June 28, 2013
The Honorable Marilyn Tavenner, RN, MHA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6045-P
Baltimore, MD 21244

Re: Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment

Dear Administrator Tavenner:

The Advanced Medical Technology Association (AdvaMed) submits the following comments on the proposal to revoke a provider’s or supplier’s Medicare billing privileges if the Centers for Medicare & Medicaid Services (CMS) determines that the provider or supplier has a pattern or practice of billing for services that do not meet Medicare requirements. This issue is addressed in the proposed rule published in the April 29, 2013 issue of the Federal Register.

As you know, AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Billing Privilege Revocation

The proposed rule indicates that a common scenario for the proposed revocation of billing privileges 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. CMS adds that any situation in which an unusually or abnormally high volume of claims are denied over time because they do not meet Medicare requirements could potentially trigger the new revocation reason. CMS notes in this regard that the agency would take into account several factors, including, but not limited to, the percentage of submitted claims that were denied, the total number of claims that were denied, the reason(s) for the claim denials, whether the provider or supplier has any history of “final adverse actions” (as that term is defined under §424.502), the length of time over which the pattern has continued, and how long the
provider or supplier has been enrolled in Medicare. CMS argues that its focus is on situations where a provider or supplier regularly fails to submit accurate claims in such a way as to pose a risk to the Medicare Trust Fund, not isolated and sporadic claim denials or for innocent errors in billing.

AdvaMed appreciates what CMS is attempting to accomplish in the proposed rule, but we are concerned that the proposal does not provide sufficient guidance to regulated entities as to what types of conduct could trigger revocation, specifically as it relates to the definition of “pattern or practice” of inaccurate or erroneous claims. We believe a significant factor to consider is whether all levels of appeal have been exhausted with respect to the claims in question, prior to a determination that a provider has demonstrated a pattern of inappropriate billing behavior. We are also concerned about the potential negative impact that this provision could have on the decision of providers to pursue legitimate appeals of claims denials.

Medicare currently provides several levels of appeals. It is not unusual for providers or suppliers to prevail on appeal and thus initial claims denials may actually be in error. For example, for the first level of Medicare appeals (redeterminations by the Medicare payment processor), the results for calendar year 2011 Part B redeterminations were partially or fully favorable to the appellant 53.6 percent of the time. For DME redeterminations during this same period, 46 percent were partially or fully favorable to the appellant. And decisions favorable to the appellant occur at all levels of appeal. For example, 53 percent of Administrative Law Judge appeals were fully favorable to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier appellants in fiscal year 2010, according to Office of Inspector General analysis of Medicare Appeals System data. Similarly, the results of the American Hospital Association’s RACTrac Survey for the first quarter of 2013 revealed, among other things, that hospitals reported appealing 44 percent of recovery audit contractor (RAC) denials, with a 72 percent success rate in the appeals process.

In light of the above data, any proposal that bases revocation of provider or supplier billing privileges on initial claims denials could be problematic. The current revocation authority focuses narrowly on services that could not have been furnished to a specific individual on the date of service, such as situations where the beneficiary is deceased, the directing physician or beneficiary is not in the state or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred. AdvaMed does not have a problem with this existing policy. However, AdvaMed believes that the proposed expansion to include denials in less well defined situations, such as medical necessity (“reasonable and necessary”), could increase the risk of unjustified billing privilege revocations that will impact Medicare providers and beneficiaries. Further, AdvaMed does not believe that the opportunity to appeal the proposed revocations would provide sufficient protection to affected providers and suppliers.
In the proposed regulation, CMS notes that its proposal is not fully defined. The agency solicits comments on five separate aspects of its proposal, each one of which is integral to its operation. In one of the five areas the agency asks for comments on what should qualify as a “pattern or practice.” As noted above, AdvaMed believes that one important consideration would be whether the provider or supplier has exercised available appeal rights with respect to the type(s) of claims in question and whether that provider or supplier has prevailed. **In other words, it would be inappropriate to trigger a revocation of billing privileges with respect to claim denials reversed upon appeal or before the provider or supplier has exhausted all levels of appeal.** This is especially true given that the proposed policy does not only relate to false claims, but also to claims where the “reasonable and necessary” standard is at issue. Before adopting any specific parameter or standard, providers should be given the opportunity to comment on the specific standard being considered.

Given the high percentage of claims denials that are overturned on appeal and the inability to quantify the impact of the proposed changed, AdvaMed urges CMS not to finalize this provision of the proposed. We further recommend that CMS not move forward with implementation of this expanded authority until providers have had sufficient opportunity to review and comment on the specific policy proposed by CMS for defining the “pattern or practice” of inaccurate or erroneous claims.

If you have any questions regarding the above comments or related matters, please contact Richard Price at rprice@advamed.org or (202) 434-7227.

Sincerely,

Ann-Marie Lynch  
Executive Vice President  
Payment and Health Care Delivery Policy