United States Senate
WASHINGTON, DC 20510

December 14, 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 write to express concern with the Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule, published in the Federal Register on October 1, 2015. We understand the challenge of implementing the reforms included in the *Protecting Access to Medicare Act of 2014* (Pub. L. 113–93); however, we remain concerned that the proposed rule and implementation timeline impose a significant burden on clinical laboratories across the country and may threaten access to clinical laboratory services for Medicare beneficiaries. We request that you delay implementation of this rule while you 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 and the Medicare beneficiaries who rely on its services.

The *Protecting Access to Medicare Act of 2014* (PAMA) includes the most significant reforms to the Clinical Laboratory Fee Schedule (CLFS) since the fee schedule was established in 1984. PAMA requires the Centers for Medicare and Medicaid Services (CMS) to update the way clinical laboratories are paid under the Medicare program through the development and implementation of a new, mandatory reporting system and revised fee schedule. We believe the proposed rule fails to provide the clinical laboratory community with the information and time frame necessary to meet the goals of PAMA. We are also concerned with the proposed rule's approach on other issues, including how, under the current proposal, a significant part of the laboratory market is excluded from participation, limiting the market data CMS will have for review, and how Advanced Diagnostic Laboratory Tests (ADLTs) are defined.

Under CMS's current proposal, clinical laboratories are expected to establish new information systems, collect, assess, and validate data sets according to regulations that have yet to be finalized, and quickly report 2015 data to CMS from as late as December 31, 2015 between January 1, 2016 and March 31, 2016, or face penalties in the amount of $10,000 per day. This unrealistic timeline provides the laboratory community with less than two months to prepare, certify, and report complex sets of data through a reporting system that has not been tested in the field and submit millions of data sets that follow a set of agency requirements that CMS has not yet finalized. It is unlikely that all clinical laboratories – including small community independent laboratories, physician office laboratories, hospital outreach laboratories, and large national independent laboratories – could successfully prepare millions of data sets that follow a set of agency requirements that have yet to be completed within this time period. We are concerned that the proposed timeline risks unduly rushed data collection that could lead to inaccurate rate-setting.

In addition, the reporting system described in the proposed rule lacks transparency and clarity necessary for successful implementation. Under the proposed rule, clinical laboratories have no way of understanding what data CMS has calculated in order to issue new Medicare rates for laboratory testing services. The proposed rule sets up a blind system and then outlines that laboratories will be provided a revised fee schedule approximately two months before it becomes active, leaving no time for laboratories to make business decisions in response to planned payment adjustments.

CMS must ensure that any new rules affecting Medicare providers will not threaten access to care. We are concerned that the significant Medicare laboratory payment reform effort as proposed could impede an individual's access to physician-ordered laboratory services – whether they obtain laboratory services in a patient service center, a rural health care setting, a hospital, or in a long-term care setting. More time is needed to achieve a workable regulation that complies with statutory intent, provides the clinical laboratory community with finalized guidelines and expectations in advance of the implementation period, preserves market competition, and ensures continued access to needed laboratory services during and after transitioning to the new reporting system and fee schedule.

We urge CMS to work with the laboratory, physician, hospital, and beneficiary communities affected by CMS's rule to ensure that the new market assessment, coverage, and payment processes for clinical and other laboratory tests are not unduly burdensome on laboratory businesses or detrimental to patient access.

Thank you for your consideration of our request. We look forward to your timely response.

Sincerely,

Sherrod Brown
United States Senator

Michael Bennet
United States Senator

Barbara A. Mikulski
United States Senator

Robert Menendez
United States Senator

David Vitter
United States Senator

Benjamin L. Cardin
United States Senator

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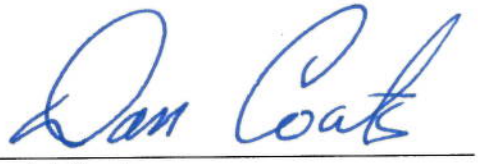

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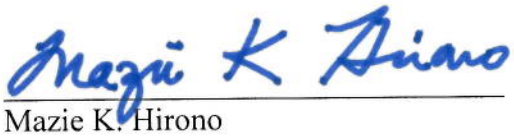

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