May 22, 2023

The Honorable Kevin McCarthy Speaker U.S. House of Representatives Washington, DC 20515

The Honorable Hakeem Jeffries Minority Leader U.S. House of Representatives Washington, DC 20515 The Honorable Charles Schumer Majority Leader U.S. Senate Washington, DC 20510

The Honorable Mitch McConnell Minority Leader U.S. Senate Washington, DC 20510

Dear Leader Schumer, Speaker McCarthy, Minority Leaders Jeffries and McConnell:

As organizations representing clinical and pathology laboratories, health care providers, laboratory professionals, and diagnostic manufacturers, we urge Congress to take immediate action to pass S. 1000 / H.R. 2377, the *Saving Access to Laboratory Services Act (SALSA)*. This bicameral, bipartisan legislation would update Medicare's payment system for laboratory services to make it predictable and sustainable, ensuring our nation's laboratory infrastructure is equipped to support the full range of testing that patients need for day-to-day care as well as during times of public health crisis, while fostering innovation in new diagnostics.

Without congressional action, Medicare reimbursement cuts – a fourth round scheduled to begin January 1, 2024 – could jeopardize access to many clinical laboratory tests that are used to diagnose, monitor, prevent, and manage common diseases for Medicare beneficiaries.

Clinical diagnostic tests are foundational to clinical decision making, informing 70 percent of medical decisions that guide patient care. For example, in 2020 Medicare beneficiary care was supported by more than 17 million hemoglobin A1C tests that assessed diabetes risk, 28 million tests that diagnosed and monitored heart disease, and 90,000 tests that diagnosed leukemia and hereditary breast and colon cancer.

A strong, national laboratory infrastructure is critical to ensuring that testing can be rapidly developed and made widely available when pathogens of concern are identified. Simply put, clinical laboratories strive to be prepared for whatever the next pathogen of concern may be and in times of emergency are part of the nation's critical infrastructure.

Furthermore, a healthy laboratory industry is essential to foster innovation in advanced diagnostics, which has not only led to earlier detection of disease but has also become a crucial tool in how care is delivered. In cancer, early detection and diagnosis of cancer and cancer biomarkers facilitate an understanding of disease progression and selection of an appropriate treatment regimen for each patient.

Enactment of SALSA would address what has been years of deep Medicare payment cuts, while updating Medicare's payment system to ensure clinical laboratory services are on a sustainable pathway forward. Between 2017 and 2022, payment for some common tests for diseases like diabetes, cancer, and heart disease were cut by 27 percent. The next round of Medicare cuts would drop reimbursement up to another 15 percent for about 800 laboratory tests widely used to screen and manage many serious diseases. It is essential that Congress protect patients by acting this year to fix the Medicare payment model for clinical diagnostic tests.

Because of the serious implications for patients who rely on routine as well as advanced diagnostic laboratory services, Congress has acted three times to delay these cuts in recent years, but permanent reform is needed now. Fortunately, the Saving Access to Laboratory Services Act would update Medicare's payment system, which would help protect access to clinical laboratory testing, support investment in innovation, and strengthen America's clinical laboratory infrastructure.

On behalf of clinical laboratories, laboratory professionals, health care providers and stakeholders across the country, we urge you to pass *the Saving Access to Laboratory Services Act* before the end of the year. We would welcome the opportunity to discuss this critical issue with you and your staff, further. Please reach out to Holly Grosholz at hgrosholz@acla.com and Meg Riley at mriley@dc-crd.com should you have additional questions or wish to schedule a meeting with our organizations.

Sincerely,

AdvaMedDx

ADVION (Formerly the National Association for the Support of Long Term Care (NASL))

American Academy of Family Physicians

American Association for Clinical Chemistry

American Association of Bioanalysts

American Clinical Laboratory Association

American College of Medical Genetics and Genomics

American College of Osteopathic Family Physicians

American Hospital Association

American Medical Association

American Medical Technologists

American Society for Clinical Laboratory Science

American Society for Clinical Pathology

American Society for Histocompatibility and Immunogenetics

American Society for Microbiology

American Society of Nephrology

AMGA

Association for Molecular Pathology

Association of American Medical Colleges

Association of Pathology Chairs

Association of Public Health Laboratories

California Clinical Laboratory Association

COLA Inc.

College of American Pathologists

Federation of American Hospitals

Infectious Diseases Society of America (IDSA)

Medical Group Management Association (MGMA)
National Independent Laboratory Association
National Rural Health Association
New Jersey Association of Mental Health and Addiction Agencies, Inc.
New York State Clinical Laboratory Association
Personalized Medicine Coalition
Point of Care Testing Association
The Gerontological Society of America