



United States Senate

WASHINGTON, DC 20510-0905

November 3, 2017

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

Dear Administrator Verma:

We write to share our concerns with the proposed Medicare Clinical Diagnostic Laboratory Tests Payments System, released by the Centers for Medicare and Medicaid Services (CMS) on September 22, 2017. This proposal fails to take into account many of the concerns our offices and the stakeholder community have raised with CMS throughout the implementation of the *Protecting Access to Medicare Act* (PAMA) [Pub. L. 113-93]. We urge CMS to resolve these concerns and engage with stakeholders to ensure that all Medicare beneficiaries maintain access to critical laboratory services before moving forward with the new laboratory payment rates.

PAMA requires CMS to update the way clinical laboratories are paid under the Medicare program through the creation of a new mandatory reporting system and revised fee schedule. In order for this new system to be successful, it is critical that CMS collect the data necessary to establish a market-based payment system that is representative of the entire laboratory community. However, our offices have met with laboratories that are concerned about the integrity of the data used to establish the new payment rates and the method of data collection.

For example, it is our understanding that the payment data collected by CMS for tests on the new Clinical Laboratory Fee Schedule does not result in an accurate weighted median of private payer rates for most tests. The data does not represent all segments of the laboratory market as some are excluded from participation, limiting the market data CMS reviewed. Finally, we are concerned by areas where CMS relied on a flawed attempt to crosswalk certain code sets to propose inadequate rates for entire sets of testing services, such as the tests for definitive testing for drugs, which are integral in our nation's fight against the addiction epidemic. Taken together, these issues have the potential to skew the data's veracity and corresponding payment rates, which could have a significant, detrimental impact on public health and clinical laboratory testing services access and for Medicare beneficiaries across the country.

We request that CMS address these concerns before finalizing the draft laboratory payment rates, which are currently scheduled to go into effect on January 1, 2018. Failure to ensure that the CMS regulations are a fair reflection of the clinical laboratory market may threaten patient

access to care, especially for those individuals residing in rural communities. More time is required to achieve a workable regulation that reflects the Congressional intent behind PAMA while providing certainty to the clinical laboratory community.

To that end, we urge CMS to continue its work with those affected by the new payment rates, including laboratory, beneficiary, and provider communities, to ensure these concerns are adequately addressed before moving forward with implementation.

Thank you for your attention to our request. We look forward to partnering with you to safeguard access to quality laboratory services for Medicare beneficiaries.

Sincerely,



BILL NELSON
United States Senator



SHERROD BROWN
United States Senator



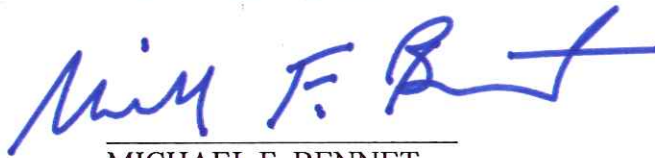
ROBERT MENENDEZ
United States Senator



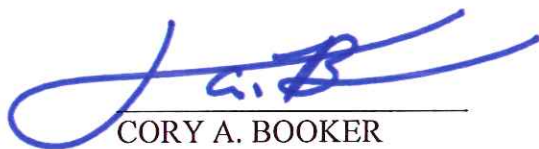
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