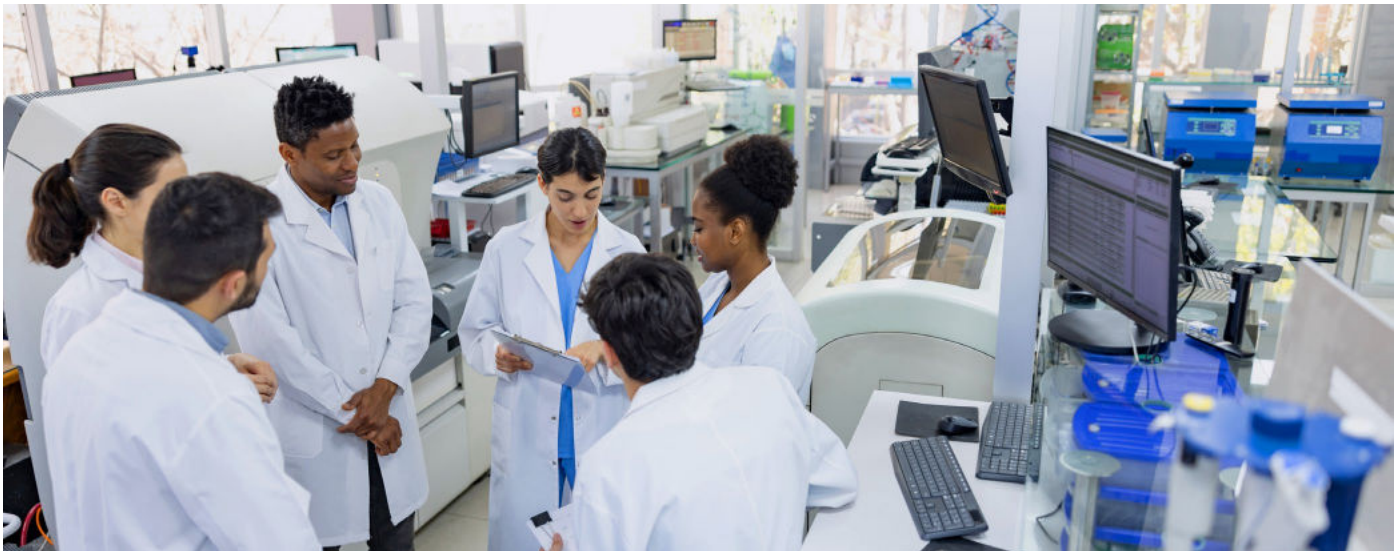
ACLA

AMERICAN CLINICAL LABORATORY ASSOCIATION

2026 PRIORITIES:
Advancing Patient Access to Innovative Clinical Laboratory Services

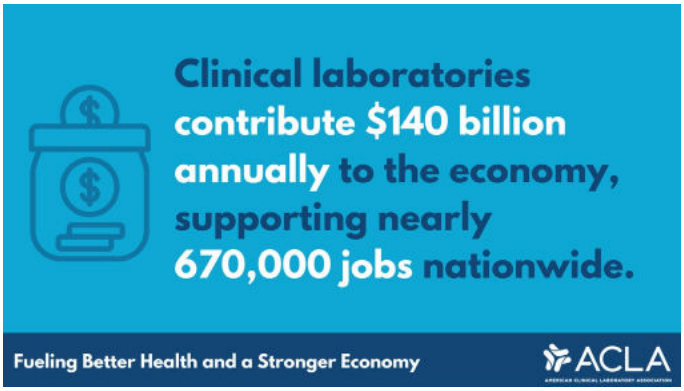


The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve 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 empower patients and clinicians with actionable information, guiding and supporting preventative care and screening for disease while improving the lives of patients living with a wide range of common and rare diseases and conditions, including infectious diseases and cancer.

America's clinical laboratories serve as the foundation for clinical decision-making as laboratory test results inform 70% of medical decisions.[1] From routine blood tests to ground-breaking genetic tests that guide therapy selection, 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, laboratories' investments in cutting edge diagnostic solutions are leading to extraordinary advancements and changing health care as we know it for patients across the country. Clinical laboratories deliver tremendous value, even though Medicare spending on the Part B Clinical Laboratory Fee Schedule (CLFS) accounts for less than 1% of total Medicare spending.[2]

1 Center for Disease Control and Prevention: https://www.cdc.gov/lab-week/about-archive.html

2 MedPAC Payment Basics, Clinical Laboratory Services Payment System (Nov. 2025): https://www.medpac.gov/document/clinical-laboratory-services-payment-system-2/



Clinical laboratories also drive job creation and contribute to local economies across the country. ACLA estimates that clinical laboratories contribute over $140 billion in total national economic output annually, supporting nearly 670,000 jobs, generating $56 billion in wages, and paying more than $19 billion in state and federal taxes. (See economic impact of clinical laboratories by state and congressional district on the ACLA website).

ACLA's 2026 advocacy agenda aims to foster patient access to innovative testing services to prevent and identify diseases and guide increasingly personalized care. Advocacy priorities are focused on the areas of **Reimbursement, Regulation, Infrastructure & Innovation, and Public Affairs**.



Reimbursement: Ensuring Patient Access to Essential Clinical Laboratory Services

ACLA advocates for rational public and private payor coding, coverage, and payment policies that reflect the value of laboratory services, reduce burden, protect and extend patient access to appropriate services, and promote innovation in diagnostics to advance patient care.

- **Foundational PAMA reform, relief from cuts: ACLA urges Congress to pass the *Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act,* H.R. 5269 / S. 2761.** Following years of artificially suppressed Medicare rates, destabilizing payment cuts, and uncertainty, the time is now for Congress to reform the Medicare clinical laboratory payment system. The RESULTS Act would:
  - Reform the Protecting Access to Medicare Act (PAMA) by dramatically improving the data used to set rates on the CLFS.
  - Support and enhance beneficiary access to innovative clinical laboratory services.
  - Reduce the administrative burden of data collection and reporting for laboratories and the Centers for Medicare and Medicaid Services (CMS).
  - Provide stability to the CLFS through improved rate setting and mitigation of steep year-to-year rate reductions.

Over 60 patient, consumer, laboratory, physician, hospital and health system organizations have endorsed the RESULTS Act. Visit the Stop Lab Cuts website for more information on PAMA and the RESULTS Act.

- **Reimbursement process reforms to expand access and reduce burden:** ACLA advocates for public and private payor 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 with 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 policies that would increase transparency in the establishment of new codes, appropriate use of codes, and recognition of codes by states.** Correct coding is essential to provide transparency for payors into which tests are ordered and performed, and for payment purposes. ACLA is encouraging increased transparency and stakeholder input in the processes deployed by the American Medical Association (AMA), which establishes, maintains, and owns CPT® codes, develops detailed coding guidance for the use of CPT codes. ACLA is urging CMS to modify its National Correct Coding Initiative (NCCI) Policy Manual and claims edits policies, which focus on facilitating correct coding and use by public and private payors, to recognize and address discord between its guidance and AMA coding guidance. This conflict can result in denials for claims that were properly coded per AMA guidance. ACLA is urging states to recognize all codes for innovative tests, including Proprietary Laboratory Analysis (PLA) codes, to ensure patient access to critical 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.** More and more frequently, CMS has ignored near unanimous recommendations of the CDLT Advisory Panel, comprised of clinical laboratory experts. Input from those who know the field best is crucial to ensuring appropriate rate-setting to support patient access to innovative testing services.

PAMA Has Failed to Reflect the Commercial Market as Congress Intended, Leading to Billions in Cuts to Clinical Laboratory Payments

The Protecting Access to Medicare Act (PAMA), which passed in 2014, was meant to establish market-based rates for clinical laboratory services paid under the CLFS through collection of private payor rate data and volumes from independent, hospital outreach, and physician office laboratories. However, when PAMA was implemented, this goal was not achieved, as CLFS rates were set based on 2016 commercial market data collected from less than 1% of all laboratories, resulting in artificially low payment rates. Medicare payments to laboratories were cut by nearly $4 billion between 2018 and 2020, well beyond the projections of $2.5 billion over 10 years when PAMA became law.

In recognition of the severity of the reductions, Congress has stepped in since 2020 to delay further cuts and data reporting. Medicare continues to pay for laboratory services at rates based on those same 2016 data. Without congressional action, about 800 laboratory tests' CLFS rates will be cut by up to 15% beginning January 31, 2026, with further deep reductions planned for 2027 and beyond, threatening timely patient access to routine and life-saving diagnostics.

Now is the time for urgently needed PAMA reform and relief through passage of the RESULTS Act.

- **Coverage: ACLA urges CMS to require increased transparency of Medicare Administrative Contractors' (MACs) and Medicare Advantage Plans' coverage determination processes; urges states to expand coverage of innovative testing; and urges private payors to establish transparent coverage policies.** ACLA advocates for robust coverage policies and transparent coverage determination processes that help ensure access to innovative laboratory services. The association engages CMS to improve national coverage policy determinations and local determinations made by MACs, while encouraging state policy makers also to expand patient access to innovative laboratory services, such as biomarker testing. ACLA also urges private payors to increase the transparency of their coverage policies, particularly when established by third-party Laboratory Benefit Managers (LBMs).

- **Addressing impediments to appropriate reimbursement: ACLA urges CMS and Congress to increase transparency, decrease inappropriate claims denials, and reduce burdens associated with prior authorization and onerous medical documentation practices used by health plans and third-party LBMs.** Various payors, including Medicare Advantage (MA) and Medicaid Managed Care Organization (MMCO) plans, often deploy convoluted and aggressive prior authorization and medical document requirements inconsistent with ordering provider and clinical laboratory workflows. Plans often use "middlemen" LBMs, similar to Pharmacy Benefit Managers (PBMs), to implement these practices in a nontransparent fashion. These tactics can reduce patient access to necessary services and block appropriate reimbursement to clinical laboratories for services delivered, even following prior authorization approval.

  - **Prior authorization reform: ACLA urges CMS and Congress to build upon prior HHS regulations and health insurers' public commitments to streamline prior authorization beginning in 2026, including by expanding real-time approvals to 80% of prior authorizations and reducing the number of services requiring prior authorization, by advancing laboratory-specific reforms:** (1) Require payors 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 (payors often require prior authorization to be completed by the date of specimen collection—often before a laboratory is made aware a test has been ordered by a clinician); (2) Require payors to accept prior authorization requests from clinical laboratories, as suppliers of services; and (3) Require payors to request only medical documentation that is reasonably necessary to evaluate a prior authorization request.

  - ACLA also urges Congress to advance the *Improving Seniors' Timely Access to Care Act*, H.R 3514 / S. 1816, modified to address laboratory specific concerns.

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

- **Telehealth: ACLA supports continued telehealth flexibilities that extend beyond January 2026 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: Advancing Clinical Laboratory Innovation through CLIA and Data Interoperability

ACLA advocates for a clear and predictable regulatory environment that reflects the unique role of clinical laboratories and supports innovation in clinical laboratory services. CMS regulates clinical laboratory testing through the Clinical Laboratory Improvement Amendments (CLIA), a program intended to ensure valid and reliable laboratory testing. In 2025, ACLA secured a landmark victory in *ACLA v. FDA*, affirming that professional laboratory testing services are not medical devices subject to regulation by the Food and Drug Administration (FDA). This ruling protects patient access to critical testing services and prevents imposition of unnecessary, burdensome regulations that would have undermined the clinical laboratory system in this country. ACLA remains committed to working with the Administration and Congress to ensure that federal regulation supports—and does not undermine—clinical laboratories in delivering innovative and reliable diagnostic testing services to patients and providers.

- **Reinforce CLIA Regulation to Support Clinical Laboratory Innovation:** ACLA is committed to working with the Administration and Congress to reinforce CLIA as the framework for regulation of clinical laboratories, including by modernizing CLIA to reflect advances in laboratory services, such as remote review of digital slides and the use of artificial intelligence to advance clinical care.

ACLA advocates for improved laboratory data exchange through efficient and manageable interoperability standards. ACLA is committed to working with electronic health record vendors and policy makers on interoperability to improve clinical care and seeks adequate industry representation in standards development processes.

- **Interoperability:** ACLA encourages the Administration to improve and advance laboratory data interoperability through the new Health Tech Ecosystem initiative and implementation of APIs, identifying lab-specific interoperability gaps.

- **E-Signature:** ACLA urges standards to be established for e-signatures for laboratory orders to improve the ordering process and promote confidence in a clinician's intent to order.



Infrastructure for Preparedness & Response

ACLA members routinely demonstrate leadership by swiftly developing laboratory developed testing services when new pathogens of concern arise, while supporting our nation's public health response efforts, including during Public Health Emergencies (PHEs). Essential to a robust response is strong public-private collaboration rooted in an appreciation for the critical role that clinical laboratories play in our nation's emergency preparedness. Several ACLA members are part of public-private sector agreements for warm base test development and test capacity to ensure preparedness. ACLA is committed to robust engagement with the Administration on emerging pathogens for situational awareness and preparedness and response efforts.

- **Preparedness and response: ACLA encourages 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.**

- **PAHPA Reauthorization: ACLA urges Congress to recognize the critical nature of clinical laboratories in preparedness and response in any legislative effort to reauthorize the narrow set of national health security authorities, and the Pandemic and All Hazards Preparedness Act (PAHPA).** Most PAHPA provisions expired September 30, 2023.

- **Standard Results 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 for use during PHEs.** 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.



- **Strengthening the Nation's Clinical Laboratory Workforce: ACLA encourages Congress to advance policies focused on education, training, and licensure policies to strengthen the 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.

Innovation in the Next Generation of Diagnostics

ACLA members' investments in innovation are leading to extraordinary advancements, positively changing health care as we know it, and improving and saving lives. Innovations abound, from companion diagnostics, which are specialized laboratory tests that identify genetic, molecular, or biological markers of disease can help determine whether a patient is likely to benefit from a specific drug or therapy, particularly in cancer care and immunology, to new neurobiomarker blood tests that can help diagnose neurological conditions, guiding disease management and treatment for patients.

Artificial intelligence (AI) is being leveraged in laboratory medicine, given its ability to analyze large amounts of data quickly, identify trends, and produce accurate insights that can support clinical decision making.

- **Artificial Intelligence: ACLA encourages the Administration and Congress to ensure that any policies that regulate the use of AI in health care 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.

For more information on ACLA and our 2026 advocacy agenda, please visit **www.ACLA.com** or email **info@acla.com**.

Public Affairs: ACLA's Power of Knowing Campaign Highlights Innovations Improving Patient Health and Health Care

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.

