CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

December 3, 2010

Ms. Marilyn Tavenner
Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Tavenner:

The undersigned laboratory, hospital, and health care organizations write to express our opposition to the January 1, 2011 implementation date for the provision in the 2011 Medicare Physician Fee Schedule Final Rule that requires a physician's or qualified non physician practitioner's signature on all requisitions for clinical diagnostic laboratory tests paid for on the basis of the Clinical Laboratory Fee Schedule (CLFS). We have previously expressed opposition to this requirement and are now deeply concerned that it will go into effect on January 1, 2011, giving the health care community less than two months to comply with a still undefined provision. This requirement not only will have an adverse impact on health care businesses but could harm the health and well-being of our most vulnerable Medicare patients. As such, we strongly urge you to delay implementation of this provision by at least one year, until January 1, 2012, allowing for adequate time for all involved parties to discuss the implications of this requirement and clarify the myriad issues surrounding implementation, such as the role of the clinical laboratory in ensuring compliance.

The current practice, which does not require a signature on laboratory requisitions, came as a result of the November 23, 2001 final rule, after a negotiated rulemaking session involving the Centers for Medicare and Medicaid Services (CMS) and 18 laboratory and health care organizations, including the Medical Group Management Association and American Medical Association. As a result, most physicians who collect laboratory specimens in their offices have well-established systems in place for coordinating their charted orders for laboratory testing and the generation of the associated requisition. Therefore, in many cases, physicians do not see or sign the subsequent laboratory test requisitions because requisitions often are generated automatically from a physician order via phone call, fax, electronic submission, a standing order in a health record, or another form of an accepted order. The current system is efficient and serves patients well, while also reducing the administrative burden on health care providers and

minimizing the cost to the health care system. Requiring an additional step in the form of a physician signature on the requisition is duplicative, provides no benefit or value-added to patient care, increases the burden and cost to the health care system, and – of greatest concern – poses a threat to Medicare beneficiaries' access to timely and necessary care.

Standard laboratory practice is to perform a test immediately, and timely laboratory testing is essential to quality patient care. We are concerned that unsigned requisitions could cause severe delays for patient testing as laboratories may have difficulty in tracking down a physician-signed requisition. In the skilled nursing home environment, this is particularly troublesome as most of the patients have long-standing health care issues, requiring frequent and immediate laboratory tests, and the associated laboratory testing requisitions are completed by nursing home staff, not physicians. If a nursing home cannot locate a physician to sign the laboratory requisition, the facility could be forced to transport the patient to the emergency room for care – an expensive, unnecessary, and risky move for vulnerable beneficiaries.

Changing this policy now will have the opposite effect of what the agency purports is its goal of a less confusing process. The myriad potential harmful consequences of this policy on Medicare beneficiaries' timely access to laboratory testing, coupled with the increased administrative burden on health care providers and cost to the health care system, necessitate a delay in the implementation of this requirement. Given the time and effort that went into the carefully crafted policy resulting from the earlier negotiated rulemaking on this matter, it follows that additional time is necessary for further dialogue between CMS and the affected health care community. We must work together to explore whether this policy is the appropriate solution and to discuss the anticipated negative impact of the policy on patients and providers. Again, our organizations strongly urge you to delay the implementation of this requirement.

If you have questions or would like more information regarding the threat to patient access to laboratory testing that this policy poses, please contact any of the organizations listed below. We stand ready to work with you to address the agency's concerns about the current system and are eager to discuss alternative policy solutions. Thank you for your consideration of our concerns.

Sincerely,

ACL Laboratories
American Association of Bioanalysts
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Health Care Association
American Hospital Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Aurora Health Care
California Clinical Laboratory Association
Cheyenne Regional Medical Center

Clinical Laboratory Management Association
College of American Pathologists
Diagnostic Laboratory Medicine
Diagnostic Laboratory Services, Inc.
Laboratory Corporation of America Holdings
Marshfield Clinic
Mayo Clinic
Medical Group Management Association
National Independent Laboratory Association
Nationwide Laboratory Services
New York State Clinical Laboratory Association, Inc.
PeaceHealth Laboratories
Quest Diagnostics Incorporated
Roche Diagnostics Corporation
Siemens Healthcare Diagnostics
Sonic Healthcare USA