AMERICAN CLINICAL LABORATORY ASSOCIATION

Statement
of the
American Clinical Laboratory Association
for the
Committee on Ways and Means
of the
U.S. House of Representatives

"Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity"

July 12, 2024

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to share our perspective on how the Committee can help advance innovation in clinical laboratory diagnostics. The ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

Clinical Laboratory Innovations: Improving and Saving Lives

America's clinical laboratories serve as the foundation for public health preparedness and response and for everyday prevention, diagnosis, and treatment of disease for patients across the country. Clinical laboratories play a vital role in answering some of life's most important questions. While accounting for less than 3% of Medicare Part B spending[1], clinical laboratory tests inform 70 percent of medical decisions—[2] from routine blood tests to ground-breaking genetic tests that guide therapy selection. In addition to providing essential medical insights for patients, clinical laboratory services are cost effective. While accounting for only a small fraction of healthcare spending, the clinical laboratory industry provides significant economic benefits to the U.S. economy, contributing over $118 billion in total economic output, supporting over 652,000 jobs in the U.S. and generating $48 billion in wages.[3]

Laboratories' investments in innovation are leading to extraordinary advancements, changing health care as we know it, and improving and saving lives. One such innovation, rapid whole genome sequencing (rWGS), is being leveraged by ACLA members—including at the very site of the Committee's field hearing—to make real and quantifiable differences in the lives of the most vulnerable patients. It is a particularly potent tool for patients with rare or undiagnosed conditions. For example, for critically ill infants with genetic disorders, rWGS can make it

[1] https://www.oig.hhs.gov/oei/reports/OEI-09-23-00350.pdf
[2] https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html.
[3] https://acla.guerrillaeconomics.net/res/methodology.pdf.

possible to reach a diagnosis in time to change acute medical or surgical management and improve outcomes, with the added benefit of reduced costs and shorter hospital stays[4].

ACLA encourages the Committee to support the continued development of the next generation of diagnostics through sustainable reimbursement policies and responsible regulatory mechanisms that foster clinical laboratory innovations.

SUSTAINABLE MEDICARE REIMBURSEMENT METHODOLOGY

Supporting Continued Innovation through Enactment of SALSA

A sustainable and predictable Medicare reimbursement methodology is essential to the ability of clinical laboratories to continue to invest in innovative new diagnostics that will further improve and save lives. While we appreciate the Committee's work to advance legislation to provide short-term relief from Protecting Access to Medicare Act (PAMA) required reimbursement cuts, long-term payment reform rooted in sound policy is essential to ensuring patient access to innovative diagnostics. **ACLA respectfully urges the Committee to prioritize enactment of long-term Medicare payment reform through passage of the Saving Access to Laboratory Services Act (SALSA, H.R. 2377/S. 1000), which has more than 60 bipartisan sponsors.**

ACLA is grateful for the last four years of delays in Medicare cuts and data reporting, following three years of the PAMA-required cuts of up to 10%. But reimbursement cuts or rate freezes in result in Medicare payments lagging well behind inflation. In 18 of the last 25 years, clinical laboratories have faced reductions or freezes in Medicare rates. Inflation has greatly increased costs associated with maintaining a skilled workforce, transportation to move patient samples from all 50 states and territories to ACLA member laboratories, and the purchasing diagnostic supplies. Further, clinical laboratories are also now facing costly new U.S. Food and Drug Administration (FDA) regulations, the most significant in the 36 years since enactment of the Clinical Laboratory Improvement Amendments in 1988. **This combination of payment uncertainty and the most significant new regulatory obligations in decades could compromise patient access and laboratory investments in novel diagnostics.**

By ensuring that the data the Centers for Medicare and Medicaid Services (CMS) collects to set Medicare rates for clinical laboratory services truly reflects rates in the commercial market, and by limiting year-to-year Medicare payment increases and decreases, SALSA would create a sustainable and moderate pathway forward for the Medicare program, clinical laboratories, and the patients they serve.

Promoting Access to Innovative Tests and Breakthrough Medical Devices

ACLA strongly supports meaningful efforts to expand coverage and patient access to innovative screening tests and breakthrough medical devices and technologies. We thank the Committee for its work, including advancement of H.R. 2407, *the Nancy Gardner Sewell Multi-Cancer Early Detection Screening Coverage Act,* to support the cause of patient access to medical innovations like multi-cancer early detection (MCED) screening tests, which have been proven to help find cancers earlier, potentially leading to better patient outcomes. ACLA looks forward to working with Committee staff as the bill works through the legislative process to address a recently added provision to H.R. 2407 that would change how certain rates are set moving forward.

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[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8818891/#:~:text=Recent%20analyses%20of%20critically%20ill,4%2C%209%2C%2017

RESPONSIBLE REGULATION

Enabling, Not Hampering Innovation

As the Committee examines access to health care and medical innovation and potential policy solutions within its jurisdiction, ACLA appreciates the opportunity to underscore the confluence of serious challenges facing clinical laboratories.

The FDA's rule to regulate laboratory testing services as medical devices is not supported by the text of the Food, Drug, and Cosmetic Act and would impose exorbitant costs and far-reaching regulatory obligations on clinical laboratories, diverting resources away from innovations that this Committee endeavors to foster.

ACLA has long maintained that legislation is the right – and only – approach for FDA to regulate laboratory testing services offered by ACLA members and other laboratories. ACLA is challenging the Final Rule in federal court, as the FDA's actions exceed the agency's authority. For years, ACLA has worked collaboratively with Congress, FDA, and other stakeholders to develop legislation that would establish an appropriate regulatory framework for diagnostics. Rather than continue that dialogue, FDA chose instead to act unilaterally and impose an ill-fitting device regime on laboratory testing services. ACLA remains committed to working with Congress, FDA and other stakeholders to advance appropriate legislation that preserves the critical role of laboratory diagnostics and ensures that patients continue to have access to lifesaving testing services.

We urge the Committee to keep this in mind as it considers PAMA relief. Against the backdrop of the FDA's regulatory overreach that could compromise patient access and reduce laboratory investments in innovation, long-term payment certainty is more important than ever.

ACLA thanks the Committee for its focus on the important topic of medical innovation. We are eager to work together to advance policies that support and foster clinical laboratory innovations to improve patient outcomes and enable the next generation of personalized care. Please contact Mary Lee Watts, ACLA Vice President of Government Affairs and Policy, at mlwatts@acla.com if you have any questions.