



Better health through
laboratory medicine.

April 26, 2019

Mr. James Cosgrove
Director, Health Care
US Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Director Cosgrove:

The American Association for Clinical Chemistry (AACCC) urges the Government Accountability Office (GAO) to complete its congressionally mandated research on the implementation of the Protecting Access to Medicare Act (PAMA) and report its findings to Congress. The GAO issued a report in November 2018, entitled “*Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments*,” which focused on certain payment issues of interest to legislators, but failed to address questions pertaining to patient access to care.

AACCC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACCC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of clinical laboratory science to advance healthcare through collaboration, knowledge, expertise, and innovation.

Congress directed the GAO to conduct a study on the impact of the new private market-based Clinical Laboratory Fee Schedule (CLFS). Two of the 10 areas of interest to legislators pertained to the ability of patients to receive the care they needed. Congress directed the GAO to provide an analysis of:

- The impact of such implementation on beneficiary access; and
- The impact of the new payment system on laboratories that furnish a low volume of services and laboratories that specialize in a small number of tests.

Unfortunately, neither of these issues were addressed in the November 2018 GAO report. However, the answers to these questions could provide legislators with a clearer understanding of the consequences of this law. For example, we would expect the GAO in a subsequent report to cover such issues as:

- What impact is PAMA having on patient access to testing?
- How are smaller laboratories faring under PAMA?

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- How are patients in underserved areas being affected by PAMA?
- How are low volume laboratories changing their operations (e.g., test menu) because of PAMA?

Some preliminary data released within the last year by the National Independent Laboratory Association (NILA) and COLA, a laboratory accrediting organization, have shed some light on these issues.

A preliminary 2018 survey of small commercial laboratories conducted by NILA reported that many laboratories planned on reducing their workforce, limiting their test menu, and scaling back the number of Medicare/Medicaid beneficiaries they serve. Similarly, a 2018 Clinical Laboratory Fee Schedule Survey conducted by COLA found that 39 percent of the responding laboratories stated they would refer more tests to other laboratories because of PAMA, while 33 percent stated they would alter their test menu. These data indicate that patient access to testing will diminish under new payment law and that patient care will thereby deteriorate.

AACC urges you to conduct a detailed analysis on how PAMA is affecting patient access to care and low-volume laboratories, particularly those in underserved areas, and provide those findings to Congress. In designing this study, we encourage you to use statistically valid data collection methods to ensure that legislators get evidence-based data to inform their decision-making.

If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC