laboratory may then appeal those denials in order to establish that the service is in fact medically necessary. Clearly, a mere difference of opinion about what is medically necessary should not be the basis for a denial of enrollment.

CMS envisions that a common scenario in which this provision could apply would be one where a provider or supplier is placed on prepayment review and a significant number of its claims are denied for failing to meet medical necessity requirements over time. But laboratories oftentimes are selected for prepayment review for a variety of reasons not completely within the laboratory's control. For example, despite the fact that CMS has rescinded proposals to require a physician's signature on laboratory test requisitions, and despite the fact that the medical records

[2] Further, the date of service for a lab service can be either the date the specimen was collected, the date an archived specimen was removed from storage, or the date the test was actually performed. *See* 42 C.F.R. § 414.510. In the latter two instances, the date of service for the test could easily coincide with a time when patient is out of the state or country.

containing physician signatures evidencing the intent to order a laboratory test are in the possession and control of the ordering physician, laboratories routinely are subjected to prepayment review for physician signatures and accused by CERT contractors of billing errors relating to physician signature requirements over which the laboratory has no control. Laboratories also are subjected to prepayment reviews on claims containing the new molecular pathology CPT codes or other new testing methodologies, so that contractors can review the information associated with the test. These prepayment reviews should not be considered evidence of a pattern or practice or submitting claims that do not meet Medicare requirements and should not trigger enrollment revocation.

The current proposal gives unbridled discretion to CMS to determine when it should revoke a provider's enrollment on the basis or whether or not there has been a "pattern or practice of submitting claims for services that fail to meet Medicare requirements." CMS notes that in each case it would take into account several factors when determining whether a "pattern or practice" exists, but those factors do not appear in the proposed regulatory text itself. Further, this section of the Proposed Rule lacks any standards with respect to the state of mind of the entity – whether the entity acted with some nefarious intent. CMS specifically asks whether additional factors should be considered, which of the suggested factors should not be considered, whether some factors should be weighted more heavily than others, whether a minimum or maximum threshold should be considered for the "percentage of claims denied" and "total number of claims denied" factors, and whether it should impose a knowledge requirement before taking action under this provision (for example, it suggests a requirement that the provider either acted with reckless disregard as to the accuracy of the claims or that the provider "knew or should have known that the claims did not meet Medicare requirements").[3]

With respect to the factors to be applied in determining whether a "pattern or practice" exists, ACLA urges CMS to incorporate the following factors into the regulatory text, to be weighted from most to least important as follows:

1) The reason(s) for the claim denials;
2) The percentage of submitted claims that were denied (for which there should be a minimum established threshold);
3) How long the provider or supplier has been enrolled in Medicare;
4) Whether the provider or supplier has any history of "final adverse actions"; and
5) The length of time over which the pattern or practice has continued.

We specifically request that CMS not consider the total number of claims denied, since doing so would disproportionately and unfairly impact clinical laboratories due to the large volume of claims they submit in the ordinary course of business. CMS also should clarify whether the percentage of submitted claims that were denied will be determined using individual, subpart, or organizational National Provider Identifiers ("NPIs").

[3] 78 Fed. Reg. 25023.

With respect to a knowledge or intent standard, ACLA believes that such a standard is clearly required before this provision is made effective. Optimally, revocation of billing privileges should be applied only where the entity has knowingly and willfully engaged in a pattern or practice of submitting claims for services that pose an undue risk of fraud, waste or abuse by failing to meet Medicare requirements and where the provider or supplier has no other legitimate justification for submitting the claims as submitted. The most direct way to limit the application of the provision would be requiring a showing that the provider had intent to defraud the Medicare Program. At the very least, however, the regulation should require that the provider knew or reasonably should have known that the claims did not meet Medicare requirements and did not have another legitimate justification for the claims as submitted. There also should be an opportunity for the provider to show that it has remedied any error that occurred. Finally, the requirements should be limited to information that is within the control of the particular provider. For example, laboratories routinely depend on physicians to provide information that then must be included on the claim. If such information is incorrect, it should not be considered to be the fault of the laboratory or constitute the basis for a revocation.

In sum, we believe that unless these provisions are clarified and further defined as we are proposing, they could be applied inappropriately to revoke billing privileges of clinical laboratories and other providers and suppliers who are not engaged in activities posing undue risk to the Medicare program. We urge CMS to review these sections more carefully, to consider the requirements more closely, and to adopt our recommendations to ensure that the Medicare program is appropriately protected without creating unintended consequences that could jeopardize beneficiary access to legitimately provided services.

Sincerely,

JoAnne Glisson
Senior Vice President
American Clinical Laboratory Association