



May 22, 2025

The Honorable Russell T. Vought
Director
Office of Management and Budget
Executive Office of the President
1650 Pennsylvania Ave, NW
Washington, DC 20503

Dear Director Vought:

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) appreciate the opportunity to provide recommendations to the Office of Management and Budget (OMB) on the administration's implementation of the President's deregulatory agenda.

NILA represents community, regional, and specialty clinical laboratories that work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. NILA members are community-based businesses that range in size from small to large multi-state regional laboratories. For most NILA members, 30-50 percent of their testing services are provided to Medicare beneficiaries. NILA laboratories provide a full range of testing services, some focused on providing quick turnaround and emergency diagnostic services to allow physicians to manage chronic diseases.

AAB, founded in 1956, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers, and supervisors), medical technologists, medical laboratory technicians, and physician office laboratory technicians.

AAB and NILA recommend that the administration take immediate action to address administrative flaws with the Clinical Laboratory Fee Schedule (CLFS) payment system, which is the only Medicare fee schedule that is based on commercial payor rates. Since its passage, AAB and NILA have expressed concerns with the impact of the Protecting Access to Medicare Act of 2014 (P.L. 113-93) (PAMA) on regional and community laboratories and the Medicare beneficiaries that they serve. Further, AAB and NILA have commented numerous times to CMS that the implementation of PAMA by the agency was flawed. The purposefully deficient data collection process used to establish new clinical laboratory payment rates resulted in unreliable

The Honorable Russell T. Vought
Director, Office of Management and Budget
May 22, 2025
Page Two

data and unsustainable rates that fell short of Congress' goal to establish a market-based system. Fewer than one percent of laboratories reported data, and this did not reflect all sectors of the laboratory market. The result has been detrimental to AAB's and NILA's members, causing many community-based laboratories to limit services, including home visits and emergency STAT testing, and has caused many laboratories to reduce their workforce.

While Congress is considering more permanent solutions to the Medicare reimbursement system, the administration can take action now to fix the flaws with the CLFS payment system. We request that you take the following actions:

- The Center for Medicare & Medicaid Services (CMS) should maintain current CLFS rates for 2026 in the Medicare Physician Fee Schedule (MPFS) proposed rule. This can be achieved by using the flexibilities of the PAMA statute and not taking further reductions of up to 15 percent on 800 tests that would go into effect on January 1, 2026.
- In the MPFS proposed rule, CMS should revise the next PAMA data collection period from January 1, 2019 – June 30, 2019 to January 1, 2025 – June 30, 2025. Under current law, commercial payor rates and volumes from January 1, 2019 to June 30, 2019 are to be reported to CMS starting on January 1, 2026; this will be used to set rates that would take effect on January 1, 2027. This data was supposed to be reported in 2020; however, Congress has repeatedly delayed implementation due to concerns with how the law was implemented. Continuing to use 2019 as the data collection period is inconsistent with the intent of the law and will not lead to accurate or fair rates for independent and community-based laboratories.

AAB and NILA appreciate your consideration of this recommendation as the administration considers ways to reduce the regulatory burden and allow for independent and community-based laboratories to provide the best access to patient care. Please reach out to Erin Morton at emorton@dc-crd.com if you have any questions or if we can provide additional information on this recommendation.

Sincerely,



Mark S. Birenbaum, Ph.D.
Executive Director

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