October 6, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

As stakeholders representing all segments of the U.S. laboratory market – national, regional, and community independent laboratories; hospital laboratories; physician office laboratories; and diagnostic manufacturers, and patients served, we urge the Centers for Medicare and Medicaid Services (CMS) to take immediate action to address the significantly deficient data collection process used to establish new clinical laboratory payment rates, which resulted in unreliable and unsustainable rates that fall short of Congress' goal of establishing a market-based system. We urge CMS to suspend implementation of the draft payment rates until these deficiencies can be addressed.

The payment data collected by CMS for tests on the Clinical Laboratory Fee Schedule (CLFS) does not result in an accurate weighted median of private payer rates for most tests on the CLFS, as required by the *Protecting Access to Medicare Act (PAMA)*. We believe the data used to set the proposed rates would not stand up to statistical validity review. The data sources used to determine the preliminary rates do not appear to reflect the various market segments, which CMS has the authority to consider in order to validate the data submitted. It is also clear from our review that the overly burdensome regulatory requirements resulted in the submission of inaccurate and incomplete laboratory payment data that is not reliable for use in its current form. As a stakeholder community, we have repeatedly pointed out to CMS, HHS, and Congress in formal comments and in meetings our concerns with the final PAMA regulation, including the serious limitations and skewed process the regulation created.

The proposed CLFS rates will now result in significant harm to the nation's surveillance network for emergent public health issues, job losses across the United States, and significantly reduced access to clinical laboratory testing for Medicare beneficiaries, particularly those in rural geographic and post-acute care settings.

We stand together in our position that before CMS proceeds with making any revisions to the CLFS, the agency must first:

- Modify the PAMA regulation to address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers;
- Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and
- Provide a transparent process to allow for the validation of the data collected by CMS.

In light of these significant concerns, we call on CMS to take swift action to engage in a constructive dialogue with stakeholders on ways to improve the PAMA data process and calculation, and establish a clear path forward for the clinical laboratory community and the Medicare beneficiaries who rely on its services. We urge CMS to suspend implementation of the revised payment rates while this path forward is determined.

Sincerely,

American Academy of Family Physicians
American Association for Clinical Chemistry
American Association of Bioanalysts
American Clinical Laboratory Association
AdvaMedDx
American Hospital Association
American Medical Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Association of American Medical Colleges
Association of Public Health Laboratories
Clinical Laboratory Management Association
COLA
College of American Pathologists
Medical Group Management Association
National Association for the Support of Long Term Care
National Independent Laboratory Association
New York State Clinical Laboratory Association
New York State Society of Pathologists
Point of Care Testing Association