



RESULTS

American Clinical Laboratory Association

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President's Message

RESULTS is a monthly report to ACLA member companies

In This Issue

- President's Message (p. 1)
- Comp. Bidding Repeal (p. 1)
- Comp. Bidding Leg. (p. 2)
- POD Lab Legislation (p. 2)
- Physician Signature (p. 2)
- Ionized Calcium (p. 2)
- Genetic Tests (p. 2)
- AHIC Successor (p. 3)
- Florida Medicaid (p. 3)
- ACLA LABLine (p. 3)
- **Results for Life** (p. 3)
- ACLA in the News (p. 4)
- Calendar (p. 4)

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As I write this message, we are putting the final touches on ACLA's 13th Annual Meeting, "Laboratories: Rx for the Future!," April 17-18. If you have not registered yet, there are a few precious seats left! The speaker line up is perhaps our best yet.

There is plenty about our key issues inside this *Results*, but, I wanted to use "my space" to recognize a few special people who have contributed so much to ACLA, and whose roles are changing.

First, Ron Weiss, President and COO of ARUP Laboratories, will complete his second two year term as ACLA Chairman of the Board on April 17. It's no accident that ACLA has seen its membership grow, has had a string of advocacy wins, is more visible than ever, and has successfully launched the *Results for Life* Campaign during Ron's tenure!

Ron has that perfect leadership balance of being involved, supportive, and always available, while giving the ACLA staff the latitude to execute the day to day work as it sees fit. His experience as a pathologist, as part of senior management of a major laboratory, as well as with ACLA have combined to make Ron a terrific chairman.

But, Ron is in no way "retiring" from his leadership role at ACLA. We are thrilled that he will be chairing ACLA's Public Relations Committee that oversees the *Results for Life* campaign, as well as continuing to serve on the ACLA Board. Thank you Ron!

ACLA's Board will continue to have strong and involved leadership when Marc Grodman, President, CEO and Chairman of Bio-Reference Laboratories takes over as Chairman in April. Marc also has the kind of experience that makes a great leader of the Board, as he is a practicing physician, head of a growing laboratory, and is a very active ACLA Board member. Marc was the chairman of the ACLA PR committee that developed the *Results for Life* campaign.

Before closing, I also want to recognize one of ACLA's longest serving Board members, Gary Hilburn, President of Acadiana Medical Laboratories (AML). Gary has represented so well the interests of small laboratories on the Board. Also, amazingly, Acadiana Medical Laboratories is the last original ACLA member that has remained under the same name! Gary, and Reggie Ringuet, AML's long-standing counsel, have contributed so much to ACLA over the years. Now that AML has been acquired by LabCorp, Gary will not technically be on the Board after April, but he will continue to be a part of the ACLA "family!"

Competitive Bidding Update: Repeal Efforts Continues

Efforts to repeal the competitive bidding program continue on Capitol Hill with the looming announcement date of April 11th fast approaching (CMS has indicated that winners and losers will be chosen April 11th for San Diego, CA). In recent weeks ACLA and members of the Clinical Laboratory Coalition have been meeting with Members of Congress on the committees of jurisdiction in an effort to expand the list of supporters of legislation pending in the House and Senate to repeal the competitive bidding demonstration project.

At press time, the Community Clinical Laboratory Fairness in Competition Act of 2007, HR 3453, has 37 co-sponsors; the Senate bill, Preserving Access to Laboratory Services Act of 2007, S 2099, has 7 co-sponsors.

Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Charles Grassley (R-IA) have agreed to proceed directly to the floor of the U.S. Senate, eschewing a formal mark-up of any Medicare bill in the Senate Finance Committee. The timing for consideration on the floor of the Senate remains the same – the first two weeks of May.

Recent Litigation Developments of Lab Interest - Competitive Bidding/POD Labs

[As we were going to press on this issue of Results, the court issued an order on April 4th on the San Diego Competitive Bidding Demo stating that the court did, indeed, have jurisdiction and that the plaintiffs do have standing.] There are two pieces of litigation that ACLA has been following. First, several laboratories in the San Diego area have sued to stop the Medicare competitive bidding demonstration. They filed a request for a temporary restraining order, which was denied by Judge Thomas J. Whelan in February. The parties then refiled for a preliminary injunction, and requested that the judge halt the announcement of winners before April 11, the date when winners are scheduled to be announced, and prohibit CMS from using the bids for any purpose. An oral argument before the judge on the preliminary injunction request has been scheduled for Tuesday, April 8, 2008. It is expected the judge will rule shortly after that time.

The judge's action could take three different forms. First, he could determine that he does not have jurisdiction to hear the case at all and dismiss the entire lawsuit. Second, he could determine he does have jurisdiction to hear the case but determine that the parties have not met their burden of showing the need for a preliminary injunction. In that case, the case could proceed to a full trial on the merits; however, that would not occur until after the competitive bidding process had been eliminated. Third, the judge could grant the preliminary injunction. ACLA will, of course, let members know as soon as possible of the judge's decision.

The second case of interest to ACLA members is *Atlantic Urological Associates, et al. v. Michael Leavitt, Secretary, HHS*. In that case, several urology group practices and UroPath, LLC, have sued to delay implementation of the anti-markup requirements for pathology services that were announced in the physician fee schedule of 2007. As you may recall, CMS delayed the effective date of the anti-markup rules for all services other than pathology services. This lawsuit challenges CMS' failure to delay the anti-markup rule for pathology services as well.

The government had agreed with the plaintiffs to a stay on the anti-markup requirements until a decision could be rendered on the preliminary injunction. That decision was expected before April

1, 2008. However, the judge announced in an oral argument on Friday, March 28 that she needed more time to study the issues and was not yet ready to rule. Therefore, she asked the parties to agree to maintain the status quo for an additional 30 days. CMS indicated they were prepared to do so but wanted the right to seek recoupment if they ultimately won the case for any services. The judge did not feel this was sufficient and therefore issued a preliminary injunction.

The status of this case is now somewhat unclear. The plaintiffs have asked CMS to produce other documents showing the basis for CMS' decision to delay for services other than pathology; however, so far the government has not done so. In addition, while the judge granted the preliminary injunction, she indicated that she still intended to determine whether or not she had jurisdiction to hear the case or whether it should be dismissed. Thus, the judge could still ultimately decide to rescind the injunction and dismiss the entire case once she has reviewed all of the issues. The government is still determining how to respond to the request for the administrative record.

At this point, it is not clear when this matter will be finally resolved or what form such a resolution might take. We will continue to follow this issue.

ACLA Objects to CMS Contractor Requests for Physician Signed Reqs

On March 14, ACLA wrote to Timothy Hill, CMS Chief Financial Officer, expressing serious objections to the activities of Comprehensive Error Rate Testing (CERT) program contractors and requesting a meeting to discuss the issue in more detail. A meeting with Mr. Hill and Ms. Kimberly Brandt, Director of the Office of Program Integrity has been scheduled for April 8 in Baltimore.

CERT contract auditors have recently begun to request test requisitions signed by the ordering physician and inform the laboratory that the testing is inappropriate if signed requisitions cannot be produced. In our letter we pointed out that it is CMS' longstanding policy, formulated during the congressionally-mandated Laboratory Negotiated Rule-making process, that physician signatures are not required on laboratory requisitions. In some cases, the CERT contractor seems to be relying on a January 2008 CMS transmittal (Transmittal 80) that erroneously states that signatures are required and backdates the requirement to January 2003. Unless the language is corrected quickly, the CERT contractor may begin to request recoupment of millions of dollars in laboratory payments.

ACLA has also written to Terry Kay in CMS Hospital and Ambulatory Policy Group asking that the transmittal be rescinded and corrected. Our letters to CMS discuss these issues in greater detail and are posted on the ACLA website.

ACLA Seeks CMS Meeting on Payment and Coverage for Ionized Calcium

On March 14, ACLA wrote to Ms. Janet Samen, Director of CMS Division of Chronic Care Management to request a meeting to discuss the recent change in CMS' payment and coverage rules for a new automated test panel, 80047, that includes ionized calcium. ACLA is also concerned that CMS incorrectly will be treating ionized calcium as an ESRD Composite Rate test. CMS has contacted ACLA and has agreed to meet with us in the near future.

In our letter, we pointed out that the AMA created the new CPT code, 80047, which includes seven common chemistry tests plus ionized calcium because a new point of care, hand-held instrument is capable of performing all of these tests at the bedside. CMS determined that the new code would be paid as an automated multichannel chemistry (AMCC) based on the AMCC panel payment algorithm. Essentially, the new code would be paid for as an automated chemistry panel composed of eight tests. In addition, CMS indicated that for ESRD patients, the new panel will be considered a composite rate this new panel would be considered a composite rate test when ionized calcium is done to replace serum calcium. Finally, it included ionized calcium in the calculation of the 50/50 rule applicable to ESRD patients.

ACLA believes the new policy of CMS is erroneous on several fronts. First, it is incorrect to consider ionized calcium as an automated chemistry test as it does not meet the criteria for such a test. It is also incorrect to pay for it based on the AMCC payment algorithm. Further, it is inappropriate to consider ionized calcium as an ESRD test because it is not routinely or commonly used for ESRD patients. Finally, it is incorrect to include ionized calcium in the 50/50 rule. Our letter discusses these points in detail and is posted on the ACLA website.

Genetic Test Oversight

ACLA continued efforts to communicate with important stakeholders the need for a flexible risk-based approach to genetic test oversight and the important

role laboratory developed tests (LDTs) play to keep pace with the rapid developments in this area. On March 21st, ACLA met with members of the AdvaMed Diagnostic Committee to discuss their “Least Burdensome Proposal for the Regulation of All Diagnostic Tests” and to discuss ACLA’s “FDA Consultative” regulatory model for IVDMIAs that provides a formalized consultative role for FDA while maintaining CMS/CLIA as the lead regulatory agency. Both parties indicated the meeting was informative, productive and dialogue could continue on the definition of high risk and the criteria for clinical validity among other issues.

The HHS Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has submitted their recommendations to HHS Secretary Michael Leavitt. Last March, SACGHS was commissioned by HHS to draft a plan to address observed gaps in genetic test oversight. The SACGHS recommendations for regulatory oversight include having all laboratory tests addressed by FDA in a manner that takes advantage of its current experience in evaluating laboratory tests. SACGHS recognized that this is a resource intensive process which will require commitment of additional resources. To inform the recommendations, SACGHS recommended that HHS convene a multi-stakeholder public and private sector group for both risk characterization and test registry issues. The risk characterization group should consider new and existing regulatory models and data sources and address and eliminate duplicative oversight procedures. SACGHS called for a registry stakeholders meeting later this year to inform the lead HHS agency in determining the data elements associated with analytic validity, clinical validity, clinical utility, and accessibility that could be included in the test registry.

AHIC Successor Group Holds First Stakeholder Meeting

The team of LMI Government Consulting and The Engelberg Center for Health Care Reform at the Brookings Institution, working under a cooperative agreement with the Department of Health and Human Services, has taken the first step in the transition to a new public-private partnership envisioned at the inception of the American Health Information Community (AHIC) in 2005. On March 10th LMI/Brookings held its first of several stakeholder meetings to design and establish the new AHIC successor entity. During the meeting LMI/Brook-

ings sought feedback from the health community regarding a number of priorities the successor will be involved in such as accelerating and coordinating current AHIC interoperability initiatives, including harmonizing and certifying standards of health IT; prioritizing stakeholder requirements for nationwide health IT interoperability; and advancing the harmonization of technology standards and policies. ACLA and its member companies used the opportunity to raise the crucial role that laboratories play in electronic health records and the need for separate representation on the AHIC successor. The next stakeholder meeting is scheduled for April 8th. More information on the new entity can be found at www.ahicsuccessor.org.

ACLA Meets with Florida Medicaid

On March 12, ACLA and representatives from ACLA member companies met with officials of the Florida Agency for Health Care Administration and the Medicaid program to discuss payment policies for units of service for certain CPT codes. We are cautiously optimistic that the program will revise its policies to increase units for drug screening and certain multiplex codes. They also agreed to meet with ACLA on a periodic basis to discuss lab policy issues generally. We hope to schedule the first meeting sometime in July 2008 after the legislature has adjourned.

ACLA LABLine – CLIA Steps Up Enforcement

ACLA held an important LABLine audio conference, March 18th focusing on areas that the Centers for Medicare and Medicaid Services (CMS) see as important CLIA compliance requirements. Also discussed were quality based enhancements from the College of American Pathologists Laboratory Accreditation Program.

Presenting on behalf of the CMS CLIA Program was Judy Yost, the Director of the Division of Laboratory Services. Judy provided details on the breakdown of CLIA labs by certificate, discussed how quality control policy changes impact the survey process, provided helpful hints related to the top deficiencies found on laboratory inspections and communicated areas of concern identified by CMS and how to prevent their occurrence in your laboratory.

Dr. Bruce Williams, Chair of the Commission on Laboratory Accreditation from the College of American Pathologists Laboratory Accreditation Program discussed how Accrediting Organization

compliance requirements meet or exceed CLIA requirements, the recent enhancements to the program, institution of quality improvement data system and the introduction of a new ISO accreditation availability.

Both presenters discussed their respective programs' actions following a June 2006 U.S. Government Accountability Office report on clinical lab quality and specifically on the oversight role of CMS and the survey organizations. Based on recommendations from that report and the new quality control requirements for non-waived testing issued in 2003, CMS and its partners have heightened interest in laboratory quality oversight.

One particular topic of interest was the announcement that CMS will provide a clarification letter to all CLIA labs to end confusion that has arisen recently over the rules barring referral of proficiency testing (PT) samples to other labs. It is a CLIA prohibition to send any PT sample or part of a sample to another lab for testing. CAP is also alerting its accredited labs that any lab may report for PT only testing actually done at the lab. Both presenters reminded the participants that the penalty for violating this rule is severe, including revocation of the lab's certification for at least one year and the potential suspension of the medical director's license for two years.

ACLA's LABLine audio conferences are designed to bring up-to-date information on topics of interest to the laboratory community. Please look for the next offering.

Results for Life Update

In light of National Kidney Month, *Results for Life's* storyboard on Chronic Kidney Disease was distributed to over 200 key congressional offices last week. The storyboard outlines the key role that laboratory testing plays in early detection, screening, and diagnosis of kidney disease. This distribution will be followed by calls to the offices requesting meetings to discuss *Results for Life*. We are very pleased that a number of congressional offices have indicated their interest in meeting with us to learn more about the *Results for Life* Campaign.

Additionally, in working with North American Precis Syndicate, *Results for Life* has released a short written piece on the value of laboratory tests that ran in several regional newspapers throughout the country. This piece, and a recently released one minute radio spot, are available to various media outlets and will be continually run over the next month. A front page article, “Genetic Testing Gets

Personal”, published in the Washington Post last week, could leave the public with the impression that genetic tests are not valuable to patient care and are without regulatory oversight. ACLA responded with a letter to the editor in hopes pointing out that genetic tests allow for earlier diagnosis of disease and individually tailored treatment, and are indeed regulated by the Food and Drug Administration and/or the Centers for Medicare

and Medicaid Services. A full page open letter from **Results for Life** will run later this month in The Hill – a widely read Congressional newspaper - entitled “Correcting the Record on DNA Tests” educating decision makers on the value in both improved patient outcomes and health care cost savings.

This March was no exception to **Results for Life’s** increased visibility. At both the AdvaMed Annual Meeting and the Caro-

lina’s Clinical Connection regional meeting, the campaign was on display and materials were available to all interested. These were great opportunities to spread the message and gain support in the form of sponsors and additional ambassadors. The next **Results for Life** committee call is Friday, April 25th.

ACLA In The News

National Intelligence Report - March 17, 2008
*San Diego Labs Seek Injunction Against Bidding Demo
 CMS to ACLA: ‘No Demo Delay’*

Meantime, CMS has told the American Clinical Laboratory Association that it sees “no basis” for delaying the bidding demo. ACLA had written to the HHS Secretary on February 13, requesting an immediate halt to the demo for at least 180 days.

National Intelligence Report - March 31, 2008
Current CLIA ‘Hot Spots’ & What They Mean for Labs

Updates on these issues were presented by the top CLIA official at CMS, Judy Yost, at a briefing of the Clinical Laboratory Improvement Advisory Committee (CLIA) during its February 20-21 meeting in Atlanta, and in a March 18 LABLine audio conference sponsored by the American Clinical Laboratory Association and also featuring R. Bruce Williams, MD, FCAP, who chairs the College of American Pathologists’ Lab Accreditation Commission.

Diagnostic Testing & Technology Report - April 2008
ACLA Presses SACGHS for Clarification on Genetic Testing Oversight

The American Clinical Laboratory Association is urging a top federal panel to clarify its explanation of the oversight of genetic tests. The industry group recently submitted its comments to the HHS Secretary’s Advisory Committee on Genetics, Health, & Society (SACGHS).

ACLA urged SACGHS to amend “one particularly important recommendation that, if not carefully communicated to the Secretary, could have unintended consequences.” In the recommendation, SACGHS affirms its support for the Food & Drug Administration’s regulation of LDTs and the flexible risk-based approach the agency is taking to prioritize review of these tests.

Concerned that this could be interpreted to mean that FDA requirements should be applied to LDTs without interagency coordination, ACLA noted: “Though there are many similarities between FDA’s and CLIA’s quality validation, there are clear redundancies and duplications that if not coordinated, harmonized, and streamlined will stifle innovations in this area. These include separate requirements for inspection, quality systems, reporting and labeling, and other rules for design control, corrective action, and prevention.”

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Calendar of Events/Meetings

April 3	Meeting with Senator Blanche Lincoln's (D-AR) staff	Washington, DC
April 3	Health IT Data Standards Call	Conference Call
April 4	Clinical Laboratory Coalition Call	Conference Call
April 4	ACLA Weekly Call	Conference Call
April 7	Confidentiality Coalition Hearing on Health IT	Washington, DC
April 7	Clinical Laboratory Coalition Call	Conference Call
April 8	Physician Signature Meeting	Baltimore, MD
April 9	Meeting with Senator Kent Conrad's (D-ND) staff	Washington, DC
April 10	Fundraiser for Senator Pat Roberts (R-KS)	Washington, DC
April 10	FDA Committee Meeting	Conference Call
April 11	ACLA Weekly Call	Conference Call
April 16	CPT Committee Meeting	Conference Call
April 17-18	ACLA’s 13th Annual Meeting - Laboratories: Rx for the Future	Washington, DC
April 23	Clinical Laboratory Coalition Fundraiser for Chairwoman Nydia Velázquez	Washington, DC
April 25	ACLA Weekly Call	Conference Call
April 25	Results for Life Meeting	Conference Call