ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

2024 PRIORITIES

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 striving to improve and save patient lives, including those living with infectious diseases, cancer, numerous rare diseases, and scores of other diseases and conditions, serving as the foundation for informed clinical decision making.

Diagnostic laboratory testing accounts for only about 3 percent of total Medicare Part B spending, yet it delivers tremendous value to society, allowing clinicians to help keep patients and the public healthy by determining the cause of an illness and identifying specific therapies to treat the illness and monitor a treatment's effectiveness. In addition to the essential medical insights and cost-effective services performed by clinical laboratories, 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 2024 advocacy agenda promotes policy priorities in the areas of **reimbursement**, **regulation**, and **preparedness & infrastructure**, including laboratory workforce. As a whole, the advocacy agenda strives to promote policies that reflect the **value of clinical laboratories**, support innovation, and expand access to testing services that improve and save lives.

Key elements of the 2024 advocacy agenda follow.

REIMBURSEMENT: ENSURING APPROPRIATE ACCESS TO CLINICAL LABORATORY SERVICES

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

- **Setting Medicare Payment for the Clinical Laboratory Fee Schedule (CLFS) on a Predictable and Sustainable Pathway:** ACLA urges Congress to pass the *Saving Access to Laboratory Services Act* (SALSA) (H.R. 2377/S. 1000) in 2024. ACLA appreciates that Congress has stepped in with strong bipartisan support to delay the resumption of deep cuts of up to 15% for ~800 laboratory tests under the Medicare CLFS for four straight years. The cuts now are scheduled to return January 1, 2025. It is time for Congress to enact a responsible approach for long-term Medicare payment reform for laboratory services under the CLFS, which is essential to protect patient access to laboratory services, support innovation in diagnostics, and bolster the nation's critical laboratory infrastructure. SALSA is that responsible approach. The bipartisan and bicameral legislation is spearheaded by Reps. Richard Hudson (R-NC) and Gus Bilirakis (R-FL), Bill Pascrell (D-NJ) and Scott Peters (D-CA) and Sens. Sherrod Brown (D-OH) and Thom Tillis (R-NC), and it is supported by 70 stakeholder organizations.

BACKGROUND:

The *Protecting Access to Medicare Act of 2014* (PAMA) fundamentally changed how Medicare payment rates under the CLFS are established, basing Medicare rates on commercial rates. New Medicare payment rates under the revised process were implemented in 2018, with many tests realizing cuts of up to 27% between 2018–2020. Recognizing that the cuts were far deeper than projected (originally estimated by the Congressional Budget Office (CBO) to cut $2.5 billion from the CLFS over ten years, yet actually cutting nearly $4 billion in the first 3 years), **Congress has intervened to delay further payment cuts for four straight years.** Further, 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 on both 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:** 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. ACLA engages with policymakers and payers to pursue policies that support the appropriate use of clinical laboratory and pathology services.

- **CODING:** ACLA urges Congress to advance association-developed legislation, the *Correct Coding Improvement Act* (CCIA), which would bring greater transparency and a formal stakeholder engagement process to CMS's National Correct Coding Initiative (NCCI) updates to the Current Procedural Terminology (CPT®) code set. Currently these updates, which have significant implications for patient access to services, are made without a formal public comment period. Further, CCIA would, improve state Medicaid program and private payer recognition of proprietary laboratory analysis (PLA) codes and require HHS to fulfill its obligation to ensure HIPAA code sets, including CPT® codes, are made accessible to all providers efficiently and at a low cost.
- **COVERAGE:** Through engagement with commercial payers, Medicare Administrative Contractors (MACs), and federal and state policymakers, ACLA advocates for robust and transparent coverage policies and processes that help ensure access to existing and new laboratory services.
- **PAYMENT:** ACLA urges CMS to ensure full consideration of expert advisory panel recommendations, including that of the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel, when it establishes Medicare rates for new tests. CMS has ignored near unanimous recommendations of the CDLT Advisory Panel on a number of occasions recently. Further, ACLA urges CMS to establish payment pathways for technologies that improve access to testing.
- **PRIOR AUTHORIZATION, MEDICAL DOCUMENTATION, LABORATORY BENEFIT MANAGERS (LBMs):** ACLA is advocating for the Administration and Congress to take meaningful steps to curtail convoluted and aggressive prior authorization processes and medical documentation requests being deployed by various payers, including Medicare Advantage (MA) and Medicaid Managed Care Organization (MMCO) plans, which reduce patient access to necessary services and block appropriate reimbursement to clinical laboratories for services delivered, even following a prior authorization approval. These plans often use LBMs, similar to Pharmacy Benefit Managers (PBMs), to gate-keep access to laboratory services and payment for these services. ACLA is engaging with a broad range of patient and provider stakeholders to encourage lawmakers to provide oversight of Medicare and Medicaid managed care plans' use of prior authorization and medical documentation requests. ACLA is also urging the Administration to augment its ongoing efforts to regulate prior authorization practices, to address inappropriate medical documentation requests sent to clinical laboratories, rather than to ordering providers, and to require all MA and MMCO plans to provider payment for covered services appropriately delivered to patients.
- **ELECTRONIC TEST ORDERING:** ACLA, in collaboration with electronic health record organizations and provider organizations, urges CMS to update guidance so that a health care practitioner's intent to order a laboratory test can be evidenced by an electronically-placed order, reducing burdensome post-payment audit problems for laboratories.
- **TELEHEALTH:** ACLA supports continued telehealth flexibilities that allow for all clinical laboratory services to be ordered pursuant to a telehealth visit. To that end, as Congress considers extension of telehealth policies scheduled to expire at the end of 2024, ACLA opposes any legislative provisions that would restrict access to any testing services ordered pursuant to a telehealth visit, such as requiring face-to-face visits as a condition of ordering tests.

REGULATION: INNOVATIVE LABORATORY DEVELOPED TESTS (LDTs) ARE ESSENTIAL TO INFORMED PATIENT CARE

Patient and provider access to innovative diagnostics testing services benefits from a clear and predictable regulatory environment that recognizes the role of laboratories and the characteristics of clinical laboratory services.

- **Protecting Patient Access to Innovative LDTs:** LDTs offered by ACLA members play an indispensable role in delivering cutting edge healthcare to patients. For several years, ACLA has worked collaboratively with the U.S. Food and Drug Administration (FDA), Congress, and key stakeholders on legislation that could establish a diagnostic-specific regulatory framework for all diagnostics, complementary to the already robust regulation of laboratories that includes CMS oversight through the Clinical Laboratory Improvement Amendments (CLIA). The goal has been to develop a regulatory approach that would account for the unique attributes of laboratory diagnostics, while balancing diagnostic innovation and maintained access to important tests with right-sized regulatory oversight.

  Regrettably, in 2023 FDA moved away from discussion on legislation, taking unilateral action to issue a proposed rule that would impose the existing framework for regulating medical devices onto LDTs. ACLA has grave concerns with FDA's proposed rule—both as a matter of public policy and law—and urges FDA to withdraw it. FDA fails to provide a sound justification for its unilateral action, which would force the ill-suited and inflexible medical device authorities on LDTs. The net result of FDA's action would be to reduce patient access to essential testing, including for rare diseases, and hamper innovation in the next generation of diagnostics. Medical device authorities are rigid and would not allow LDTs to keep pace with scientific advances. Further, the proposed rule exceeds FDA's legal authority, as LDTs are not "devices" and cannot be regulated as such.

  In 2024, ACLA will continue to urge the FDA to withdraw the proposed rule, working instead with stakeholders and Congress 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, ensures the quality and safety of laboratory operations. Since 2022, the Clinical Laboratory Improvement Advisory Committee (CLIAC), an advisory body to the Department of Health and Human Services (HHS), has developed and communicated to HHS recommendations to update CLIA to reflect advancements and modernization of clinical laboratory work (e.g., remote review of laboratory information, such as digital pathology slides, and the establishment of new laboratory specialties). ACLA has provided dozens of recommendations to the CLIAC and will continue to engage in 2024. Further, ACLA continues to advocate for CMS 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.

- **Seeking clarity on *Eliminating Kickbacks in Recovery Act* (EKRA):** ACLA, through engagement with the Department of Justice, continues to seek clarity on the scope of EKRA, and particularly whether it applies to variable incentive compensation paid to laboratories' employed sales and marketing personnel, which can be a valuable tool to sustain a robust and capable laboratory workforce.

PREPAREDNESS & INFRASTRUCTURE: CLINICAL LABORATORIES AND THE LABORATORY WORKFORCE ARE PART OF THE NATION'S CRITICAL INFRASTRUCTURE

Throughout Public Health Emergencies (PHEs), including for COVID-19 and MPox, ACLA members have demonstrated extraordinary leadership to support our nation's response efforts, answering the call to rapidly develop quality tests and scale nationwide testing services. 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 diagnostic preparedness. ACLA member laboratories and the laboratory workforce are part of the nation's critical infrastructure deployed during emergencies.

ACLA and our 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.

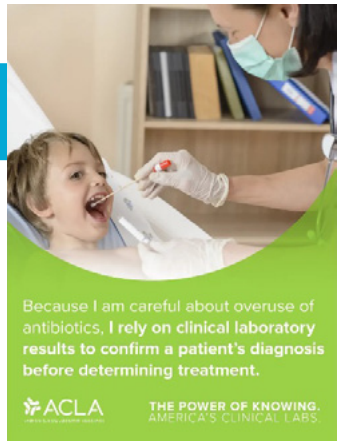
- **Establishing a National Diagnostics Action Plan:** ACLA urges Congress to reauthorize the *Pandemic and All Hazards Preparedness Act* (PAHPA) and urges the Administration to advance policies to establish a testing plan to rapidly develop, deploy, and maintain clinical laboratory capacity and diagnostic 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, including:
  - Establishment of a permanent public-private National Testing Coordination Forum focused on preparedness and response to disease emergencies.
  - Facilitation of transparent, bilateral contracts between the federal government and testing manufacturers and laboratories before a disease emergency.
  - Bolstering of the US Strategic National Stockpile via vendor-managed inventory of critical diagnostic test components, materials, and final products.
  - Swift establishment of billing codes, widespread coverage, and appropriate national payment rates for new tests.
- **Improving Public Health Data Reporting:** ACLA advocates for the standardization of clinical laboratory data reporting requirements across governments as part of public health data collection and reporting efforts 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 beyond that which is provided to laboratories by ordering

practitioners. In 2024, as Congress' efforts to reauthorize PAHPA continue, ACLA advocates for rational standards for public health data reporting by clinical laboratories across all governmental jurisdictions.

- **Strengthen the Nation's Clinical Laboratory Workforce:** Laboratories are experiencing dire workforce shortages. The laboratory workforce shortage is persistent and structural, with some laboratories operating with vacancy rates of 10–25%. While ACLA members are striving to grow, attract, and retain laboratory professionals, a long-term public-private collaboration is essential to ensure a robust laboratory workforce in the years ahead. ACLA encourages Congress to advance the following policies focused on education, training, and licensure:
  - Establish requirements for states to institute licensure reciprocity, thereby decreasing burden and cost for providers and increasing patient access.
  - Require the CLIAC to update educational and training requirements, taking into considering the workforce shortages for various laboratory specialists, while making permanent remote review flexibilities.
  - Establish federal support for clinical laboratory educational programs and loan repayment programs, as has been done for other allied health professionals.
  - Modify H1-B visa or EB-3 Permanent Resident visa processes to improve flow of qualified individuals into positions in laboratories across the country.
  - Make permanent the extension of telehealth coverage without restrictions.

COMMUNICATING THE VALUE OF CLINICAL LABORATORIES

- **ACLA's Power of Knowing Campaign:** ACLA members' investments in innovation are leading to extraordinary advancements, positively changing health care as we know it and improving and saving lives. 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.



ACLA is privileged to advocate on behalf of the nation's leading clinical laboratories and the patients and clinicians they serve.

For more information on ACLA and our 2024 advocacy agenda, please visit www.ACLA.com or email Elyse Oveson, Chief of Advocacy Operations at eoveson@acla.com.

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