United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

January 6, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

We are writing about the October 1, 2015 proposed rule (80 Fed. Reg. 59386) establishing a new Medicare payment system for clinical laboratory services that is based on private payer rates and the need to ensure: that data are reported by as many laboratories as possible consistent with the statute; and there is a reasonable timeline for reporting these data.

The new payment system, mandated by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), will rely on an assessment of private market rates for laboratory services. Clinical laboratories will report to the Centers for Medicare and Medicaid Services (CMS) information on the volume of tests they provide and the associated private insurance payment amounts they receive. In general, the Medicare payment rate will be the weighted median of private sector payment amounts for each laboratory test.

It is critical that the laboratories reporting the private sector data used to determine Medicare payment rates are representative of the marketplace. CMS' proposal to use Tax Identification Numbers (TINs) to identify laboratories that must report data is too limiting and will fall short of this goal. Use of the TIN methodology would result in Medicare payment rates that fail to reflect information from important segments of the laboratory market, especially hospital outreach laboratories paid under the Clinical Laboratory Fee Schedule. Hospital outreach laboratories, a well-defined market segment, serve beneficiary ambulatory needs and compete with other community-based laboratories.

We urge that CMS establish an alternative, more expansive methodology for identifying laboratories that must report private payment rates in the final rule. The Clinical Laboratory Improvement Act (CLIA) number, which all laboratories are required to maintain, provides one such option. We ask CMS to analyze whether there is a way to use these numbers while still meeting the statutory intent of only including laboratories that receive a majority of their Medicare revenues from the clinical laboratory or physician fee schedules.

The CMS intent to limit reporting burden, a factor it emphasizes to support its proposal to use TIN numbers, can be realized under an alternative methodology. A methodology that would result in reporting by a broader segment of the laboratory market would not cause an undue burden if a minimum Medicare revenue threshold, such as the $50,000 per year included in the

proposed rule, is maintained in the final rule. Such a more granular, expansive methodology could also still allow laboratories with multiple locations to report payment rates at the TIN level or by another means. In sum, we believe that CMS should use a methodology for identifying reporting laboratories that balances fairness and burden.

We are also concerned about the timeline that CMS proposes for laboratories to submit their private sector data. Under the proposal, laboratories would be required to coordinate and collect private payer data from July 1, 2015 through December 31, 2015 and report all of this information by March 31, 2016. The March 31 deadline is particularly unrealistic given that a final rule containing the information that laboratories will need to report has yet to be published. Even if the final rule were published today, a March 31 deadline does not give enough time for laboratories to prepare, certify and report the amount and complexity of data that will be required. Receiving precise and complete private sector data is fundamental to making certain CMS has accurate information to determine Medicare payment rates. We urge that CMS establish a reporting deadline in the final rule that is after March 31 and permits laboratories appropriate time to accurately comply with the requirements in the final rule and in the subsequent sub-regulatory guidance.

Medicare spends approximately $8 billion annually on clinical laboratory services. PAMA established a new system that dramatically changes how payments for these services are determined. It is important for both laboratories and beneficiaries that CMS implement the system in a way that fully represents the laboratory market consistent with the statute and provides sufficient time for the initial data collection and reporting process.

Sincerely,

Orrin Hatch
Chairman

Ron Wyden
Ranking Member