

# RESULTS

American Clinical Laboratory Association

VOLUME 14 • NUMBER 8

RESULTS is a monthly report to ACLA member companies

## In This Issue

- President's Message (p. 1)
- *Results for Life* Primer (p. 1)
- New Associate Membership (p. 2)
- Reimbursement Issues (p. 3)
- ACLALABLine (p. 3)
- ACLA in the News (p. 4)
- Calendar (p. 4)

### ACLA Staff

**Alan Mertz**, *President*  
**JoAnne Glisson**, *Senior Vice President*  
**David Mongillo**, *Vice President for Policy & Medical Affairs*  
**Jason DuBois**, *Vice President, Government Relations*  
**Cheryl Hawkins**, *Membership Coordinator*  
**Kimberly Bernet**, *Executive Assistant*  
**Peter Kazon**, *Legal Counsel*

202-637-9466  
 www.clinical-labs.org

### President's Message

Will 2009 be the year of major health care reform, or will record deficits and the economic crisis push reform to the sidelines? What will be the impact of a new President and larger Democrat majorities in Congress on laboratory reimbursement and regulation?

These were some of the questions posed for our November 12th "LABLine" audio conference on the election and what it means for health care reform and laboratory issues. We had plenty of expertise on hand to make predictions, including a key player in the Presidential transition on health care, Chris Jennings.

Chris Jennings took exception with the commentators and pundits by arguing that next year may, indeed, be the year for health care reform. He argued that most major legislation is passed in a time of crisis and that the economic crisis – with higher unemployment and more uninsured Americans – will drive reform. Importantly, he also contends that the forces that doomed reform in the early 1990's – employers – no longer oppose greater government intervention.

Our resident Republican consultant, Dean Rosen, raised some doubts about the prospects of major health reform due to competing economic priorities and record deficits.

All of our panelists emphasized the need for the laboratory community to educate Congress and the new Administration on the value of laboratory services and the critical role they play in providing the highest quality health care.

The other event that I must mention is the "Primer on Genetic Testing" that *Results for Life* sponsored on October 28 for media and policymakers. This was one of the best briefings I have ever attended, and the response from the audience was universally positive. We are going to reproduce this briefing in several forms, including a special LABLine on December 4th.

The ACLA Board met on November 7 and had a productive session planning for 2009.

Finally, we announced the new ACLA Associate Member program in November, and I'm pleased to announce the first to join this great new program, Roche Diagnostics Corporation.

### RFL Primer Explains Genetic Testing for the Media, Policymakers

Facts matter — especially on issues as critical as genetic testing.

That was the motivating force behind the *Results for Life* briefing—"A Primer on Genetic Testing: What Is It? How Does It Work? Why Does It Matter?"—that was held on October 28, 2008, at the National Press Club in Washington, DC. The goal was to provide policy leaders and the news media with facts about how genetic testing is enabling better, more effective care in a wide range of diseases, including leukemia, HIV, and cardiovascular disease.

In all, some 43 individuals attended, representing a broad cross-section of Congressional staff, Washington decision makers, and media from both the national and trade press. Session presentations, along with many questions from the audience, centered on how genetic testing is being used today in front-line medical care delivered in hospitals, clinics, and other medical facilities.

"The misconceptions around genetics abound," said ACLA President Alan Mertz in opening the session. "If Americans were to rely solely on popular culture to acquire their knowledge about it, they would think that the purpose of genetic testing is to help CSI labs catch criminals," said Mertz. "Those who acquire their knowledge from major media stories might see these tests as 'unproven, unnecessary, and unregulated'—an actual headline from a story about genetic testing. In reference to massive media coverage of direct-to-consumer internet tests, he reminded attendees that genetic testing is much more "front-line than online."

The session focused primarily on two podium presentations. Sherri Bale, PhD, Co-Founder, Gene Dx, presented "What Is Genetic Testing, and What is its Value?" She communicated—by categories and through examples—various forms of genetic testing. Gail Vance, MD, Department of Medical and Molecular Genetics at Indiana University School of Medicine, presented "Genetic Testing in Genomic Medicine," emphasizing the various uses of genetic tests in healthcare today. Both presentations reinforced the importance of genetic testing in accelerating the delivery of personalized healthcare.

Moderator John Iglehart, Washington Correspondent for the New England Journal of Medicine, opened the program to questions for the presenters, as well as three panelists. They included Sharon Terry, President and CEO, The Genetic Alliance; Victoria Pratt, PhD, Chief Director, Molecular Genetics, Quest Diagnostics; and Jamie McDonald, Licensed Genetic Counselor, Co-Director, Hereditary Hemorrhagic Telangiectasia Center, University of Utah and ARUP Laboratories.

In response to a question about whether the protections in the Genetic Information Non-discrimination Act (GINA) are adequate, the panelists noted that the passage of GINA took 13 years and was, thus, fully vetted. In response to a question about whether greater public availability of DTC genetic tests required additional oversight, one panelist noted that—as such tests become more available to the public—it is especially important that they provide value and information that physicians and consumers can act upon in making medical decisions.

One attendee reiterated the importance of genetic testing in reducing healthcare costs and, thus, the importance of educating medical students about it. The panelists noted that government and non-government based programs, such as the National Coalition for Health Professional Education in Genetics, are actively promoting increased education. A further suggestion was to target CME on genetics to help existing practitioners. With regard to research funding, the panelists commented that NIH and federal funding is the most crucial driver of innovation in the field. It was also noted, however, that adequate reimbursement for genetic test services is needed to enhance research and investment in new technology.

When a question was posed as to how the public can determine if a test is ready for “prime time,” panelists said consumers can look for several things. First, the test should come from a CLIA-certified laboratory in which a medical director is responsible for ensuring the test is developed based upon sound medical knowledge. Second, the test should be ordered with the assistance of a knowledgeable healthcare professional who can assist with its interpretation. Third, if claims about the test are exaggerated, it should be reviewed by the Federal Trade Commission. Finally, the public can also look to scientific publications and professional society guidelines.

The session closed with an overall question posed by moderator John Iglehart. That is: What is the most important message about genetic testing that is not being communicated to the public and providers? The consensus answer from the panel was the value

of genetic testing in real-world health care delivery. They pointed out that such value sometimes gets lost in articles focusing on recreational genetic tests. They added that everyone in the genetic testing field has a responsibility to communicate the value of genetic tests as being integral to more targeted and predictive healthcare.

An audio recording of the briefing, along with the slide presentations and related materials, is available at the **Results for Life** website, [www.labresultsforlife.org](http://www.labresultsforlife.org).

There has already been one article as a result of this Primer—Spotlight on Genetic Testing in Front-Line Health Care, published by the Washington G-2 National Intelligence Report. While there will be more media coverage to come, our longer term objective was served in that reporters left the primer with tools to write more informed articles when reporting on genetic testing and genomic medicine. It is our hope that a solid foundation of knowledge in this complex field will foster balanced coverage and slow the negative media surrounding genetic testing.

**Results for Life** was also front and center in The Hill newspaper this month with both a front page banner advertising the organization and the primer with a corresponding ad inside the paper. These placements were both successful in drawing key hill staffers and policy makers to the event.

Looking forward to 2009, **Results for Life** will be ramping up for a very robust year. The campaign has plans to shift toward objective data and white papers, putting a fresh spotlight on the lab industry. These materials, coupled with additional op-eds and hill events will fuel a vigorous front up on Capital Hill with new staffers and a new congress. There will also be a reemphasis in 2009 on higher-level media coverage including radio, print, and television media outlets.

Be on the look out for a **Results for Life's** new E-Newsletter. The publication will be a quick update on activities to keep participants, sponsors, and the public more informed and up to date on activities and events.

We are extremely pleased with the success of 2008 and are excited to carry through the momentum and gain new ground in the coming year.



*Results for Life Primer at the National Press Club, October 28, 2008.*

## ACLA Announces New Associate Memberships

ACLA is now offering a limited number of Associate Memberships to non-laboratory companies, firms, and organizations to participate and benefit from ACLA's advocacy, education, and collaborative programs. Associate Members of ACLA will receive the latest information on legislative and regulatory issues directly impacting laboratories, the opportunity to meet with leaders of national, regional, esoteric and other laboratories, participate in a special ACLA Associate Member Council, exhibit at the ACLA Annual Meeting, participate for free in LABLine Audio conferences, sponsor and help guide the “**Results for Life**” educational campaign, and many other benefits. Associate ACLA members will also be recognized in ACLA's programs, website, and publications.

The Associate Members Council is now forming. The Council will hold its first meeting with ACLA's Chairman and officers in January 2009, and interested organizations are encouraged to apply now for this special membership. Associate Member annual dues are based on revenues for “for-profit companies” with set fees for professional service firms (legal, consulting, investment) and nominal fees for non-profits. One half of the annual dues for larger companies will be contributed to the “**Results for Life**” educational campaign, a 501©3 organization.

ACLA's members represent the diversity of laboratories in the United States and include the leading national, regional, specialized and ESRD laboratories. The association is governed by a nine-member Board of Directors representing all of these major types of laboratories. ACLA members meet the highest standards in laboratory medicine today as they are required to be CLIA certified laboratories as well as accredited by the College of American Pathologists (CAP) or an equivalently rigorous accreditation organization. Those full membership requirements stand.

Interested companies and organizations may request more information by contacting Cheryl Hawkins at ACLA – (202) 637-9466, [chawk@clinical-labs.org](mailto:chawk@clinical-labs.org).

**ACLA is proud to  
announce its first  
Associate Member!**



## Reimbursement Issues Update

### *Date of Service*

On October 20, ACLA, the 21st Century Coalition and executives from two ACLA member companies met with senior HHS officials and Kerry Weems, Acting Administrator of CMS to urge a change in current Medicare regulations governing reimbursement for specimens collected during the course of a hospital visit. Current rules provide that if a test is performed by a reference laboratory on a specimen that was collected during a hospital visit, the laboratory performing the test must bill the hospital for the service, rather than billing Medicare directly, even though the test is performed after the patient leaves the hospital. The one exception to the rule is if the test is ordered at least 14 days after the patient's discharge.

At Acting Administrator Weems' request, we provided both regulatory and transmittal language to resolve the issue. Our suggested language would establish the date of service as the date the test was performed, that the change be limited to genetic, genomic, proteomic or cancer chemo-sensitivity laboratory tests and that the results of the test do not guide treatment provided during the hospital visit in which the specimen was collected.

### *Requirements for Verification of Physician Orders*

On August 29, CMS issued revised contractor instructions confirming that physician signatures are not required on lab requisitions. An earlier instruction issued in January 2008 had led Medicare contractors to challenge reimbursement for lab claims where requisitions were not signed by ordering providers. The revised instructions reinstated long standing CMS policy that the ordering provider must clearly document, in the patient's medical record, his or her intent that the test be performed.

Subsequently, at least one laboratory has been contacted by the CMS audit contractor who is now requiring the laboratory to obtain the medical record from the ordering provider to determine whether the laboratory claim is payable. This is contrary to longstanding CMS policy confirmed by the preamble to the final rule implementing negotiated rulemaking that CMS, not the laboratory, should confirm the order using the medical record. ACLA outside counsel, Alston and Bird, has contacted the audit contractor challenging their authority to require labs to obtain patient medi-

cal records and requesting a meeting. The audit contractor immediately forwarded the letter and request to CMS for follow-up. CMS has agreed to meet with ACLA to discuss our concerns.

### *Advance Beneficiary Notices*

ACLA has written to CMS to request a meeting to discuss proposed language to address good faith efforts to provide cost estimates to beneficiaries signing ABNs. On September 5, CMS published official Medicare manual instructions for use of the revised Advance Beneficiary Notice (ABN) form with the implementation deadline of March 1, 2009. The final instructions did not include earlier language allowing for good faith attempts to estimate cost "particularly in consideration of cases where the ordering and rendering providers may be different." ACLA is preparing educational material for ordering providers which we hope to share with CMS and obtain their approval.

### *ICD-10*

On October 21, ACLA submitted comments on two sets of proposed CMS rules, one implementing HIPAA standard 5010 and a second that would modify the medical data code set standards to adopt ICD-10 with October 2011 as the target date for both sets of changes. The proposed rules require implementation of the 5010 standard by April 2010 and ICD-10 by October 2011, making unavoidable an unworkable overlap in the two rules at enormously and unnecessarily excessive costs to the government and every sector of the health care delivery system. Laboratories, because they are positioned at the crossroad between payers and direct providers who must pro-


vide correct diagnosis codes on their orders, will find themselves doubly challenged – not only the challenge of educating ordering providers on the new coding system but of making separate and massive system changes simultaneously.

In our comments, ACLA asked that CMS provide two years from date of enactment for implementation of 5010. We urged CMS to exempt labs from the requirement to implement ICD-10. If CMS would not agree to exempt labs, CMS should not require labs to code to the highest degree of specificity. If labs are required to implement ICD-10 at all, CMS should provide three years from final implementation of the 5010.

ACLA is a member of a coalition comprised of the payer community, provider groups including the AMA and others seeking a more reasonable five year time frame for accomplishing the shift to HIPAA standard 5010 and the ICD-10 code set.

### *Changes to Anti-Markup Rule*

On October 30, CMS issued the 2009 Physician Fee Schedule Final Rule which included changes to the anti-markup rules for diagnostic tests. The new changes create several significant loopholes in existing policy that will make it easier for physicians to markup diagnostic services, thereby increasing utilization and driving up costs. ACLA is urging CMS to clarify that long-standing rules that restricted the ability of physicians to markup "purchased" diagnostic tests will continue to apply, regardless of who is performing or supervising the service. In addition, ACLA believes CMS should act quickly to ensure that all diagnostic services, including pathology services, are supervised by physicians with appropriate training and experience.



ACLA  
American  
Clinical Laboratory  
Association

## ACLA'S LABLINE

KEEPING YOU CURRENT

### GENETIC TESTING: WHAT IS IT? HOW DOES IT WORK? WHY DOES IT MATTER?

GET THE MOST TIMELY AND UP-TO-DATE INFORMATION ON THIS IMPORTANT TOPIC

**Thursday, December 4, 2008 • 2:00 - 3:30 pm (Eastern)**

**SPEAKERS:**  
**Gail Vance, MD, Indiana University School of Medicine**  
**Sherri Bale, PhD, Gene Dx**  
**Sharon Terry, The Genetic Alliance**  
**Jamie McDonald, MS, University of Utah and ARUP Laboratories**

**FREE to everyone, but you must register to participate.**

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

## ACLA in the News

**National Intelligence Report** - October 13, 2008  
*Medicare Publishes Edits for 'Medically Unlikely' Services*

The College of American Pathologists and the American Clinical Laboratory Association were among the many medical groups that have long urged CMS to disclose the MUEs. This is essential, they have told the agency, if providers are to submit accurate claims and avoid unwarranted denials. Otherwise, providers will not know when to apply an appropriate modifier to bypass the edit, and efforts to educate providers on MUEs and modifier use would be stymied.

*Medicare Claims Advisory: Physician Signature Policy Updated for Lab Test Orders*

Following through on its promise months ago to the American Clinical Laboratory Association, the Centers for Medicare and Medicaid Services has instructed its contractors to implement corrections to Medicare's physician signature requirements for lab claims, as of Sept. 30 (Change Request 6100). ACLA earlier this year alerted CMS that many of its member labs were receiving documentation requests from the CERT contractor for the physician's signature on both paper and electronic claims; without it, the contractor would recommend that the claim be rejected. "When the lab reports that no such document exists—nor is it required—the lab is told the testing is inappropriate. This [has happened] not only when the testing is ordered on paper (where there is no signature requirement), but even when the test is ordered electronically, where, of course, no physician signature would be expected to exist," ACLA said. Unless the situation is corrected, ACLA said, "virtually every lab in the country is at risk for millions in recoupment," going back as much as five years. CMS agreed with ACLA that according to national policy established via the congressionally mandated lab negotiated rulemaking, while a signed requisition would be proof of the treating physician's order, there are other permissible ways to document it. CMS instructed the CERT contractor to accept documentation of the treating physician's order in any format that clearly conveys the physician's intent that the test be performed. CMS also told ACLA it would update the Medicare Benefit Policy Manual to correct instructions released earlier this year (Change Request 5743, Jan. 11) which omitted the text stating that requisitions need not be signed.

**National Intelligence Report** - October 27, 2008  
*CMS Challenged Over Preliminary Fees for New Lab Codes*

Clinical laboratory and pathology organizations have strongly objected to preliminary payment rates that the Centers for Medicare and Medicaid Services has set for new CPT codes to be added to the 2009 Part B lab fee schedule, effective Jan. 1. In its comments to the agency, the American Clinical Laboratory Association said, "If CMS is going to reject all of the recommendations that were made by industry representatives, then CMS should, at least, explain why its determinations are preferable to those proposed by all of the outside organizations who have the greatest experience and expertise in this area."

*More Time Needed for ICD-10 Switch, Say Provider Groups*

According to a study commissioned by 11 health care provider groups, including the American Clinical Laboratory Association, the costs for the transition in such a short time are "markedly higher than what [the government] has estimated and will place a major burden on providers, taking valuable time away from patients and straining other resources needed to invest in health information technology." For a 10-physician practice, the estimated cost is more than \$285,000; for a three-doctor practice, \$83,290; for a 100-doctor practice, more than \$2.7 million.

**National Intelligence Report** - November 10, 2008  
*Spotlight on Genetic Testing in Front-Line Health Care*

Against the backdrop of evolving federal policy, the nonprofit group, *Results for Life*, held an Oct. 28 briefing to answer three main questions on genetic testing: What is it, how does it work, and why does it matter? The group is composed of laboratory professionals, clinical labs, and test manufacturers. The briefing, held in Washington, D.C., featured experts who discussed the science, economics, and policy issues surrounding genetic testing. The vast majority of genetic tests are used in front-line delivery to improve diagnosis and treatment for such conditions as HIV, cancer, and cardiovascular disease, *Results for Life* noted in a statement, while online direct-to-consumer genetic testing is a tiny segment the market.

## Calendar of Events/Meetings

November 17-21	Alan Mertz and David Mongillo California Lab Tour	Various cities in California
November 19	CPT Committee Meeting	Conference Call
November 19	EHRA Meeting	Conference Call
November 19	CPT Committee Meeting	Conference Call
November 20	Billing Committee Meeting	Conference Call
November 20	IOAS Meeting	Conference Call
November 24	ACLA-Coalition Update Call	Conference Call
November 27-28	Thanksgiving Holiday - ACLA Office Closed	
December 1	Clinical Lab Coalition Meeting	Conference Call
December 4	ACLA LABline on Genetic Testing	Conference Call
December 4	Health IT Data Standards Meeting	Conference Call
December 4	IOAS Meeting	Conference Call
December 5	ACLA Weekly Call	Conference Call
December 5	Results for Life Meeting with Nat'l Alliance for Hispanic Health	Washington, DC
December 8	Alan Mertz at Quest Diagnostics Incorporated	Madison, NJ
December 9	Clinical Laboratory Coalition Planning Meeting	Washington, DC
December 11	FDA Committee Meeting	Conference Call
December 12	ACLA Weekly Call	Conference Call
December 12	Results for Life Committee Meeting	Conference Call
December 17	CPT Committee Meeting	Conference Call