CMS Proposes to Retract New Physician Lab Signature Requirement

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In a proposed rule published in the June 30, 2011, *Federal Register*, the Centers for Medicare and Medicaid Services proposed to retract a recently established policy requiring physician signatures on laboratory requisitions. Although the proposal is expected to be widely supported, stakeholders should consider providing comments to further educate the agency regarding concerns with respect to the signature requirement and policy alternatives for future consideration.

In a proposed rule published in the June 30, 2011, *Federal Register* (76 *Fed. Reg.* 38,342), the Centers for Medicare and Medicaid Services (CMS) proposed to retract a recently established policy requiring physician signatures on laboratory requisitions (75 *Fed. Reg.* 73, 170, 73,483 (Nov. 29, 2010)).

Background

In the CY 2011 Medicare Physician Fee Schedule final rule, CMS adopted a policy requiring a physician or non-physician practitioner (NPP) signature on any requisition for laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS). The requisition signature requirement was separate and apart from existing requirements regarding orders. Thus, whenever a requisition was used to request a laboratory test paid under the CLFS, the requisition itself would have to be signed by the requesting physician or NPP—regardless of whether the physician or NPP also signed a separate order, such as an annotated medical record or documented telephonic request.

In establishing the new policy, CMS cited long-standing confusion regarding the distinction between a "requisition" and an "order" as one reason for equalizing the signature requirement for both types of documents. In CMS's view, if a signature was required for both an order and a requisition, the need to distinguish between the two types of documents became less important. CMS also cited a desire to reduce fraud and abuse in the Medicare program, believing that the signature requirement would further ensure that Medicare is not charged for tests that were not properly ordered.

The new policy was vigorously opposed by stakeholders, including the physician and laboratory communities. These stakeholders noted that physicians and NPPs do not typically sign laboratory requisitions, which are more ministerial in nature, and that, in many instances, even though the physician or NPP has placed the order for the lab, he or she is not available to sign the actual requisition. Moreover, even where the physician or NPP is theoretically available to sign the actual requisition, imposing such a requirement would be highly disruptive and would likely result in delayed access to care for beneficiaries. Stakeholders also questioned the ability of laboratories to enforce the policy, noting

that a laboratory that receives a specimen with an unsigned requisition would be forced to decide between running an important test for a beneficiary (which may be time sensitive due to both the beneficiary's condition and the fragile state of the specimen) for which it may be unable to bill Medicare or delaying care to the beneficiary while it obtains the requisite signature.

Stakeholders also challenged the policy imperatives underlying the new requirement. Specifically, they questioned whether the new requirement would actually reduce fraudulent activities surrounding laboratory tests, and reported that the purported confusion between "requisitions" and "orders" was overstated.

Delayed Enforcement

Although the new policy technically became effective January 1, 2011, on December 21, 2010, given the enormous opposition to the policy, CMS announced that it would focus on provider education regarding the new policy during the first quarter of 2011 and would not enforce it until the educational campaign had been implemented.

On March 30, 2011, CMS announced that it would spend the remainder of 2011 focusing on changing the regulation, citing concerns that physicians, NPPs and clinical diagnostic laboratories were having difficulty complying with the new policy.

Proposed Signature Requirements

CMS now proposes to retract the new laboratory requisition signature requirement, instead returning to its prior policy of not specifically requiring a signature on a requisition. CMS's retraction is based on what it describes as a new and better understanding of the practical realities of requiring a physician or NPP signature on all requisitions. CMS makes clear that its new position was the outgrowth of continued feedback from industry stakeholders following publication of the November 2010 final rule. The agency is now concerned that the new policy will prove to be overly burdensome and fears a negative impact on beneficiary access.

In the proposed rule, CMS emphasizes that it remains concerned regarding fraud and abuse in the Medicare program, and reiterates that clinical diagnostic laboratories and providers must have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by the physician or NPP.

Conclusions

Although CMS's proposal is expected to be widely supported, stakeholders, including clinical diagnostic laboratories, hospitals, physicians and NPPs, should consider providing comments to further educate the agency regarding

concerns with respect to the signature requirement and policy alternatives for future consideration. Comments are due August 29, 2011.

In light of its intent to formally retract the policy, there is no indication that CMS intends to enforce the signature requirement. Nonetheless, all providers should be mindful of the agency's concerns regarding fraud and abuse relating to laboratory services. Providers should ensure that they have sufficient procedures and safeguards to protect against fraudulent activity, and that these procedures and safeguards are being properly implemented.

Presuming that CMS finalizes the policy, and even in the interim, laboratories and providers should consider whether their existing processes and safeguards are sufficient to meet CMS's expectations, as this could become an area for fraud scrutiny and enforcement.