

# RESULTS

American Clinical Laboratory Association

VOLUME 13 • NUMBER 8

## President's Message

September has been a great month for ACLA, but the highlight had to be the introduction of Senate legislation repealing competitive bidding!

ACLA is grateful to Senators Salazar, Roberts, and Cantwell for sponsoring S. 2099, Preserving Access to Laboratory Services Act. The sponsorship of the bill is all the more meaningful because all of these Senators are members of the Senate Finance Committee which oversees Medicare. We continue to work toward enactment of this repeal language and are at a critical point in the drive to repeal competitive bidding. Everyone in the laboratory community (and beyond) can help by contacting their elected representatives in Washington. See the article on page 1 of this **RESULTS** for more information.

ACLA has also been a leading voice for the laboratory industry on the oversight of genetic tests. We have been communicating with Senator Obama for the past year about his legislation on the oversight of genetic testing, and were pleased to see his amendment enacted as part of the drug user fee legislation in October. In addition, ACLA continues to speak at various forums on this topic, including a recent summit sponsored by the Genetic Alliance.

We are all looking forward to a busy October, particularly the upcoming G-2 Lab Institute in Washington where we will unveil a terrific new eight minute DVD about the **Results for Life** campaign. ACLA and its members have no less than three speakers at the G-2! And, of course, we will sponsor our third annual "ACLA Meet & Greet" reception at the G-2 on Wednesday, October 10, from 3:30 to 5:30 p.m.

Before closing, I wanted to thank our fantastic staff at ACLA – JoAnne Glisson, David Mongillo, Jason DuBois, Cheryl

Hawkins, and Kathryn Froelich – for their terrific work on behalf of ACLA and its members! All of the above successes are largely the result of their hard work. I continue to boast that ACLA has the best, most experienced, and productive professional team of any industry association in Washington. While on this topic, I want to report that this will be Kathryn Froelich's last month at ACLA and **Results for Life**. We all wish her well.



Alan Mertz, President - ACLA accepts National Cervical Cancer Coalition Award, September 14, 2007 (see page 2).

## Senators Introduce Repeal Legislation, House Bill Gains Momentum

On September 26th, Senators Ken Salazar (D-CO) and Pat Roberts (R-KS) introduced the Preserving Access to Laboratory Services Act of 2007, S.2099, which would repeal the Medicare competitive bidding demonstration project for clinical laboratory services. Senator Maria Cantwell (D-WA) joined as an original co-sponsor of the bill. All three Senators serve on the Senate Finance Committee, the committee with jurisdiction over Medicare and the laboratory competitive bidding demonstration project. Similar legislation, H.R.

RESULTS is a monthly report to ACLA member companies

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3453, was introduced by Small Business Committee Chairwoman Nydia Velazquez (D-NY) on August 4, 2007.

In related news, the House bill is gaining momentum with the addition of three House Energy and Commerce Health Subcommittee members joining as co-sponsors: Reps. Diana DeGette (D-CO), Bart Gordon (D-TN) and Jim Matheson (D-UT). In addition, Congressman Charles Boustany (R-LA), one of only a few physicians in Congress, also joined as a co-sponsor of H.R. 3453 thereby making the bill bipartisan.

Several ACLA members have contacted their Senator or Representative, yet more work remains before a legislative repeal of the competitive bidding demonstration project becomes a reality. A concerted effort by ACLA members, their employees, and the rest of the clinical laboratory industry is needed to garner more support among Members of Congress. Sample letters that can be addressed to your Senator and/or Representative are available on the ACLA website at [www.clinical-labs.org](http://www.clinical-labs.org) (an official copy of the bill is also available). Write, call, fax or email your Member of Congress today and ask them to co-sponsor H.R. 3453 in the House or S.2099 in the Senate!

### **ACLA Supports CMS Response on Genetic Specialty**

In an August 15, 2007 letter, the Centers for Medicare and Medicare Services (CMS) concluded that they can more effectively oversee genetic testing under existing Clinical Laboratory Improvement Amendments (CLIA) regulations and that the arguments and evidence do not justify rulemaking to establish a new genetics specialty under CLIA. CMS's letter was in response to a citizens' petition to create a "genetic testing specialty" under CLIA. In a September 5th press release, ACLA applauded the CMS decision.

The CMS letter stated that under existing regulations, all laboratories performing genetic testing of moderate or high complexity must maintain the accuracy of their testing procedures, and at least twice annually verify the accuracy of any genetic test or

procedure they perform. CMS further stated their intent to continue to ensure that laboratories fulfill their regulatory obligations to meet these and related CLIA quality requirements. The agency stated it will continue to apply existing quality control and other CLIA requirements to genetic testing and monitor further developments in the field of genetics.

ACLA has long advocated strict enforcement of CLIA standards to ensure the accuracy and reliability of all testing performed by CLIA certified laboratories. ACLA believes that CMS' ongoing efforts to enhance the oversight of genetic testing is the most appropriate approach to maximizing the benefits to patients of this promising new technology.

### **ACLA Requests Separate Lab Seat on AHIC Successor**

ACLA responded to the Department of Health and Human Services Federal Register notice requesting comment on the design and implementation of the American Health Information Community (AHIC) successor. ACLA urged that any AHIC successor entity expand representation to establish separate laboratory and pharmacy seats due to the absolutely central roles that laboratory and pharmacy data each serve in the medical record. ACLA reinforced the importance of a separate laboratory seat on AHIC because laboratory data are the 'keystone' to the medical record – electronic or otherwise. ACLA's comment letter is posted on the ACLA web site.

### **Short Updates**

#### ***Results for Life* Receives Award**

The National Cervical Cancer Coalition (NCCC) recognized the *Results for Life* value campaign, for "the education program and the excellent job in raising awareness about the importance of laboratory testing which allows clinicians to have tools for accurate prevention, early detection, and enhanced management of disease." NCCC is a coalition of women, family members and caregivers battling cervical cancer issues. They promote grassroots efforts to educate the public about cervical cancer prevention and outreach.

In accepting the award, on behalf of the members of ACLA and the sponsors

of *Results for Life*, Alan Mertz, President of ACLA, communicated to the NCCC audience "I certainly do not have to impress upon any of you the value of laboratory testing. You have first hand knowledge of the importance of the Pap test and HPV testing – lab tests which allow physicians to identify cervical cancer early; thus 'changing the course of disease'."

ACLA launched a national campaign called *Results for Life* to communicate the value of laboratory services to help deliver the message that clinical lab tests can reduce health care costs through prevention, early detection, and management of disease. The message is particularly relevant because lab tests are only a small fraction of overall health care spending but influence as much as 60 to 70 percent of medical decision-making. *Results for Life* is supported by ACLA members and laboratory professional groups, physician groups, as well as laboratory test and equipment manufacturers – see [www.labresultsforlife.org](http://www.labresultsforlife.org).

### **Don't Miss the *Results for Life* DVD, to be released and shown during:**

ACLA's Meet and Greet at the Washington G2 Conference

Wednesday, October 10, 2007  
3:30 - 5:30 p.m.

Crystal Gateway Marriott  
The Mt. Vernon Room  
1700 Jefferson Davis Highway  
Arlington, VA 22202

Please R.S.V.P. to Cheryl Hawkins  
(202-637-9466 ext. 10 –OR–  
[chawk@clinical-labs.org](mailto:chawk@clinical-labs.org))

### **ACLA Pleased with Genetic Test Amendment to Drug User Fee Legislation**


President Bush signed into law on September 25th, a bill that will expand Food and Drug Administration oversight of prescription drug safety and reauthorize the Prescription Drug User Fee Act. Of interest to the clinical laboratory community was an amendment to the legislation titled "Section 1103, Improving Genetic Test Safety and Quality.

This amendment was originally part of a legislative proposal by Senator Barack Obama (D-IL) that would require the HHS Secretary to enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. An addition to the amendment would allow for the Secretary's Advisory Committee on Genetics, Health, and Society report on the Regulatory Oversight of Genetic/Genomic Testing to serve in lieu of the IOM study if it is provided to the Secretary by July of 2008.

### ACLA Comments on MUE Disclosure

ACLA communicated in a September 25th letter to Correct Coding Solutions (CCS) that there should be full public disclosure of Medically Unlikely Edits (MUEs). ACLA's comment was in response to an inquiry from CCS on behalf of the CMS requesting ACLA's perspective on publicly releasing MUEs.

ACLA acknowledged that it recognizes the purpose of MUEs to lower Medicare's paid claims rate through identification of obvious billing and typographical errors but sees no inconsistency with that goal by making the final MUEs public. ACLA considers MUEs in the same category as NCCI edits which are fully disclosed to the public. Secondly, an added burden accrues without public MUE disclosure. Because there is no claims denial remark code indicating an MUE denial, it is important to publish and to have a remark code specific to MUEs. Those who process claims and claims denials will not know why the claim was denied and will only become aware of the denial as an MUE issue through consideration of all the other denial possibilities – clearly a needlessly burdensome requirement. Thirdly, providers will not be able to appropriately apply a modifier to a service unless one knows the MUE. Having full knowledge of the MUE will allow claims to be submitted per the rules established by CMS. This will in turn reduce the denial process for both CMS and the providers.



**ACLA'S LABLINE** KEEPING YOU CURRENT

**Results for Life Value Campaign**

**What Is It and Why You Should Care**

**FREE REGISTRATION!**

ACLA LABLine Audioconference  
Thursday, November 1, 2007  
2:00 - 3:30 p.m. Eastern

**Results for Life Value Campaign**  
**What is It and Why**  
**You Should Care**

Marc Grodman, M.D.  
BioReference Laboratories, Inc.

Gerald McAteer  
Siemens Medical Solutions Diagnostics

Mary Jo Bonifas  
United Clinical Laboratories

Sign up at [www.clinical-labs.org](http://www.clinical-labs.org)

### ACLA in the News

#### National Intelligence Report

September 24, 2007

#### *Lab Value Educational Campaign Marks More Milestones*

Dovetailing with intensified lobbying on Capitol Hill against Medicare's competitive bidding demonstration for laboratory services, the **Results for Life** campaign, spearheaded by the American Clinical Laboratory Association, is moving ahead with its effort to continue to educate lawmakers and the public about the value of lab testing in diagnostic and preventive medicine. One goal is to make lawmakers "think twice" about any further cuts in Medicare fees for lab services. **Results for Life** has sent a communication package to staff of members of Congress, explaining how lab tests contribute to quality, cost-effective care. This will be followed, says ACLA's newsletter *Results* in the September issue, by meetings with members, in particular those who have an ACLA member headquartered or a **Results for Life** supporting sponsor in their district. The initiative also continues to recruit and train lab professionals as "ambassadors," ACLA said, to spread the word to decision-makers and community leaders in their locale. Most recently, Alan Mertz, ACLA president, accepted an award from the National Cervical Cancer Coalition on behalf of ACLA members and the **Results for Life** campaign. The coalition promotes grass-

roots efforts to educate the public about cervical cancer prevention and outreach. In accepting the award, Mertz said, "I certainly do not have to impress on any of you the value of lab testing. You have firsthand knowledge of the importance of the Pap test and HPV testing, which allow physicians to identify cervical cancer early, thus 'changing the course of disease.'" ACLA officially rolled out **Results for Life** at a Capitol Hill special event earlier this year, with Rep. Charles Rangel (D-NY), chairman of the House Ways & Means Committee, as a featured speaker. Rangel's panel has key jurisdiction over lab payment and policy issues. The campaign also recently released a new consumer fact sheet pointing to gains in testing children for blood lead levels. Use of a \$17 lab test, the brochure noted, has led to a 98% drop in blood lead levels in children over the past 30 years, making this one of the most significant public health achievements of the 20th century. Lead poisoning destroys brains and causes mental retardation, nerve damage, and reduced IQ, but lab tests allow doctors to identify lead poisoning and stop it. In particular, notes the brochure, the blood lead test has been a key factor in saving the lives and minds of countless youth. By protecting a child from the harmful effects of lead, their IQ and mental capacity are preserved, allowing for success in school, personal esteem, and employment. Other lab tests that provide vital information include:

- Iron deficiency tests that evaluate the level of iron in the blood and the cells of the body. Lead can disrupt absorption of iron.
- Hemoglobin and hematocrit tests that indicate whether a patient has anemia, which can be caused by iron deficiency.
- Zinc Protoporphyrin, which evaluates the level of zinc in red blood cells, which can suggest iron deficiency caused by lead poisoning.

Additional brochures in the education series have highlighted the role of lab testing in HIV diagnosis, treatment, and monitoring ("From Killer to Chronic Disease") and in diabetes care management ("Changing the Course of Diabetes"). **Results for Life** is especially important, ACLA president Alan Mertz has noted, as healthcare is being transformed by scientific advances in gene- and protein-based testing. While lab tests make up

## ACLA in the News *(continued)*

only a small portion of overall healthcare spending, they influence as much as 60% of the patient's medical record. The initiative is structured as a 501(c)(3) educational entity, facilitating partnering with other organizations, ACLA notes, including Bayer, Roche, Sysmex, the College of American Pathologists, the American Society for Microbiology, and the American Association for Clinical Chemistry, and others are in the wings. The campaign is important, ACLA board member Marc Grodman, MD, told NIR as the campaign was getting underway. Grodman, who is president of Bio-Reference Laboratories, Inc., in Elmwood Park, NJ, noted that the messages are conveyed in real-life stories that can strike a "resonant chord" with legislators and the public. Labs have nothing to apologize for by doing good work, he emphasized, but need to get the "value" message across at the local level and have it filter up to the national scene. Response has been very positive to date, he said.

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### **G-2 Compliance Report** – October 2007

*ACLA, CAP Advocate Separate "Lab Seat" in New E-Health Entity*

"As the Department of Health and Human Services (HHS) prepares to shift responsibility for development of a nationwide exchange system for personal e-health records to a new public-private partnership, the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP) are urging that laboratory services be given a separate seat in the entity that will succeed the American Health Information Community (AHIC)." "This is a chance to 'correct the wrongs of the past,'" says Jason DuBois, ACLA vice president of government relations. He notes that labs had sought their own representation on AHIC before its primary members were chosen, but in the end were lumped with pharmacy under 'ancillary services.'"

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### **National Intelligence Report** – September 10, 2007

*CAP, ACLA Continue Challenge to FDA on Lab-Developed Tests*

"In late July, the Food & Drug Administration issued some changes to its revised draft guidance requiring, for the first time, premarket review of certain types of lab-developed tests (LDTs), known as in vitro diagnostic multivariate index assays (IVDMIA). The deadline for comments on the latest version ended August 27, and the College of American Pathologists and the American Clinical Laboratory Association again registered fundamental concerns with FDA's expanded oversight of these genetic and other testing services and with its definition of IVDMIA, which they contend is still too subjective and open to conflicting and confusing interpretations."

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## Calendar of Events/Meetings

October 1	ACLA PODs Call	Conference Call
October 4	Health IT Call	Conference Call
October 5	ACLA Member Weekly Call	Conference Call
October 5	ACLA PR Committee/Results for Life Committee Meeting	Conference Call
October 8	ACLA Office Closed - Columbus Day	
October 8	Clinical Laboratory Coalition Meeting	Conference Call
October 10	ACLA Billing Committee Meeting	Washington, DC
October 10	ACLA "Meet and Greet" Reception at G2 Conference	Arlington, VA
October 11	Jason DuBois - Presentation at G2 Conference	Arlington, VA
October 11	Alan Mertz - Presentation at G2 Conference	Arlington, VA
October 12	ACLA Member Weekly Call	Conference Call
October 13	Dr. Marc Grodman - Presentation at G2 Conference	Arlington, VA
October 17	ACLA CPT Committee Call	Conference Call
October 19	ACLA Member Weekly Call	Conference Call
October 22	ACLA Board of Directors Meeting	Washington, DC
October 23	EHR Workgroup Meeting	Washington, DC
October 26	ACLA Member Weekly Call	Conference Call

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