OBER | KALER
Attorneys at Law

Payment Matters®
Update on Medicare and Medicaid Payment Issues

Subscribe | Payment Group | Payment Matters Archive

November 29, 2011

www.ober.com

IN THIS ISSUE

Editors: Leslie Demaree Goldsmith and Carel T. Hedlund

CMS Final Rule Eliminates Requirement for Signed Laboratory Requisition: The Good, the Bad and the Unknown

By: Robert E. Mazer

In a previous *Payment Matters* article, we reported that CMS had proposed to retract its rule requiring a physician or qualified non-physician practitioner (NPP) to sign the requisition for a clinical diagnostic laboratory test. "CMS Proposes Rule on Signature on Laboratory Requisitions – A Trip Back to the Future" (July 14, 2011) The proposed rule was viewed as extremely good news by independent clinical laboratories and hospital laboratories that furnished services to non-hospital patients because of the difficulty they were having in obtaining signed requisitions from physicians and NPPs. We cautioned, however, that the proposed rule included potentially bad news – the agency did not appear willing to abandon totally the physician signature requirement. CMS indicated that, although the test requisition would not need to be signed, it would require generally that there be a signed order for a clinical laboratory test, such as a signed entry in the medical records.

The physician fee schedule final rule for calendar year 2012 [PDF] adopts the proposed rule's provision eliminating the requirement that laboratory requisitions include a physician's signature. CMS, however, restated its position that a clinical laboratory test must be supported by an order signed by the physician or NPP. CMS states: "The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP." This requirement could leave laboratories potentially more vulnerable than they were when CMS required a signed laboratory requisition. A laboratory that received a signed requisition knew that the physician signature requirement was satisfied. If it received an unsigned requisition, it had the opportunity to follow up with the physician's or NPP's office promptly and to

***Payment Matters*® is not to be construed as legal or financial advice, and the review of this information does not create an attorney-client relationship.**

Copyright© 2011, Ober, Kaler, Grimes & Shriver

assert that CMS required a signature on the requisition. As a result of the rule change, clinical laboratories are likely to receive fewer test requisitions that are signed by the physician or NPP, which may serve as an acceptable test order. A laboratory that performs a test based on an unsigned requisition – and which receives Medicare payment for the service – will be vulnerable to a recoupment action if the physician's records do not include a signed test order. CMS states in the final rule that it is permissible for a laboratory to require a physician or NPP to sign a requisition. Laboratories, however, will have substantial difficulties requiring physicians to sign test requisitions, after CMS has expressly stated that they are not required to do so.

CMS states that "it is the responsibility of the clinical diagnostic laboratory . . . to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP." In fact, CMS appears to be requiring a laboratory to "ensure" that there is a signed test order. According to CMS, a "laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order." CMS indicates that these procedures "could include internal audits, agreements with ordering physicians or NPPs to provide medical record evidence of the order in the event of an internal or external audit, steps to confirm the existence of an order under certain circumstances, or any other measures including the acceptance of risk by the clinical laboratory."

Ober|Kaler's Comments

CMS's suggested compliance procedures offer little protection for laboratories. A laboratory cannot determine the extent to which a physician's records include signed test orders based on an audit of its own records. Additionally, physicians may be unwilling to agree to provide a laboratory with medical records if the laboratory is audited, or may refuse to abide by the terms of any such agreement. Moreover, even if the physician does provide the requested medical records, they may not include a signed order, as required for the laboratory to retain payments that it may have received (unless a laboratory is able to demonstrate that it is protected by the Medicare statute's "limitation of liability" provisions). In fact,

Payment Matters® is not to be construed as legal or financial advice, and the review of this information does not create an attorney-client relationship.

Copyright© 2011, Ober, Kaler, Grimes & Shriver

"acceptance of risk" may be the only "compliance procedure" that is generally available to providers of clinical laboratory services.

Thus, while the final rule changed specific requirements related to physician signatures, laboratories should be aware that they remain vulnerable financially if physicians do not sign test orders. CMS has left them at risk for physician behavior that they cannot control and cannot monitor effectively. The extent of this risk will depend upon the frequency of Medicare audits of laboratories for this purpose, and the extent to which medical record documentation fails to include signed orders. Increased use of electronic health records by physicians should tend to reduce the occurrence of inadequate documentation, but will not eliminate it.

***Payment Matters*® is not to be construed as legal or financial advice, and the review of this information does not create an attorney-client relationship.**

Copyright© 2011, Ober, Kaler, Grimes & Shriver