

## HEALTH LAW NEWS

JULY 01, 2011

## CMS PROPOSES TO RESCIND SIGNATURE REQUIREMENT ON LAB REQUISITIONS

On June 30, 2011, CMS published a Proposed Rule ("Proposed Rule") to retract the November 29, 2010 Medicare Physician Fee Schedule Final Rule ("Final Rule") that required a physician's or non-physician practitioner's ("NPP") signature on all paper requisitions for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule. CMS proposed to reinstate the prior policy that a physician or NPP signature is not required on a laboratory requisition.

In the Proposed Rule, CMS stated that it did not realize that the Final Rule would be inconvenient and disruptive to physicians, NPPs and patients. In November, CMS stated that it was requiring a physician or NPP signature on laboratory requisitions to promote program integrity and to resolve confusion over the difference between an order and a requisition. CMS believed the signature requirement would make it easier for laboratory technicians to know whether a test is appropriately requested and would not burden physicians or NPPs.

After industry stakeholders expressed much concern, CMS announced in December 2010 that it would delay enforcement until after the first quarter of 2011. CMS intended to use the first quarter to release educational materials regarding how the Final Rule would be implemented. While developing its educational campaign, CMS realized how difficult and burdensome the actual implementation would be for physicians and NPPs. In February 2011, CMS decided to further delay enforcement so that it could re-examine the requirement.

In the Proposed Rule, CMS recognized stakeholders' concerns regarding the difficulty of obtaining a signed laboratory requisition in long-term care and emergency circumstances, in situations involving specimen transport, when the physician or NPP is off-site or when the laboratory requisition is not available for signing at the time the order is made. Further, CMS agreed with practitioners' concerns that the signature requirement could create unnecessary paperwork for practitioners using electronic health records.

CMS stated that it still believes that it would not burden practitioners to sign a laboratory requisition if the requisition is issued at the same time as the order, and that the Final Rule would have made it easier for a reference laboratory to know if a test was appropriately requested. However, CMS estimated that the financial benefit for reducing fraud and abuse in this area would be minimal in comparison to the burden on practitioners. CMS reiterated that no change has been made to the requirement that the treating physician or NPP must document the ordering of the test and that all orders, including those for clinical diagnostic laboratory tests, be signed by the ordering physician or NPP.

In summary, CMS is still concerned about the risk of fraud and abuse but has proposed to repeal the requirement that a physician or NPP sign laboratory requisitions. CMS recognized that the requirement could be detrimental to expeditious patient care and have a negative impact on beneficiary health and safety. As opposed to laboratory requisitions, orders for clinical diagnostic laboratory tests must be signed. Finally, CMS urged laboratories to create their own policies to ensure that they are only furnishing services in response to a physician or NPP order. Comments on the Proposed Rule are due at 5:00 PM EDT on August 29, 2011.

The Proposed Rule is available at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-30/pdf/2011-16366.pdf.

If you would like further guidance on this Proposed Rule, or you would like to submit comments, please contact your regular Hall Render attorney or:

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