American Clinical Laboratory Association

www.acla.com
Value of Diagnostic Innovation

Diagnostic tests are performed more than a billion times each year in the United States. There are thousands of different tests available today. Laboratory tests are developed and performed by thousands of authorized laboratories in the United States to help physicians diagnose diseases and assist them in deciding on a course of treatment.

Diagnostic testing is an integral and longstanding component of the practice of medicine and has made immeasurable contributions to public health and the treatment of chronic, complex, as well as rare diseases.
The Value of ACLA Membership

ACLA members represent the diversity of the clinical lab industry and include national, regional, esoteric, hospital, ESRD, anatomic pathology, skilled nursing facility and academic medical center laboratories.

ACLA represents its members before Congress and federal agencies, provides access to legislative and regulatory information on health care policies impacting clinical laboratories, and promotes communications strategies that educate consumers, policymakers and the greater health care community about the value of diagnostic testing. ACLA has a remarkable record of success in advocating on behalf of its members on legislative and regulatory issues impacting the coverage, payment and regulation of laboratory testing. ACLA members also benefit from interaction with other key leaders in the laboratory industry through ACLA’s programs, committees and meetings.
Our Mission

- Advocate for laws and regulations that recognize the essential role that laboratory services play in delivering cost-effective health care;
- Encourage the highest standards of quality, service and ethical conduct among our members;
- Promote public awareness about the value of laboratory services in preventing illness, diagnosing and treating disease, and monitoring medical treatment.
Our Experience & Leadership

ACLA members benefit from an association staff comprised of seasoned professionals with years of experience in health care policy, research, and analysis of regulatory and payment issues.

Providing expertise in the areas of issues advocacy, regulatory oversight and a historical perspective of research and diagnostic innovations performed in clinical laboratories across the country, ACLA staff is a “go-to” source for members on an array of policy provisions and regulatory measures impacting clinical labs.

Being an ACLA member has been very positive for Mayo Medical Laboratories. ACLA brings a deep knowledge and expertise regarding governmental regulation and reimbursement of laboratory tests that we could not have developed on our own. They are clearly responsive to the needs of clinical laboratories and are always up-to-date on the current issues that affect us. The services that ACLA provides are well worth the membership fee and more. ACLA also provides an interactive forum for clinical laboratory top management to discuss, collaborate, and develop strategies that can proactively address the regulatory challenges we face. Most importantly, the ACLA membership remains focused on always providing the highest value laboratory testing for our patients.

Curtis A. Hanson, MD
Professor and Chief Medical Officer
Mayo Medical Laboratories
Advocacy Priorities

The laboratory industry is facing unprecedented policy challenges, including comprehensive reform of the Medicare Clinical Laboratory Fee Schedule (CLFS) and proposed Food and Drug Administration (FDA) guidance to regulate laboratory developed tests (LDTs). ACLA is recognized as the lab industry’s leading advocate on these issues, as well as other important priorities.

ACLA’s lobbyists and policy experts understand the legislative process, as well as the inner workings of the complicated regulatory and payment structures that impact your lab’s bottom line.
ACLAs Top Advocacy Priorities Include:

- Fighting for fair and accurate Medicare reimbursement during implementation of PAMA market-based pricing provisions.
- Opposing unnecessary and duplicative regulation of LDTs as proposed by the FDA.
- Creating a regulatory and reimbursement environment that encourages innovation in molecular diagnostics and personalized medicine.
- Closing self-referral loopholes in anatomic pathology services to achieve program integrity.
- Articulating the value of clinical lab services to patients, payors, the health care system, and our national and local economies.
Accomplishments

- After ACLA submitted comments and organized a Congressional sign-on letter of more than 100 legislators, CMS dropped a proposal to cut Medicare payments for pathology services by as much as 75 percent in the 2014 Physician Fee Schedule.

- ACLA has successfully pushed back legislative proposals to impose coinsurance for laboratory services three times.

- ACLA built a coalition of supporters and organized a Congressional sign-on letter to pressure CMS to delay a physician signature requirement for laboratory requisitions. CMS ultimately rescinded this requirement.

- ACLA led legislative and legal battles that resulted in the repeal of competitive bidding of laboratory services in Medicare.

- ACLA has successfully advocated against FDA regulation of LDTs for over a decade. When the FDA announced its intention to issue guidance in this area, ACLA took the leadership role in opposing the proposal, testifying before Congress and speaking at a public forum in addition to submitting written comments.
Member Benefits

- Take an active role in advocating for the clinical laboratory industry before Congress and executive branch agencies, such as the FDA and CMS.
- Educate key legislative and regulatory policymakers on issues critical to the lab industry through meetings, conference calls, roundtables, media opportunities and other public forums.
- Serve on association committees that guide ACLA policy priorities.
- Receive real time updates on the latest news from Washington through weekly newsletters and email updates.
- Participate in member conference calls to hear issue updates and discuss strategies for advancing the lab industry’s agenda.
- Meet colleagues and key decision makers at the ACLA Annual Meeting and other forums.
Our Members

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Strategic Partnerships

- Alliance for Integrity in Medicare (AIM) Coalition
- The Personalized Medicine Coalition
- Diabetes Advocacy Alliance
- Clinical Laboratory Coalition
Join Us

Please contact Cheryl Hawkins at 202.637.9466 or chawk@acla.com