February 11, 2019

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

Dear Director Cosgrove:

On behalf of the undersigned organizations that represent independent clinical laboratories, diagnostic manufacturers, pathologists, and point of care testing, we write to respectfully express our strong disagreement with key assertions made by the Government Accountability Office (GAO) in the November 30, 2018 report entitled, "Medicare Laboratory Tests Implementation of New Rates May Lead to Billions in Excess Payments." While the report accurately details the problems with the *Protecting to Access to Medicare Act of 2014* (PAMA) data collection process CMS conducted in 2017, the report makes flawed and dangerous assertions, and suggests that initial PAMA reimbursement reductions should have been more severe. The GAO recommendations ignore statutory requirements and demonstrate a serious misunderstanding of actual, real-world billing practices of clinical laboratories. We request a meeting with you to discuss our concerns in greater detail.

Diagnostic tests provide incredible value to the U.S health care system. These tests are a cornerstone of modern medicine, accounting for a small percentage of health care expenditures but guiding much of the medical decision-making underlying patient care. Prior to passage of PAMA, Medicare's payment system did not reflect the changing cost between different services over time and it largely priced new services by linking them to payment for an existing service. PAMA was intended as an opportunity to reframe Medicare's static payment system for laboratory diagnostic tests under the Clinical Laboratory Fee Schedule (CLFS) to a market-based system by linking Medicare payment rates to the rates paid by private payors in the commercial sector.

Unfortunately, due to a flawed approach to data collection that excluded large portions of the laboratory market, implementation by the Centers for Medicare and Medicaid Services (CMS) has had the opposite result. Payment rates for the vast majority of laboratory tests are not based on market prices and as a result, cuts have far exceeded initial projections. In the November 30th report, GAO correctly concludes that "CMS did not collect private-payer data from all laboratories required to report" data under PAMA. We agree with "Recommendation 1" that, CMS should take steps to collect all of the data from all laboratories that are required to report."

In Recommendation 2, the report suggests that CMS should have phased-in PAMA cuts using "average" Medicare payment rates as the starting benchmark. This recommendation ignores the statutory requirement under PAMA which restricted any cuts in the first three years of implementation to no greater than 10 percent compared to the prior year. By nature of an "average", half of the local Medicare fee schedules were above the average, and half were below the average. By suggesting the average as the benchmark, GAO is recommending that many laboratories should have been cut by greater than the statutory limit of 10 percent in 2018. This proposed outcome is in direct conflict with the PAMA statute, and would have resulted in disproportionate hardship across the industry, primarily based on nothing other than the geographic location of the laboratory. CMS's establishment of the benchmark for the phase-in of the National Limitation Amount (NLA) through rulemaking and public comment was the only appropriate method to avoid such disproportionate and arbitrary impact in converting to a single fee

schedule from the pre-PAMA fee schedule which included regional rate variation. We, therefore, disagree with GAO's Recommendation 2.

Most concerning in the report, however, is its discussion of billing of panel tests under PAMA. The discussion on panel test billing demonstrates a fundamental misunderstanding by GAO of actual, real-world billing practices of clinical laboratories. This misunderstanding leads to an inflammatory and false claim that Medicare is overpaying clinical laboratories for panel tests on the magnitude of billions of dollars.

The primary false assertion made in the November 30th report is that the laboratory industry, writ-large, is abandoning Medicare billing requirements and billing guidelines established by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel and inappropriately billing for the individual components of panel tests (e.g. the Comprehensive Metabolic Panel), instead of appropriately billing for the panel test codes, themselves. The premise suggests that such a practice could yield more than a six fold increase in reimbursement and that "if *every* laboratory stopped using panel test billing codes" (*emphasis added*), Medicare *could* overpay by over $10 billion.

We strongly disagree that this is occurring. A survey of clinical laboratories conducted under attorney-client privilege by counsel on behalf of the American Clinical Laboratory Association (ACLA) found virtually no change in laboratories' billing practices between 2017 (pre-PAMA) and 2018 (Year 1 of PAMA) for the test panels at issue. Out of tens of millions of claims, laboratories billed for individual codes in a panel, rather than the panel code, in less than one-tenth of one percent of claims. The percentages are comparable before PAMA rates were implemented and after.

In light of these findings, we are concerned that the GAO report made such broad claims, not only due to the report's lack of supporting data, but also because the GAO failed to utilize open channels of communication with the undersigned organizations to truly understand actual billing practices. Each of the undersigned have actively participated in PAMA discussions with numerous stakeholders, including some with GAO through 2017 and 2018. Engaging with our organizations and utilizing technical experts within our membership on the issue of panel billing would have resulted in a better informed, accurate report.

We seek and would welcome a constructive dialogue with GAO on PAMA, and respectfully request a meeting with GAO to discuss these matters in greater detail. Thank you for your attention on this critical matter.

Sincerely,

AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association
Point of Care Testing Association

cc: Martin T. Gahart, Assistant Director
Gay Hee Lee, Senior Analyst
Russell Voth, Senior Analyst