CMS proposes retraction of physician signature requirement for lab requisitions

The Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the *Federal Register* on June 30, 2011, that would retract the CMS policy requiring that requisitions for clinical diagnostic laboratory tests be signed by a physician or non-physician practitioner (NPP). This signature requirement had been scheduled to take effect on January 1, 2011, but enforcement had been postponed. This requirement and the proposed change are discussed below.

Background

Medicare regulations require that diagnostic laboratory tests and various other diagnostic tests be ordered by the physician or NPP who is treating the patient. The regulations also mandate that the ordering physician or NPP maintain documentation of medical necessity in the patient's medical record and that the laboratory or other entity submitting the claim for the test maintain the documentation that it received from the ordering physician or NPP.

CMS has traditionally required that orders for clinical diagnostic laboratory tests be signed by the ordering physician or NPP. In contrast, CMS has not required signatures on requisitions, although CMS has acknowledged some confusion between an order and a requisition.

For Medicare reimbursement purposes, an "order" is a communication from the treating physician or NPP requesting that a diagnostic test be performed for a beneficiary. An order may be delivered to the testing facility in writing signed by the treating physician or NPP, by telephone call from the treating physician or NPP (or his or her office), or by e-mail or other electronic means. If the order is by telephone call, the treating physician or NPP (or his or her office) and the laboratory are required to document the telephone call in their copies of the patient's medical records.

In commentary, CMS has defined a "requisition" as the paperwork that is furnished to the lab and identifies the test(s) to be performed for a patient. CMS has explained that the requisition is a ministerial document designed to assist labs with billing and handling the results of lab tests and to serve as an administrative convenience to providers and patients. CMS views a written order and a requisition as separate documents, but recognizes that a requisition that is signed can also serve as an order.

Physician signature policy and proposed retraction

The 2011 Medicare Physician Fee Schedule Rule was published in the *Federal Register* on November 29, 2010 and included a policy change requiring a physician's or NPP's signature on requisitions for clinical laboratory tests. CMS believed that this policy would reduce confusion relating to the distinction between orders and requisitions, that it would not be burdensome for physicians, and that it would make it easier for laboratory technicians to know whether a test is properly requested.

The physician signature requirement was scheduled to take effect on January 1, 2011. In the face of criticism that it would be difficult in various situations to obtain the physician's or NPP's signature without creating delays and affecting patient care, CMS announced on December 20, 2010 that it would focus on educating physicians, NPPs and labs during the first quarter of 2011, and would then begin enforcing the policy. CMS issued a memorandum on March 31, 2011 instructing its contractors not to enforce the signature requirement and stated that it would change the policy due to concern that physicians, NPPs and laboratories were having difficulty complying with it.

Three months later, CMS published its formal proposal to retract the written signature requirement for lab requisitions and to reinstate its prior policy that the physician's or NPP's signature is not required on a requisition for a clinical diagnostic laboratory test under the Medicare Clinical Laboratory Fee Schedule. This process appears to be designed to satisfy requirements under the Administrative Procedure Act for notice and comment period for this change in the announced policy. CMS has now acknowledged that it underestimated the potential impact on the health and safety of patients.

It is important to keep in mind, however, that CMS continues to emphasize the compliance obligation of labs to implement processes and safeguards to ensure that all tests are provided in response to an order by the treating physician or NPP. CMS commentary suggests an expectation that labs adopt procedures such as internal audits, agreements with ordering physicians or NPPs to furnish medical record evidence of the order upon any internal or external audit, or other steps to

confirm the existence of an order. Moreover, CMS noted that labs are not precluded from requiring the signature of a physician or NPP on a requisition.

This commentary serves as a reminder of the need for laboratory and other test facilities, as well as ordering physicians and NPPs, to follow policies and procedures to ensure that diagnostic tests are appropriate and satisfy all applicable legal and reimbursement requirements. Failure to satisfy these compliance standards could deprive a laboratory of reimbursement and could even generate false claims exposure and other sanctions, such as exclusion from federal health care programs.

Comments on the proposed rule will be accepted until 5:00 p.m. E.D.T. on August 29, 2011.

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