ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

2025 PRIORITIES

Policies to Advance Patient Access to Innovative Clinical Laboratory Services

The American Clinical Laboratory Association (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. ACLA members include the nation's largest clinical laboratories, providing comprehensive test menus and patient access to innovative services in every state and U.S. territory, and laboratories focused on delivering advanced precision diagnostics. Together, ACLA members are guiding and supporting preventative care, while improving the lives of patients living with a wide range of diseases and conditions, including infectious diseases, cancer, and many rare diseases and conditions.

America's clinical laboratories serve as the foundation for informed clinical decision making for everyday prevention, diagnosis, and treatment of disease for patients across the country and function as the part of the nation's critical infrastructure for public health preparedness and response. 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, and from toxicology testing that is critical to addressing the ongoing opioid crisis to developments in artificial intelligence that are empowering precision medicine and enhancing laboratory workflows to expand access to laboratory services, laboratories' investments in cutting edge diagnostic solutions are leading to extraordinary advancements, changing health care as we know it for patients across the country.

1 Source: Department of Health and Human Services Office of the Inspector General: https://www.oig.hhs.gov/oei/reports/OEI-09-23-00350.pdf

2 Source: Center for Disease Control and Prevention: https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html

Beyond clinical laboratories' delivery of essential medical insights and cost-effective services, the industry drives job creation and contributes to local economies across the country. ACLA estimates that clinical laboratories contribute over $118 billion in total national economic output annually, supporting over 652,000 jobs, generating $48 billion in wages and paying more than $11 billion in state and federal taxes. (The economic impact of clinical laboratories by state and congressional district is available on the ACLA web site).

ACLA's 2025 advocacy agenda aims to foster patient access to innovate testing services to prevent and identify diseases and guide increasingly personalized care. Advocacy priorities are focused in the areas of **Reimbursement**, **Regulation**, and **Preparedness & Innovation**.

REIMBURSEMENT: ENSURING PATIENT ACCESS TO CLINICAL LABORATORY SERVICES

ACLA advocates for rational public and private payer coding, coverage, and payment policies that reflect the value of laboratory services, protect and extend patient access to appropriate services, and promote innovation in diagnostics, including data-driven technologies, to advance patient care.

- **Reforming The Protecting Access to Medicare Act of 2014 (PAMA): ACLA urges Congress to pass meaningful long-term PAMA reform to update Medicare Clinical Laboratory Fee Schedule (CLFS) payments based on accurate and robust private payer data collection and reporting.** ACLA appreciates that in December 2024, Congress stepped in for the fifth time to delay the resumption of deep cuts of up to 15% for about 800 laboratory tests under the Medicare CLFS. The cuts now are scheduled to resume January 1, 2026. It is time for Congress to enact long-term reform of the establishment of Medicare payment rates for laboratory services, which is essential to protect patient access to laboratory services, support innovation in diagnostics, and bolster the nation's critical laboratory infrastructure.

PAMA Background: A Flawed Implementation Led to Billions in Reductions

PAMA fundamentally changed how Medicare sets payment rates under the CLFS, requiring rates to be based on those paid by private payers. Medicare payment rates under PAMA were implemented in 2018 using private payer data from fewer than 1% of clinical laboratories, thus leading to inappropriately deep Medicare reductions with many tests realizing cuts of as much as 27% between 2018–2020. Originally estimated by the Congressional Budget Office (CBO) to cut $2.5 billion from the CLFS over ten years, PAMA cut nearly $4 billion in the first 3 years of its implementation. Recognizing that the cuts were far deeper than projected, Congress has intervened to delay further payment cuts for five straight years. ACLA successfully brought a federal lawsuit against the Centers for Medicare & Medicaid Services (CMS), challenging its interpretation and implementation of PAMA. In July 2022, the U.S. Court of Appeals for the D.C. Circuit ruled in ACLA's favor both on substantive grounds and on process in *American Clinical Laboratory Association v. Becerra*. The court could not require CMS to recalculate rates because the law prohibits judicial review of "the establishment of payment amounts," giving rise to the urgent need for legislation to reform PAMA sustainably.

- **Reimbursement Process Reforms to Expand Access and Reduce Burden:** ACLA advocates for public and private payer policies and processes that support the appropriate use, coverage, and payment of clinical laboratory and pathology services. The reimbursement process for medical services is highly complex. When policy is misaligned with innovation and the value of diagnostics to patients and public health, the impact can impede patient and provider access to necessary testing services.

  - **CODING: ACLA urges CMS and Congress to advance policy that would require the National Correct Coding Initiative (NCCI) use CPT® coding guidance.** Correct coding is essential to provide transparency for payers into which tests are ordered and performed, and for payment purposes. The American Medical Association (AMA), which establishes, maintains, and owns CPT® codes, develops detailed coding guidance for the use of CPT codes. Today, CMS' National Correct Coding Initiative (NCCI) Policy Manual and claims edits policies, focused on facilitating correct coding and used by public and private payers, often deviate from AMA coding guidance. As such, rather than facilitating correct coding, CMS' NCCI policies can require clinical laboratories to use codes in a manner that conflicts the code developer's guidance. This conflict can result in denials for claims that were properly coded per AMA guidance.

  - **COVERAGE: ACLA urges CMS to require increased transparency of MACs' and Medicare Advantage Plans' coverage determination processes.** Through engagement with private payers, Medicare Administrative Contractors (MACs), and federal and state policymakers, ACLA advocates for robust coverage policies and transparent coverage determination processes that help ensure access to existing and new and innovative laboratory services.

  - **PAYMENT: ACLA urges CMS to give full consideration to the recommendations of the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel when it establishes Medicare rates for new tests.** CMS has increasingly ignored near unanimous recommendations of the CDLT Advisory Panel.

  - **CURBING AGGRESSIVE PAYER PRIOR AUTHORIZATION AND MEDICAL DOCUMENTATION REQUIREMENTS, INCLUDING WHEN OVERSEEN BY LABORATORY BENEFIT MANAGERS (LBMS): ACLA urges CMS and Congress to increase transparency, decrease inappropriate claims denials, and reduce burdens associated with emerging payer utilization management tactics.** These tactics include convoluted and aggressive prior authorization processes and excessive medical documentation requests deployed by various payers, including Medicare Advantage (MA) and Medicaid Managed Care Organization (MMCO) plans. The results can reduce patient access to necessary services and block appropriate reimbursement to clinical laboratories for services delivered, even following prior authorization approval. These plans often use "middlemen" LBMs, similar to Pharmacy Benefit Managers (PBMs), that impede access to laboratory services and payment for these services.

    - **ACLA urges CMS and Congress to build upon the positive reforms in CMS's Interoperability and Prior Authorization Final Rule (CMS-0057-F) by advancing prior authorization policies that recognize clinical laboratory workflows.** In 2024 CMS finalized a regulation that applies to Medicare Advantage, Medicaid Managed Care, Children's Health Insurance, and health plans available on the federally-funded exchanges. During last session, Congress considered legislation to codify these policies. ACLA urges CMS to put forward guidance to clarify that plans subject to its rule must address laboratory specific matters to ensure prior authorization processes do not delay clinical laboratory testing, nor result in denied payment, for covered

services. ACLA also urges Congress to reintroduce the *Improving Seniors Timely Access to Care Act*, modified to address laboratory specific concerns. ACLA is also urging CMS and Congress to pursue prior authorization reforms that focus on the following goals: (1) Require payers to accept a prior authorization request either before specimen collection or at any time between specimen collection and the date a timely claim for reimbursement is submitted to the plan; (2) Require payers to accept prior authorization requests from clinical laboratories, as suppliers of services; and (3) Require payers to request only medical documentation that is reasonably necessary to evaluate a prior authorization request.

- See ACLA's Prior Authorization Reform Recommendations for more information.

- **TELEHEALTH: ACLA supports continued telehealth flexibilities that extend beyond March 2025 and that allow for all clinical laboratory services to be ordered and reimbursed pursuant to a telehealth visit, without barriers such as requiring a face-to-face visit as a condition of ordering a test.**

REGULATION: INNOVATIVE LABORATORY DEVELOPED TESTING SERVICES (LDTS) ARE ESSENTIAL TO INFORMED PATIENT CARE

ACLA advocates for a clear and predictable regulatory environment that recognizes the role of clinical laboratories and the characteristics of clinical laboratory services. By developing LDTs, including for rare diseases, clinical laboratories are able to bring the latest innovative diagnostics testing services to patients and providers.

- **Protecting Patient Access to Innovative LDTs:** LDTs offered by ACLA members play an indispensable role in delivering cutting edge healthcare to patients. CMS provides robust oversight of clinical laboratories through the Clinical Laboratory Improvement Amendments (CLIA). Further, all ACLA member clinical laboratories are accredited by the College of American Pathologists (CAP).

  Regrettably, FDA disregarded bipartisan Congressional discussions with stakeholders, including ACLA, on potential diagnostics regulatory reform legislation, taking unilateral action in 2024 to finalize a rule that will impose the existing framework for regulating medical devices onto LDTs. ACLA has grave concerns with FDA's Final Rule—both as a matter of public policy and law. Laboratory developed testing services are professional services, not medical devices. Medical device authorities are rigid and would not allow LDTs to keep pace with scientific advances. Further, the Final Rule exceeds FDA's legal authority, as LDTs are not "devices" and cannot be regulated as such. The net result of Agency's action would be to reduce patient access to essential testing, including for rare diseases, and hamper innovation in the next generation of diagnostics. ACLA urges the FDA to withdraw the final rule, Stage 1 of which is scheduled to take effect May 2025.

  Given the far-reaching negative impacts on our nation's laboratory community, ACLA is challenging the FDA's May 6, 2024, Final Rule in a lawsuit filed in the United States District Court for the Eastern District of Texas.

  In 2025, ACLA will continue to urge the FDA to rescind the Final Rule, as litigation proceeds. ACLA looks forward to working with Congress and other stakeholders on legislation that would protect patient access to LDTs and safeguard the ability of laboratories to ensure that patients benefit from the latest scientific advancements in diagnostics.

- **Modernizing CLIA Policies:** The CLIA program, overseen by CMS, is designed to ensure the quality and safety of laboratory operations. The Clinical Laboratory Improvement Advisory Committee (CLIAC), an advisory body to the Department of Health and Human Services (HHS), has developed and recommended to HHS updates CLIA to reflect advancements and modernization of clinical laboratory work. including for the remote review of laboratory information, such as digital pathology slide images. **ACLA is advocating for HHS to issue regulations to make permanent the policy that allows pathologists and other laboratory professionals to review digital slide images remotely under a main laboratory's CLIA certificate, without needing a separate CLIA certificate where the slides are reviewed.** A permanent remote review policy would help address patient access and the workforce shortages facing clinical laboratories across the country.
- **Promoting Improved Interoperability of Laboratory Data: ACLA, in collaboration with electronic health record vendors, is advocating to HHS for efficient and manageable interoperability standards for laboratory data and adequate industry representation in standards development processes.**

PREPAREDNESS & INNOVATION: CLINICAL LABORATORIES SUPPORT PUBLIC HEALTH WHILE DRIVING THE NEXT GENERATION OF DIAGNOSTICS

- **Preparedness:** ACLA members routinely demonstrate leadership and support for our nation's public health response efforts, answering the call to rapidly develop quality tests and scale nationwide testing services, including for COVID-19 and MPox Public Health Emergencies (PHEs). Essential to a robust response is strong public–private collaboration, rooted in an appreciation of the critical role that clinical laboratories play in our nation's diagnostic preparedness. ACLA member laboratories and the laboratory workforce are part of the nation's critical infrastructure deployed during emergencies.

  ACLA and its members are committed to working with governments and other stakeholders to promote a national diagnostics rapid response plan to improve our nation's ability to plan for and respond to future pathogens of concern swiftly and meaningfully.
- **Establishing a National Diagnostics Action Plan: ACLA urges Congress to reauthorize the *Pandemic and All Hazards Preparedness Act* (PAHPA) and urges the Administration to advance policies to establish a testing plan to rapidly develop, deploy, and maintain clinical laboratory capacity and diagnostic testing at a national scale in the earliest days of the identification of a new pathogen of concern.** The ACLA–Johns Hopkins Center for Health Security Proposal for a National Diagnostics Action Plan for the United States, published in 2023, includes essential recommendations, such as a call for the establishment of a permanent public–private National Testing Coordination Forum focused on preparedness and response to disease emergencies and the swift establishment of billing codes, widespread coverage, and appropriate national payment rates for new tests.
- **Improving Public Health Data Reporting: ACLA urges HHS and Congress to standardize an appropriately limited data set and improved exchange pathways for clinical laboratory data reporting requirements across governments as for use during public health emergencies.** Currently, public health data reporting requirements vary from state-to-state and even locality-to-locality. This lack of standardization creates unnecessary complexity, leading to inefficient and ineffective reporting requirements. Laboratories are often required to report data elements of patient characteristics that are not provided to them

by ordering practitioners. In 2025, as Congress' efforts to reauthorize PAHPA continue, ACLA advocates for rational standards for an appropriately limited data set for public health data reporting by clinical laboratories across all governmental jurisdictions.

- **Strengthening the Nation's Clinical Laboratory Workforce:** Laboratories are experiencing persistent workforce shortages, with some laboratories operating with vacancy rates of 10–25%. ACLA members are striving to attract and retain laboratory professionals, and a long-term public–private collaboration is essential to ensure a robust laboratory workforce in the years ahead. **ACLA encourages Congress to advance legislation focused on education, training, and licensure policies to strengthen the laboratory workforce.**

INNOVATION: ACLA MEMBERS' INVESTMENTS IN INNOVATION ARE LEADING TO EXTRAORDINARY ADVANCEMENTS, POSITIVELY CHANGING HEALTH CARE AS WE KNOW IT AND IMPROVING AND SAVING LIVES.

- **Artificial Intelligence: Empowering Innovation for Enhanced Patient Care:** AI is one of many innovative technologies ACLA member laboratories utilize to streamline business processes, prioritize and increase the efficiency of workflows, and synthesize data to reduce employee burnout, all to ensure the highest quality services for patients. ACLA encourages policymakers to ensure that any policies that regulate the use of AI in healthcare and specifically clinical laboratories maximize the benefit of AI tools, minimize risks, and foster innovation. ACLA's AI policy paper outlines core principles around regulatory clarity, risked-based approaches, transparency and bias mitigation, federal preemption, privacy, and reimbursement.

ACLA's *Power of Knowing* campaign shares the latest on clinical laboratory science and services, bringing to life the value of clinical laboratories for policy makers. For millions of Americans and their health providers, laboratory tests are the start of any comprehensive care plan, empowering patients and clinicians with the answers they need to guide health care decisions. Effective use of clinical laboratory screening and diagnostic tests supports disease prevention, detection, diagnosis, treatment selection and monitoring. Clinical laboratory services allow patients to receive the right care at the right time while often reducing overall health care costs. Learn more about the role of clinical laboratories in supporting the delivery of informed clinical care for patients and the public by visiting ACLA's *Power of Knowing* website.

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For more information on ACLA and our 2025 advocacy agenda, please visit www.ACLA.com or email Elyse Oveson, Chief of Advocacy Operations, at eoveson@acla.com.