

National Independent Laboratory Association American Association of Bioanalysts

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Laboratory Community Opposes CMS Proposed Rule on Physician Signature Requirements for Clinical Laboratory Requisitions

Friday, August 6, 2010, Washington, D.C. – The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule, "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011," on Tuesday, July 13, 2010. In a section entitled, "Clinical Laboratory Fee Schedule: Signature on Requisition" of the proposed rule, CMS proposes to require a physician's, or qualified, non-physician practitioner's (NPP's), signature on requisitions for clinical diagnostic laboratory tests paid through the clinical laboratory fee schedule. The clinical laboratory community does not support this proposal.

The National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB) brought this issue to the attention of the Clinical Laboratory Coalition (CLC), a coalition that includes 10 major laboratory associations, and led the coalition in drafting comments to CMS regarding the groups' opposition to the proposal. In a conference call on July 21, 2010, all CLC participants expressed their opposition to CMS's proposal. The CLC is currently collecting signatories for its comments to CMS, and expects to have the majority of the laboratory community on board.

The justification given by CMS for this change in policy is to create a less confusing process that would eliminate any uncertainty over whether a document is a requisition or an order, as signatures would be required on both. The clinical laboratory community feels strongly that requiring a physician's signature on all requisitions for clinical diagnostic laboratory tests is not an effective solution and will only lead to further confusion, a complicated and unnecessary administrative process, and potential harm to patients forced to wait too long for laboratory tests.

The decision that a physician's signature was not the only permissible way to document the ordering of a test came as a result of the November 23, 2001, final rule after a negotiated rulemaking session involving 18 laboratory and health care organizations, including the

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American Medical Association and CMS. Changing this policy solely on the basis of establishing "a less confusing process" is not enough of a reason to do so. The confusion that exists regarding the difference between "order" and "requisition" is, in part, the result of confusing language in CMS manuals, and can be cleared up without adding the extra and repetitive step of requiring a physician signature on all requisitions.

The National Independent Laboratory Association (NILA) is a trade association for clinical laboratories that provides a forum for the sharing of technical and business expertise. NILA focuses on business/management issues facing laboratories, such as marketing/sales, contracting with managed care companies, finding and keeping good employees, financial management, expanding test menus, managing growth, competing with big, publicly traded laboratories, and acting on legislative and regulatory issues facing the laboratory industry.

The American Association of Bioanalysts (AAB), founded in 1956, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists, medical laboratory technicians, and physician office laboratory technicians. AAB is committed to the pursuit of excellence in clinical laboratory testing by enhancing the professional skills of each of its members; promoting more efficient and productive operations; and representing the interests of its members. AAB's specialized membership sections include the AAB Associate Member Section (AMS), College of Reproductive Biology (CRB), Environmental Biology and Public Health (EBPH) Section, and the National Independent Laboratory Association (NILA). AAB provides a broad range of services, including representation before federal and state legislative and regulatory agencies, educational programs and publications. AAB's Proficiency Testing Service is approved under the federal CLIA regulations and is one of the largest PT providers in the United States.