



October 4, 2023

The Honorable Jason Smith
Chair
Ways and Means Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chair Smith,

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to provide comments on the health disparities impacting Americans in rural and underserved communities, specifically regarding access to care via sustainable provider and facility financing and the health care workforce. We are grateful the Ways and Means Committee understands the urgency of health care accessibility and is committed to advancing bipartisan solutions. NILA urges you to consider policies that will sustain community and regional clinical laboratories, which are an essential component of the country's health care and public health response infrastructure.

NILA represents community, regional, and health system clinical laboratories that serve a wide variety of communities and patient populations—many of which serve underserved rural and urban communities that are not served by the nation's largest independent clinical laboratories. NILA members provide a wide variety of vital laboratory services that include clinical chemistry testing, genetic testing, infectious disease testing, toxicology, hematology, and more. Despite facing significant financial challenges brought on by the flawed implementation of the Protecting Access to Medicare Act of 2014 (PAMA), NILA's member laboratories have remained steadfast in their commitment to patient care.

Sustainable Provider and Facility Financing:

Background on PAMA's Impact on Community and Regional Clinical Laboratories

PAMA aimed to establish a fair Medicare Part B Clinical Laboratory Fee Schedule (CLFS) based on private-payer rates for laboratory tests. However, the reality has been far from its intended goals. Under PAMA, clinical laboratories were mandated to report their private-payer rates on a test-by-test basis along with associated test volumes. The Centers for Medicare & Medicaid Services (CMS) collected this data, but the sampling process was flawed, with data collected from fewer than one percent of laboratories and primarily relying on rates from the two largest independent clinical laboratories. This resulted in extreme reimbursement rate cuts, with some tests seeing reductions of as much as 30-60 percent. These cuts have had a profound and detrimental impact on the sustainability of regional and community clinical laboratories.

One of the most concerning outcomes of these plummeting reimbursement rates has been the increased consolidation in the laboratory market. This trend poses a direct threat to access to essential clinical laboratory testing in rural and underserved areas. In 2020 alone, there were a total of 148 laboratory closures based on Clinical Laboratory Improvement Amendments (CLIA) certificate terminations. The number of laboratory closures has continued to steadily increase since 2011. These closures directly impact patient access to essential laboratory services, forcing residents to travel long distances or face delays in receiving vital medical diagnoses.

Community and regional clinical laboratories fill a gap in health care for rural and underserved communities, which often lack the infrastructure and resources to support large, centralized clinical laboratories. NILA member laboratories are often community-based and operate close to the patient, providing critical diagnostic and testing services that are essential for timely and accurate patient care. These clinical laboratories work closely with rural clinics, hospitals, and health care providers to ensure patients receive prompt and effective care. Laboratory closures disrupt this delicate balance, putting vulnerable populations at risk.

Following years of reimbursement cuts to Medicare's CLFS, the first three years of the implementation of PAMA resulted in an additional 30 percent reduction in reimbursement for many common laboratory tests. The convergence of continuing Medicare CLFS rate cuts and mounting labor costs has devastated regional and community independent laboratories. In addition to the reimbursement challenges posed by PAMA, NILA's laboratories are grappling with the impact of inflation on their operational costs. Rising inflation rates have placed an additional burden on our laboratories, making it increasingly difficult to sustain high-quality patient care while covering operational expenses.

Community and regional clinical laboratories are facing potentially drastic cuts to reimbursement on January 1, 2024, due to the flawed implementation of PAMA. To address these pressing issues and to ensure the long-term viability of essential laboratory services in underserved communities, NILA supports the bipartisan and bicameral legislation, Saving Access to Laboratory Services Act (SALSA). SALSA (H.R. 2377/S.1000) proposes vital reforms to CMS' approach to determining CLFS rates, including:

- Requiring CMS to use a statistically valid, representative sample of the laboratory market for the determination of CLFS rates for widely available clinical laboratory tests. This approach would help ensure that reimbursement rates are more reflective of the actual costs incurred by laboratories and, therefore, that laboratories are fairly compensated for the vital services they provide.
- Reducing the frequency of required data reporting periods from every three years to every four years, thereby easing the administrative burden on clinical laboratories, enabling them to focus more on patient care and less on bureaucratic paperwork. This will particularly benefit clinical laboratories in rural areas, where staff and resources may be limited.
- Providing laboratories with permanent protection against excessive cuts by lowering the cap on cuts from 15% to 5% annually. This change would offer clinical laboratories more stability in planning for the future and prevent abrupt and unsustainable reductions in reimbursement rates, thus maintaining health care access for those who need it most.
- Ensuring the sustainability of the Medicare program by phasing in a cap on rate increases for widely available tests at a manageable rate of 5% each year. This balanced approach would allow for responsible growth in reimbursement rates while controlling costs.

Congress must pass SALSA before the end of 2023 or community and regional clinical laboratories will face devastating cuts to reimbursement that threaten their ability to provide services to rural and other underserved communities.

Health Care Workforce

Clinical laboratories continue working to mitigate staffing shortages, while many are also providing higher wages to meet increased minimum wage requirements and to compensate for the recent surge in inflation, as mentioned above. Clinical laboratories are being squeezed from lowered reimbursements and increased costs with no leverage to increase their reimbursement. There are fewer employees to do more work and limited time to train staff and interns. It is a relentless downward spiral that threatens the existence of community and regional clinical laboratories and the public health of our nation.

In addition to passing SALSA, to help laboratories attract and retain qualified laboratory personnel the Committee should consider federal support for laboratory education and training programs, including sensible revisions to education and training requirements. The availability of clinical laboratory training programs is declining, and with it, opportunities for individuals to get their start in laboratory careers that uphold our clinical laboratory infrastructure. Though at least a two-year college degree is required for high complexity testing, less costly and time-consuming training programs would provide sufficient preparation for certain laboratory jobs. An appropriate reduction of education requirements would create greater access to these positions and aid in staff retention.

Many laboratory-based processes are repetitive and by rote, i.e., staff follow “recipes.” For example, the extraction of samples prior to instrumental analysis should not require a college degree and is highly repetitive with no allowable deviations. Most college graduates find this work to be monotonous and do not pursue it after achieving a college degree. This work can be performed by trained individuals without a college degree, especially with supervisory oversight.

NILA also recommends federal funding for CLIA-certified laboratories to provide three-month internships to college students to enable them to complete their laboratory degrees and meet CLIA’s training and experience requirements for high complexity testing. In the past two decades, the number of laboratories providing these internships has decreased significantly, creating a bottleneck for getting students through their educational programs. Many laboratories do not have sufficient resources to devote to trainees. Financial incentives for laboratories will allow them to provide training internships and to fill positions in their own laboratories with graduates who they have trained.

Also, federally supported public awareness efforts aimed at students in high schools, community colleges, and universities, will help students understand and pursue career options in clinical laboratories. At these touchpoints, when students are making career choices, education about the laboratory sciences is critical. Students who are aware of the clinical laboratory field could select appropriate courses and training programs that will prepare them for a clinical laboratory career upon completion of a degree program. Laboratory science careers should also be incorporated into new and existing efforts to involve high school students in Science, Technology, Engineering, and Math (STEM), with the potential to create a pipeline from high school to certification programs for appropriate careers in clinical laboratory science.

Last, access to federal scholarships and fellowships, as well as federal loan repayment programs, are as important to the clinical laboratory sector as they are to other areas of health care. We encourage the committee to consider expanding these opportunities to increase access to the clinical laboratory field. Please ensure that aspiring laboratory professionals have access to these programs. We appreciate your efforts to address workforce shortages across the U.S. health care system and ask that clinical laboratories be included in those efforts.

We urge the House Ways and Means Committee to recognize the critical role that community and regional clinical laboratories play in ensuring access to care, particularly in rural and underserved communities. By recognizing the unique challenges faced by community and regional clinical laboratories in these regions and enacting reforms that ensure fair reimbursement and an energized workforce, policymakers can directly contribute to improved health care outcomes, and a more equitable health care system for all Americans, regardless of where they live.

First and foremost, NILA urges you to support SALSA and work with your colleagues towards its enactment by Congress before the end of this year. Your support for SALSA will represent a powerful statement of your commitment to addressing health disparities and securing access to care for those in need. The flawed implementation of PAMA and the resulting challenges faced by community and regional clinical laboratories demand immediate attention and action and we believe that SALSA offers a pragmatic, effective, and sustainable solution. NILA stands ready to support your efforts in advancing this legislation that will safeguard access to essential clinical laboratory services for all Americans.

Thank you for your dedication to addressing health disparities and for considering our perspective on this vital matter. If you have questions or wish to discuss this issue further, please contact Meghan Riley at mriley@dc-crd.com.

Sincerely yours,



Mark S. Birenbaum, PhD

Executive Director

National Independent Laboratory Association (NILA)

NILA members work in regional and community independent clinical laboratories across the United States performing laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals. NILA members serve a wide variety of communities and patient populations—including rural areas, underserved urban neighborhoods, mid- and small-sized cities and municipalities, congregate facilities, and critical access hospitals.