Congress of the United States
Washington, DC 20515

December 16, 2015

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

Dear Acting Administrator Slavitt:

We are writing to express our concerns with the Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule, published in the *Federal Register* on October 1, 2015. We are primarily concerned that laboratories will be unable to comply with the proposed implementation timeline. Delays in the rulemaking process, which the statute required to be completed by June 30, 2015, provide laboratories with little time to begin undertaking significant data collection. We respectfully request that you make the necessary changes so the final rule reflects the intent of Congress, and adjust the implementation timeline to provide the necessary time for laboratories to comply. It is critical that the Centers for Medicare & Medicaid Services (CMS) engage in a constructive dialogue with stakeholders on ways to improve the proposed rule and establish a clear path forward for the clinical laboratory community, clinicians, and the millions of Medicare beneficiaries who rely on its services.

The Protecting Access to Medicare Act of 2014 (PAMA) (P. L. 113-93) includes the most significant reforms to the Clinical Laboratory Fee Schedule (CLFS) since it was established in 1984. PAMA requires the development of a first-of-its-kind, mandatory reporting system in which "applicable laboratories" must report all of their private payment rates and test volumes to CMS. The goal of this new reporting system is to develop a market-based reimbursement system to replace the current fee schedule. Clinical laboratories ranging from community independent laboratories, physician office laboratories, hospital-based laboratories, national laboratories, and other laboratories would report private market data, and CMS would calculate median rates so that Medicare rates could be reset based on a true picture of the laboratory market.

However, under CMS's current proposal, a number of laboratories are prohibited from participating in the reporting process. We are deeply concerned that this prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices. We recommend that CMS consider a more inclusive approach to determining which laboratories should report data and to allow any laboratory to voluntarily report data.

In addition to the need to broaden the universe of reporting laboratories, CMS must reconsider the proposed timeline. Laboratories will be establishing new information systems to collect, assess, and validate data sets according to regulations that have yet to be finalized, and then quickly reporting the data to CMS beginning in January 2016. Failure to meet this deadline or

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errors in reporting could yield penalties of up to $10,000 per day. The proposed timeline presents a significant challenge to the laboratory community as it provides little time to prepare, certify, and submit upwards of millions of data points based on a yet-to-be-released set of Agency requirements. Accurate reporting is essential to establishing appropriate reimbursement rates. Additionally, we encourage CMS to provide greater time between the publication of revised reimbursement rates and their effective date as well as outline a formal process for laboratories to call attention to potential errors in calculating the rates.

Additionally, PAMA also creates a new category of tests, Advanced Diagnostic Laboratory Tests (ADLTs). In order to be considered an ADLT, a test must analyze multiple biomarkers of "DNA, RNA, or proteins," among other factors. Despite this clear language, the proposed rule excludes "proteins" from the criteria. Protein-based diagnostics are being used to make clinical decisions regarding patient care today, and encouraging further development in this area is crucial. CMS should revise the ADLT definition to reflect the statute's inclusion of proteins.

As the Agency works to finalize the rule, we ask that CMS make changes to the proposed policy to reflect Congressional intent, provide clinical laboratories with sufficient time to implement these important changes, and preserve market competition to ensure continued access to laboratory services.

We urge CMS to work with Congress as well as the laboratory and beneficiary communities affected by the rule to resolve these concerns. Thank you for consideration of our request. We look forward to your timely response.

Sincerely,

Bill Pascrell, Jr.
Member of Congress

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Member of Congress

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Member of Congress

Bill Shuster
Member of Congress

Brian Higgins
Member of Congress

Chris Stewart
Member of Congress

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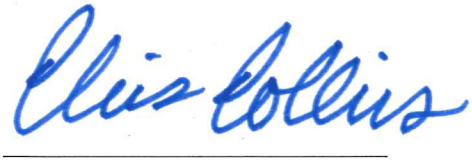
Member of Congress



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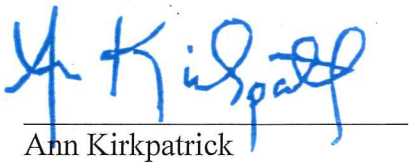

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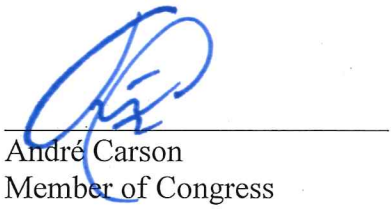
Member of Congress



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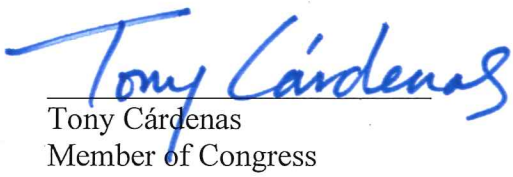

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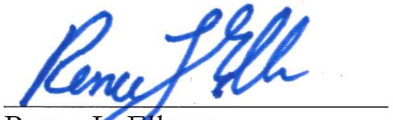

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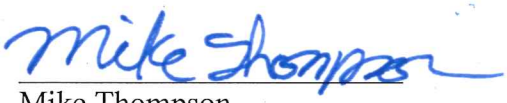

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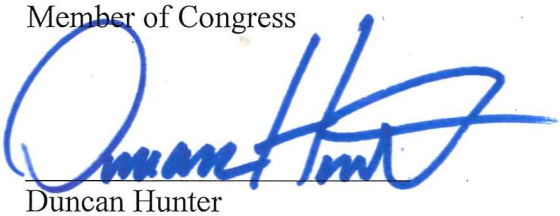

Duncan Hunter
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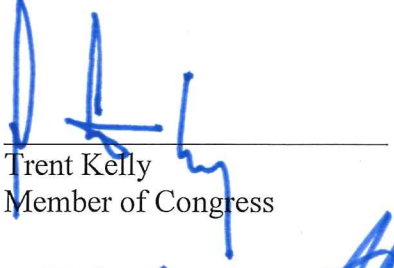

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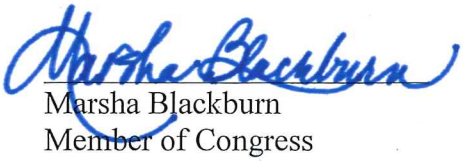

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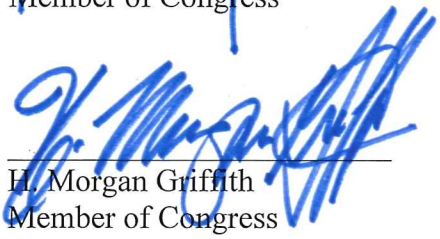

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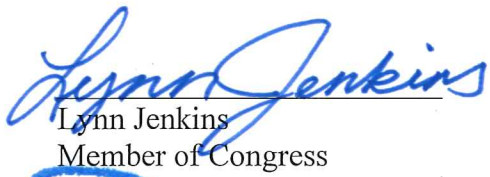

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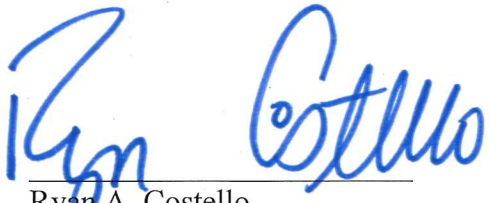

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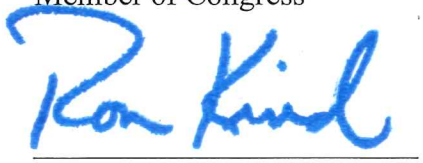

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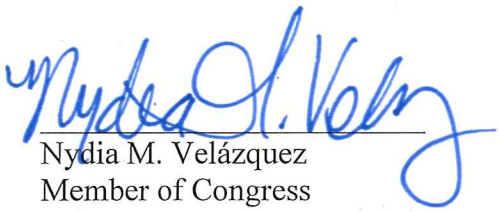

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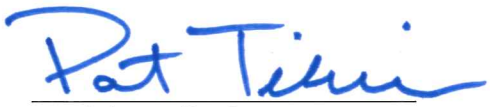

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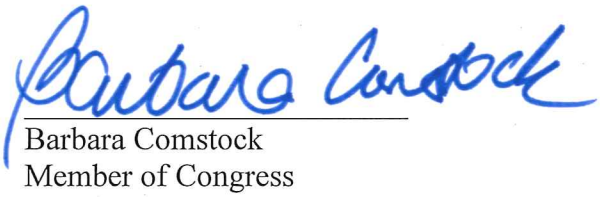

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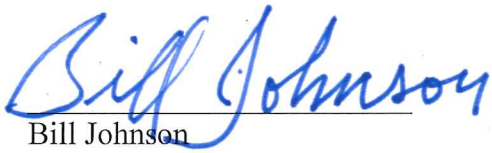

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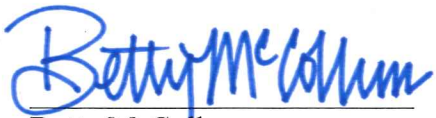

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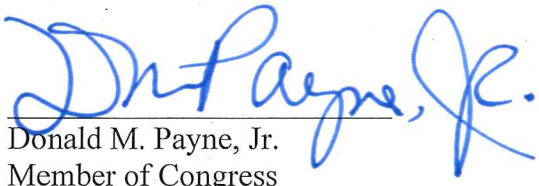

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Scott H. Peters
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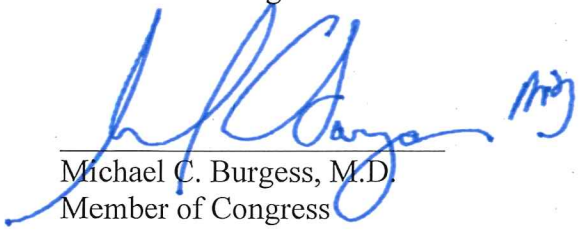

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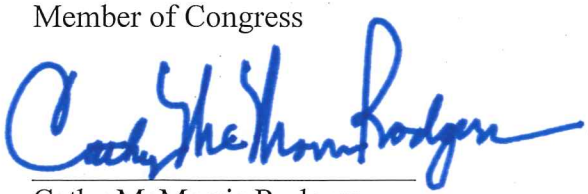

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