American
Clinical Laboratory
Association

May 2, 2011

Jonathan D. Blum
Centers for Medicare & Medicaid Services
Director, Center for Medicare Management
Mail Stop 314G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Blum:

On behalf of the American Clinical Laboratory Association ("ACLA"), I am writing to express our appreciation for your assistance with the "physician signature" rule that was included in the 2011 Physician Fee Schedule (PFS) Rule. In that rule, CMS announced a new policy that would have required physicians to sign requisitions for clinical laboratory tests, a requirement that laboratories, physicians, nursing homes and hospitals agreed would impose tremendous burdens and adversely affect the ability of patients to obtain necessary services. We are very appreciative that CMS has announced that it will not enforce this policy and will rescind it as part of the 2012 PFS rule.

Because of the confusion that has persisted in this area, ACLA wanted to take this opportunity to state what it believes the rule should be in the future. We are mindful of CMS' need to ensure that all services are properly ordered; however, we are hopeful that CMS can achieve those goals without imposing undue burdens on providers or patients. We believe each of those goals can be met by following the guidelines below.

First, since the completion of the laboratory negotiated rulemaking in 2001, the rule has always been that the signature of the physician on a requisition is one way of documenting that the treating physician ordered the test, but it is not the only permissible way of doing so. We believe that basic principle, which would have been overturned by the physician signature requirement, should remain in effect. Further, as became clear during our recent discussions, there is no clear distinction between a requisition and other forms of laboratory orders, such as those written on physician prescription pads; therefore, the same rules should apply to all forms of written laboratory orders, including requisitions and other written orders.

Further, where there is not a physician signature on the requisition or other order, then the physician should document in the medical record the testing that has been ordered for the patient. Again, this was the rule before the changes made by the physician signature requirement. The medical record should be signed or initialed by the ordering physician in a manner that indicates that the physician intended to order the laboratory tests. However, we urge CMS to apply a "rule of reason" with regard to what is required so that contractors can look at the entire record to determine

whether there is reasonable evidence in the medical record demonstrating that the physician ordered the laboratory testing.

Further, these requirements should apply to all forms of laboratory testing, regardless of whether the testing is paid based on the clinical laboratory fee schedule ("CLFS"), as most clinical lab tests are, or on the physician fee schedule, as most pathology services are. Both types of testing can be ordered from the same laboratory, as part of a single patient encounter. However, when ordering laboratory tests, physicians simply do not distinguish between how the services are paid for. Indeed, it is highly unlikely that physicians have any awareness of these issues. Therefore, both laboratory testing paid on the basis of the CLFS and other laboratory services paid on the basis of the PFS should be subject to the same rules.

Finally, these rules would apply only to testing that is ordered by a paper requisition or order. With regard to services that are ordered electronically, CMS should clearly state that if testing is ordered electronically, the laboratory should be able to demonstrate safeguards that permit only physicians or other authorized persons to order the testing. Such safeguards could include a showing of a secure access (e.g., password protected) system or a showing that testing is ordered through a "certified EHR technology or a certified "EHR" module," as these terms are defined by the Office of National Coordinator. In those instances, CMS should state that no physician signature is required, as it is clear that the physician in fact ordered the testing.

We hope CMS will keep these comments in mind as it moves forward to revise the physician signature rule.

Sincerely yours,

Alan Mertz
President