SCOTT H. PETERS
52ND DISTRICT, CALIFORNIA

1122 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-0508

Congress of the United States
House of Representatives
Washington, DC 20515–0552

November 8, 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:

I am writing to share my deep 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 the stakeholder community has raised with CMS throughout the implementation of the *Protecting Access to Medicare Act* (PAMA). I urge CMS to delay implementation of new laboratory payment rates until you have worked with stakeholders to resolve the many outstanding concerns that will negatively impact patient access to lifesaving diagnostic tests.

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, I am concerned about the integrity of the data used to establish the new payment rates and the method of data collection.

I am concerned that the 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.

For example, a relatively low number of physician office labs reported payment rates. These labs have are vital for administering point-of-care tests that provide immediate results and treatment. Physician office labs represented only 7.5 percent of the laboratory data reported to CMS, and as a result, payment rates for these tests will be dictated by the larger independent and reference laboratories. This will lead to a reduction of tests performed in this setting, ultimately delaying patient care.

In addition, I am concerned that there was confusion over data collection and reporting for drugs of abuse tests, which have been impacted by coding changes over the past few years. Private payers have not adopted these Medicare changes across the board, and as a result, a dual coding system has emerged in which some commercial payers require use of one code set, while others continue to require use of a different code set. Absent clear instructions from CMS regarding the process for collecting and reporting this data for purposes of PAMA, it is very likely that laboratories inaccurately reported their private payer data for these drug testing codes.

I strongly 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. More time is required to achieve a workable regulation that reflects the Congressional intent behind PAMA while providing certainty for diagnostic manufacturers and the clinical laboratory community.

Thank you for your attention to this matter. I look forward to working with you to safeguard access to high quality laboratory services for Medicare beneficiaries.

Sincerely,

SCOTT H. PETERS
Member of Congress