June 26, 2017

The Honorable Thomas E. Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

DELIVERED VIA E-MAIL

Dear Secretary Price:

We respectfully request to meet with you on imminent issues with implementation of the Clinical Laboratory Fee Schedule (CLFS) provisions (Section 216) of the Protecting Access to Medicare Act of 2014 (PAMA). Our organizations represent a diverse cross section of clinical laboratory stakeholders, including physicians, independent laboratories, hospital laboratories, and manufacturers of IVD test kits and supplies.

We have worked closely with Congress and the Centers for Medicare and Medicaid Services (CMS) on PAMA implementation. However, given the exclusion of most hospital and physician office laboratories from data reporting, and concerns with data accuracy and integrity, we believe that under the current regulatory requirements, the new program will not reflect accurate private market rates that are representative of the full laboratory market, including physician office, hospital and independent laboratories.[1] Given the significance and urgency of these ongoing concerns, we respectfully request a delay in the implementation of the CLFS rates under PAMA until the rule is fixed and accurate. By ensuring smooth and successful implementation, we can maintain Medicare beneficiary access to clinical laboratory services without disruption.

PAMA established Medicare CLFS prices based on rates paid by private payors for laboratory tests.[2] The exclusion of laboratory sectors, particularly physician office and hospital outreach laboratories, harms the integrity of rate calculations under PAMA and is inconsistent with the clear intent of Congress. This could ultimately threaten beneficiary access to laboratory services from laboratory closures and significant consolidation of the laboratory market. Maintaining access to needed clinical testing is critical to the diagnosis, prevention and treatment of disease.

We request a meeting with you to discuss implementation of PAMA in a manner that is consistent with congressional intent and maintains beneficiary access to laboratory services. There is great urgency to guarantee accuracy as the proposed rates are scheduled to be published in September 2017 and go into effect on January 1, 2018. We believe it is important for CMS to work with the broad stakeholder community to ensure accurate reporting of private rates, and ultimately, new CLFS payment rates that are based on the broad scope of the clinical laboratory market.

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[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.
[2] Pub. L. 113-93.

We look forward to meeting with you to discuss these important issues. Please contact Julie Khani, president, American Clinical Laboratory Association, (202) 637-9466, jkhani@acla.com, to answer any questions or to schedule a meeting.

Sincerely,

AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association