September \_\_\_ , 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:

On behalf of hospitals and health systems serving patients across the state of \_\_\_\_\_, we write to urge you to delay and make needed changes to the Clinical Laboratory Fee Schedule (CLFS) provisions (Section 216) of the Protecting Access to Medicare Act of 2014 (PAMA). Our organizations operate hospital outreach laboratories with broad geographic presence throughout the state. In its current form, the PAMA regulation threatens to force many community-based laboratories to close or make drastic cuts in service. We are extremely concerned that patient access to needed clinical laboratory testing will be halted or significantly limited in our communities.

The PAMA statute established a new payment system for clinical laboratory tests paid on the CLFS, requiring a market-based reporting system and evaluation. However, the HHS Office of Inspector General noted that CMS’s 2016 final regulation virtually excludes an entire section of the laboratory market – hospital outreach laboratories – from data reporting. [[1]](#footnote-1) Under the current regulatory requirements, the new program will not reflect accurate private market rates that are representative of the full laboratory market, including hospital outreach, physician office, and independent laboratories. Given the significance of these 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 is intended to establish Medicare CLFS prices based on rates paid by private payors for laboratory tests.[[2]](#footnote-2) The exclusion of laboratory sectors, particularly the hospital outreach laboratory sector, harms the integrity of rate calculations under PAMA and is inconsistent with the clear intent of Congress. Under the statute, hospital laboratories are subject to the revised rates, yet under the regulation, many of our institutions were unable to report market payment data that is needed to calculate such rates. The current regulation will result in an extremely limited and skewed assessment of the laboratory market. If not addressed, this will ultimately threaten beneficiary access to laboratory services. Maintaining access to needed clinical testing is critical to the diagnosis, prevention, and treatment of disease.

We formally request your assistance in ensuring PAMA is immediately addressed. There is great urgency in this request as the proposed rates under the current regulation are expected to be published in September 2017 and go into effect on January 1, 2018. We believe it is critically important for CMS to work with hospitals and the broader stakeholder community to ensure that new CLFS payment rates are based on the full scope of the clinical laboratory market.

Thank you in advance for your prompt consideration of our request. Please contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name, email, phone) to answer any questions.

Sincerely,

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. [↑](#footnote-ref-1)
2. Pub. L. 113-93. [↑](#footnote-ref-2)