

March 24, 2017

The Honorable Tom Price, MD
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

DELIVERED BY ELECTRONIC MAIL

Dear Secretary Price:

We, the undersigned, are writing to express our continued significant concerns about the implementation of the Medicare Clinical Laboratory Fee Schedule (CLFS) reform as enacted by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA). While our organizations have worked closely with our members and the Centers for Medicare and Medicaid Services (CMS) toward PAMA implementation, we believe that under the current regulatory requirements, the new program will not reflect accurate private market rates for clinical laboratory services as required by PAMA. Given the significance of these ongoing concerns, we respectfully request CMS delay the implementation of the CLFS reforms under PAMA for one year to resolve these significant issues. By ensuring smooth and successful implementation, we can maintain Medicare beneficiary access to clinical laboratory services without disruption.

Our organizations represent a diverse cross section of clinical laboratory stakeholders, including national, community and regional independent laboratories, hospital laboratories, physician office laboratories, academic laboratories, manufacturers of IVD test kits and supplies, clinical laboratory professionals, and the broad physician community.

The data reporting period for PAMA is scheduled to conclude on March 31, 2017, but many laboratories are still in the data *collection* phase as they struggle with CMS regulatory requirements. Furthermore, we are concerned that CMS' data collection system is not yet functioning at adequate capacity as many operational problems from the 2016 test phase appear unresolved and are hampering laboratory data submissions. CMS and laboratories simply must have more time to address data collection concerns, collect, and ensure accurate submission of all applicable data as this will impact final PAMA rates.

Beyond operational data issues, the significant regulatory definition for "applicable laboratory" must be reassessed and redefined. PAMA payment reforms depend on an accurate measurement of true private market rates; however, the Health and Human Services (HHS) Office of Inspector General (OIG) analysis of the current CMS definition for "applicable laboratory" assessed that only 5 percent of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories.¹

¹ *HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040)*, Sept 2016, <https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf>, pages 7-8.

The exclusion of an entire laboratory sector, particularly hospitals operating large outreach laboratories, negatively affects the integrity of rate calculations under PAMA. The implications are immense and would ultimately threaten to reduce laboratory infrastructure across the country, and therefore, limit beneficiary access to laboratory test services that support patient clinical care management. The applicable laboratory definition should be redefined to appropriately capture the true laboratory market.

Given the widespread impact of these issues, we respectfully ask that CLFS reform implementation under PAMA be delayed for one year to allow an opportunity for all stakeholders to work with the Administration on solutions. We are committed to working in partnership with you to address our concerns. If we can answer any questions or provide additional information, please contact Julie Allen, NILA Washington Representative at 202-230-5126 or julie.allen@dbr.com or Julie Khani, President, ACLA at 202-637-4865 or jkhani@acla.com.

Sincerely,

AdvaMedDx
American Association for Clinical Chemistry (AACC)
American Association of Bioanalysts (AAB)
American Clinical Laboratory Association (ACLA)
American Medical Technologists (AMT)
American Society for Clinical Laboratory Science (ASCLS)
American Society for Clinical Pathology (ASCP)
Clinical Laboratory Management Association (CLMA)
College of American Pathologists (CAP)
National Independent Laboratory Association (NILA)

Cc: The Honorable Seema Verma, Administrator, Centers for Medicare and Medicaid Services
The Honorable Orrin Hatch, Chairman, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee
The Honorable Kevin Brady, Chairman, House Ways and Means Committee
The Honorable Richard Neal, Ranking Member, House Ways and Means Committee
The Honorable Greg Walden, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee