November 6, 2023

The Honorable Charles Schumer Majority Leader U.S. Senate Washington, DC 20510

The Honorable Mike Johnson Speaker U.S. House of Representatives Washington, DC 20515

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

The Honorable Hakeem Jeffries Minority Leader U.S. House of Representatives Washington, DC 20515

Dear Leader Schumer, Leader McConnell, Speaker Johnson, and Leader Jeffries:

As leaders in the laboratory community, we urge Congress to take immediate action to protect laboratories from potentially devastating reimbursement cuts of up to 15% set to take effect on January 1, 2024. Congress has acknowledged that repeated cuts as a result of the Protecting Access to Medicare Act (PAMA) are not sustainable and we are gratified that Congress has intervened on a bipartisan basis four times to delay the next Clinical Laboratory Fee Schedule (CLFS) reporting periods and three times to delay cuts. We urge you to include relief from PAMA cuts to clinical laboratories in the next Continuing Resolution or year-end health care package.

While delays in deep reductions have been essential to preserving patient access, it is essential that in 2024, a long-term sustainable solution to Medicare's flawed payment system, the bipartisan, bicameral, Saving Access to Laboratory Services Act (SALSA / S.1000 / H.R. 2377) is enacted. More than 70 provider and patient and consumer organizations have endorsed SALSA to protect our nation's laboratory infrastructure and ensure access to important laboratory services that are foundational to clinical decision making. As you know, laboratories are a critical component of our nation's health care infrastructure, supporting the full range of testing that patients need for diagnoses and day-to-day care as well as during times of public health crisis, while fostering innovation in new diagnostics. Continued Medicare reimbursement cuts set to take effect in January could jeopardize access to many clinical laboratory tests that are used to diagnose, monitor, prevent, and manage common diseases for Medicare beneficiaries. While we seek to advance a long-term solution through enactment of SALSA, a one-year delay in reimbursement cuts must be immediately prioritized to protect access to laboratory testing and support continued viability of the clinical laboratory infrastructure. We thank the Senate Finance Committee for including a one-year delay of cuts and data reporting requirements in the health extenders discussion draft to be considered by the committee on November 8. Our organizations look forward to working with you to advance this critical provision.

Please reach out to Meg Riley, NILA's Washington representative, at mriley@dc-crd.com and Holly Grosholz with ACLA at hgrosholz@acla.com if you have additional questions on this important issue.

Sincerely,

Mark S. Bienbaum

Mark S. Birenbaum, PhD Executive Director National Independent Laboratory Association

Sun Mr Metz

Susan Van Meter President American Clinical Laboratory Association

Attachments: Provider Stakeholder Letter in Support of SALSA; Patient and Consumer Organization Stakeholder Letter in Support of SALSA

June 7, 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 205

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

As organizations representing patients who depend on access to clinical laboratory testing to diagnose and manage a variety of conditions and diseases, 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 sustainable, ensuring our nation's clinical laboratory infrastructure is well positioned to support robust availability of the full range of testing that patients need every day and in times of public health emergency, while striving to advance the next generation of personalized care to improve and save lives.

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 play a critical role in health care by informing 70 percent of medical decisions doctors and other health care providers make to care for patients. For example, in 2020 care for Medicare beneficiaries 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 regime 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 lower 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 patients across the country, we urge you to pass *the Saving Access to Laboratory Services Act* before the end of the year.

Sincerely,

- A Breath of Hope Lung Foundation
- AliveAndKickn
- Alliance for Aging Research
- Alliance for Women's Health and Prevention
- American Association of Kidney Patients
- American Sexual Health Association
- AnCan
- Black Women's Health Imperative
- CancerCare
- Cancer Support Community
- Caregiver Action Network
- Caring Across Generations
- Cholangiocarcinoma Foundation
- Chronic Disease Coalition
- Community Liver Alliance
- Down Syndrome Association of Orange County
- FORCE: Facing Our Risk of Cancer Empowered
- Global Liver Institute
- GO2 Foundation for Lung Cancer
- HealthCare Institute of New Jersey (HINJ)
- Healthcare Leadership Council
- Healthy Men Inc.
- HealthyWomen
- ICAN, International Cancer Advocacy Network
- International Foundation for Autoimmune & Autoinflammatory Arthritis

- The Latino Coalition
- LUNGevity Foundation
- Lupus and Allied Diseases Association, Inc.
- Men's Health Network
- Minority Health Institute
- The National Association of Directors of Nursing Administration
- National Alliance of State Prostate Cancer Coalitions
- National Consumers League
- The National Grange
- RetireSafe
- Triage Cancer
- Vasculitis Foundation

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