ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

2023 PRIORITIES

The American Clinical Laboratory Association (ACLA) represents the nation's leading clinical laboratories that drive diagnostic innovation, developing tests and technologies for patients and providers to identify, prevent, monitor, and treat infectious, acute, and chronic diseases. Each day ACLA members provide testing services across the United States, delivering essential and increasingly personalized health information to aid in the diagnosis and treatment of both common and rare conditions. ACLA members also serve a vital role as part of the nation's critical infrastructure in times of public health emergency.

Diagnostic laboratory testing accounts for only about 3 percent of total Medicare Part B spending, yet delivers tremendous value to society, allowing clinicians to help keep patients and the public healthy, determine the cause of an illness, and identify specific therapies to treat the illness and monitor 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 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 2023 advocacy agenda promotes policy priorities in the areas of reimbursement, regulatory, and public health preparedness & infrastructure that reflect the value of clinical diagnostics, support innovation, and expand access to testing services that improve and save lives.

Key elements of the 2023 agenda are highlighted below.

REIMBURSEMENT: ENSURING APPROPRIATE ACCESS TO CLINICAL LABORATORY SERVICES

ACLA supports and advocates for improved coding, coverage, and payment policies that reflect the current and future value of laboratory tests, innovative diagnostics, and data-driven technologies.

- **Setting Medicare Payment for the Clinical Laboratory Fee Schedule (CLFS) on a Predictable and Sustainable Pathway:** ACLA appreciates the continued bipartisan approach Congress took in 2022 to provide temporary relief in 2023 from data reporting requirements and Medicare payment cuts of up to 15% for ~800 laboratory tests under the CLFS. In 2023, ACLA is focused on advancing bipartisan

and bicameral legislation based on the Saving Access to Laboratory Services Act of 2022 (SALSA) that would provide a long-term, responsible, and sustainable pathway for Medicare payments for laboratory services under the CLFS. SALSA was endorsed by dozens of patient, consumer, and provider organizations, and is widely recognized in Congress as a responsible approach for the long-term payment reform needed to protect patient access to laboratory services, support innovation in diagnostics, and bolster the nation's critical laboratory infrastructure.

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 cuts were far deeper than originally projected, Congress has intervened four times since 2019 to delay the second round of data reporting and further payment cuts. 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*, though it could not require CMS to recalculate rates, given that the law prohibits judicial review of "the establishment of payment amounts," urgently necessitating legislation to sustainably reform PAMA.

- **Reimbursement Process Reforms (Coding, Coverage, and Payment):** 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 encourages CMS to expand public engagement opportunities by establishing a public comment process for annual revisions of the National Correct Coding Initiative (NCCI) manual. Further, ACLA urges State Medicaid plans and other payers to recognize all CPT® and HCPCS codes, thereby expanding patient access to necessary testing.

  - **COVERAGE:** ACLA is engaging with commercial payers, Medicare Administrative Contractors (MACs), and policymakers to advocate for transparent coverage, claims, and prior authorization policies and processes to ensure access for existing and new laboratory services.

  - **PAYMENT:** ACLA encourages CMS to ensure appropriate consultation with advisory panels during Medicare rate-setting, and to establish payment pathways for technologies that improve access to testing, such as home-sample collection.

- **Improving Guidance on Medical Documentation for Laboratory Orders:** ACLA, in collaboration with electronic health record (EHR) organizations and provider organizations, is urging CMS to update guidance on what is permissible for electronically placed orders and practitioner's signature requirements to smooth processing of testing claims. Each day, physicians order tests they deem necessary for their patients. These orders are often provided to ACLA member clinical laboratories through electronic methods. Unlike electronic ordering of prescription drugs, where clear guidance on what constitutes an electronic signature exists, guidance around the requirement for laboratories to produce practitioners' signatures or medical records for laboratory orders when submitting a claim has lacked clarity for years. Some payers have instituted unreasonable requirements and pre-payment audits that deny payment for medically necessary laboratory services, forcing some laboratories to revert to paper orders.

REGULATORY: OVERSIGHT OF LABORATORY OPERATIONS AND DIAGNOSTIC TESTS; INTEROPERABILITY OF LABORATORY DATA

The healthcare system benefits from a clear and predictable regulatory environment for diagnostics. Further, ensuring the interoperability of laboratory data is critical to a patient-centered healthcare environment and requires improvement. Importantly, as laboratory diagnostic tests are not medical devices, ACLA has long advocated for reform of the diagnostic oversight framework. Such reform should be achieved primarily through legislation that would establish a diagnostics-specific, risk-based framework distinct from the FDA medical device framework. Reform should also include modernization of laboratory operations oversight under the Clinical Laboratory Improvement Amendments (CLIA). ACLA worked constructively during the last Congress to improve the Verifying Accurate Leading-edge IVCT Development Act of 2022 (VALID) that aimed to create a diagnostics-specific framework. Though VALID advanced further through the legislative process than previous reform efforts, it was not enacted. ACLA will continue to engage with Congress and stakeholders interested in legislative reform, in addition to advocating in the following areas:

- **Modernizing Laboratory Operations, CLIA Policies:** The CLIA program, operated by CMS, ensures the quality and safety of laboratory operations. In 2022, the Clinical Laboratory Improvement Advisory Committee (CLIAC), an advisory body to the Department of Health and Human Services (HHS), began work to develop recommendations to modernize CLIA. ACLA is engaging with the CLIAC and CMS as potential recommendations are developed, encouraging policy changes to enhance laboratory services, including by permanently changing regulations to recognize the digitization and remote review of pathology and laboratory data and images. While some remote review flexibilities were extended under the COVID-19 public health emergency (PHE), a permanent pathway is needed for both pathologists and other qualified laboratory professionals to operate from remote sites (i.e., home office) under the main laboratory's CLIA certificate. This is an important way to address patient access and the workforce challenges facing clinical laboratories across the country.

- **Improving Interoperability of Laboratory Data:** ACLA, in collaboration with electronic health record vendors, is advocating to the Department of Health and Human Services (HHS) for efficient and manageable interoperability standards for laboratory data and adequate industry representation in standards development processes.

PUBLIC HEALTH PREPAREDNESS & INFRASTRUCTURE

Throughout the COVID-19 pandemic and subsequent Mpox PHE, ACLA members provided extraordinary leadership and support for the U.S. Government's response efforts by rapidly developing tests and scaling 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 public health infrastructure.

ACLA is advocating for improvements to our nation's public health emergency preparedness and response efforts. On behalf of our membership, we are committed to working with governments and other stakeholders to bring meaningful improvements in data generation and sharing and support the establishment of a national diagnostics rapid response plan to improve our nation's ability to respond to future pathogens of concern swiftly and meaningfully.

- **Improving Public Health Data Reporting:** ACLA is advocating 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, or 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 data provided to laboratories by ordering practitioners. In 2023, as Congress undertakes the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), ACLA will advocate for rational standards for public health data reporting by clinical laboratories across all governmental jurisdictions.

- **Establishing a National Diagnostics Action Plan:** Even with extraordinary expertise within and outside of government and the accomplishments that have been made during the COVID-19 and Mpox PHEs, the United States does not have a plan to rapidly respond, develop, manufacture, 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. ACLA has coauthored with the Johns Hopkins Center for Health Security a proposal for a National Diagnostics Action Plan that we will urge Congress to adopt as part of PAHPA reauthorization. The proposal's recommendations include, but are not limited to:

  - 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 USG 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.

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 2023 advocacy agenda, please visit www.ACLA.com or email admin@ACLA.com.

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