August 19, 2010

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1503–P
P.O. Box 8013
Baltimore, MD 21244–8013

Dear Dr. Berwick:

On behalf of the American Association of Bioanalysts and the National Independent Laboratory Association, I would like to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" proposed rule. Our comments specifically refer to the section "Clinical Laboratory Fee Schedule: Signature on Requisition" of the proposed rule.

In the proposed rule, CMS proposes to require a physician or qualified, non-physician practitioner's (NPP) signature on requisitions for clinical diagnostic laboratory tests paid through the clinical laboratory fee schedule. The justification given 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. While we appreciate the intent to clarify the process, we feel 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 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 new requirement will significantly increase the administrative burden for laboratories. There will be duplication of record keeping, as the physician would need to sign the requisition

and the chart. Many laboratories also cite a situation in which either the chart or requisition is not signed, or they differ in some way. The decision as to which is the final order would then be at the discretion of the laboratory. There is no incentive for physicians to comply with the proposed signature requirement, or consequence for their non-compliance. Many physicians collect laboratory specimens in their offices. In this case, mandating a signature for specimens collected by office staff, based on the physician's charted orders, layers another redundant process upon the implied consent found in the use of pre-printed requisitions and on-site office collections.

Additionally, signature requirements will create confusion because Medicare will be one of very few providers that requires a signature. Currently, only three state Medicaid programs and no private insurance companies require signatures on clinical laboratory requisitions, so this is clearly not common practice. Requiring signatures for Medicare claims would be confusing and will likely create uncertainty about which providers require signatures. A question also rises regarding electronic medical records and electronic signatures. Additional guidelines or clarification might be needed in this instance, creating a new level of unnecessary paperwork.

Making physician signatures required on all laboratory requisitions puts laboratories in an unfair and potentially dangerous position if a signature is missing. Does the laboratory call the doctor's office and continue to follow-up until a signature is procured? What if the laboratory test ordered is an emergency? Standard laboratory practice is to perform the test immediately, but does this mean the lab would be held responsible and accountable for performing a test without a required signature? Is it then the laboratory's function to hold all tests until the doctor complies with the regulations? Timely laboratory testing is often essential to patient care. In the skilled nursing home environment, obtaining a physician signature for daily laboratory orders and STAT requests creates additional documentation requirements without any improvement in the order validation process. These are just a few of the questions that begin to outline the substantial administrative burden that would result from this proposed requirement.

Physicians, laboratory professionals, phlebotomists, pathologists, and health care providers in general in this country are already overburdened by administrative details and creating this additional step of a physician signature on all laboratory requisitions is an unnecessary solution to a problem that does not exist.

Again, we very much appreciate the opportunity to comment on the CMS "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" proposed rule. We feel very strongly that the proposal to require a physician's signature on all clinical diagnostic laboratory tests paid through the clinical laboratory fee schedule is not sound public policy and would create an unsafe environment for patient care. If you have questions or would like more information about any of the examples used in these comments, please feel free to contact me directly.

Sincerely,

Mark S. Birenbaum, PhD
Administrator