

RESULTS

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President's Message

The change that has swept across Washington with the inauguration of President Obama requires ACLA and the entire laboratory community to reassess our priorities. We also must intensify our efforts to advocate on behalf of laboratories as the government role in health care is bound to exponentially increase.

It is becoming clearer every week to me that the chances of enactment of major health care reform are stronger now than at any time in history.

First, this administration is committed to major reform, and they have a willing Congress with the Democrats commanding the largest majorities in the House and Senate than at any time since 1976. Also, high unemployment is driving up the number of uninsured to record heights. Moreover, unlike 1993-94 when employers vehemently opposed the Clinton health care plan, employers this time are more likely to sit on the sidelines or even support a major government health reform plan. Finally, the trillions of dollars of "bail outs" for the financial sector and automobile industry have made it much more difficult for opponents of major government intervention to cite "cost" as a reason to oppose.

Still, the enormity, complexity, cost, and potential for unintended consequences with such reform make it difficult to predict what will happen. Nevertheless, ACLA will be engaging policymakers every step of the way, making sure that they understand the value of laboratory services in most medical decision making and in early detection, screening, diagnosis, monitoring and treatment.

In fact, ACLA has already engaged with the new administration. We had the opportunity to meet with the Presidential Transition Team health staff a week before the inauguration.

ACLA is working on many issues including the "Date of Service" rule, MUE's, laboratory developed test regulation, the New York State gross receipts tax, and others. At press time for this Results, we are also reviewing the privacy provisions that the House has included in the stimulus package which appear to work at cross-purposes with the goal of encouraging electronic health information.

In closing, we are very excited about our new Associate Member program which will be kicked off with a meeting on February 4th.

ACLA Meets with President Obama's Transition Team

On January 12th ACLA met with staff from what was then President-Elect Barack Obama's Transition Team. The purpose of the meeting was to educate staff about the clinical laboratory industry, ACLA and discuss a number of pertinent issues they may confront in the short-term: the date of service issue, FDA's draft guidance document on in-vitro diagnostic multivariate index assays (IVDMIA's), and laboratory developed tests.

Staff explained to us that since they had not officially taken office yet, they would not comment on policy or take a position on issues we brought up. That said, staff asked a few questions for clarification (particularly on the history to the repeal of competitive bidding and the date of service issue) and appeared agreeable to meeting again after President Obama took office to follow up.

ACLA Responds - Genentech Citizen Petition

ACLA responded to the December 9th citizen petition filed with the federal Food and Drug Administration (FDA) by Genentech with a press advisory (posted on ACLA web site). The petition seeks to require clinical laboratory developed tests (LDTs) – especially those that guide therapeutic decisions - to be under additional regulation by FDA.

ACLA pointed out that all health care related laboratory tests are already either cleared by the FDA or are performed in a laboratory regulated under the Clinical Laboratory Improvement Amendments (CLIA) by the Center for Medicare and Medicaid Services. ACLA indicated that extensive information in the form of peer reviewed journal

articles, presentations and abstracts supporting clinical validity, medical decision impact, platform technology, assay development, and clinical trials is readily available from the companies' web sites on many of the specific products labeled "unsubstantiated" in the petition.

ACLA further recognized the foreseeable negative consequence for the individual patient's care if FDA regulates all laboratory tests particularly in the promising area of personalized medicine. CLIA allows tests to be quickly modified to take advantage of new, critically important developments in this rapidly advancing field of genetic testing and personalized medicine. There are many examples of tests initially developed in the laboratory that have provided major positive healthcare breakthroughs, especially in infectious disease and cancer.

To allow for this 21st century healthcare revolution to continue, ACLA has proposed a regulatory model that builds on interagency coordination between CMS and FDA, provides a publicly transparent test registry, is consistent with principles of least burdensome regulation, fills all the identified regulatory "gaps", avoids overlapping and potentially conflicting requirements and allows for a participatory approach that draws on the expertise of industry stakeholders.

ACLA's press advisory is posted on the web site and a more comprehensive response is being finalized.

Key Changes in the House, Senate Committees Could Benefit Laboratories

With Election Day long behind us, the real 'news' around town has been the key changes within Congress on the relevant committees in the House and Senate. For the laboratory community, several appointments within the Senate are noteworthy. On the Senate Finance Committee, which has jurisdiction over Medicare, Democrats had three vacancies to fill and Republicans had two. Unlike most current Finance Committee Members, the recent appointees come from states with larger populations. The newest Members include: Senator Robert Menendez (D-NJ); Senator Bill Nelson (D-FL); Senator Thomas Carper (D-DE); Senator John Cornyn (R-TX) and Mike Enzi (R-WY). The Chairman remains Max Baucus (D-MT) and the Ranking Member is Charles Grassley (R-IA).

Likewise, the House of Representatives welcomed a number of new Members to the committees with jurisdiction over Medicare

– the House Ways & Means and Energy and Commerce Committees. The most noteworthy changes happened to some of the leadership to the two committees. The House Energy & Commerce Committee has a new Chairman, Rep. Henry Waxman (D-CA). Chairman Waxman ousted Rep. John Dingell (D-MI) winning the chairmanship in a special election within the Democratic caucus. The rest of the 'faces' remain the same within the leadership on Energy & Commerce: Rep. Joe Barton (R-TX) remains the Ranking Member of the full Committee; Reps. Frank Pallone (D-NJ) remains Chairman of the Health Subcommittee; and Rep. Nathan Deal (R-GA) is the Ranking Member. On the House Ways & Means Committee, Rep. Charlie Rangel (D-NY) remains the Chairman of the full Committee and Pete Stark (D-CA) remains Chairman of the Health Subcommittee. Republicans, however, welcomed an overhaul of their leadership seats. Dave Camp (R-MI), formerly Chairman of the Health Subcommittee, takes over as the Ranking Member of the full Committee. Taking Rep. Camp's spot as the Ranking Member of the Health Subcommittee is Rep. Wally Herger (R-CA).

Proposed NY TAX Assessment on Lab Gross Revenues

As part of an effort to close a \$15 billion revenue shortfall, New York has proposed to replace the Department of Health's existing tax on laboratories covering the costs of overseeing clinical laboratories (the Clinical Laboratory Evaluation Program or "CLEP") with a 1% assessment on laboratory gross revenues beginning in budget year 2009-2010. The assessment, which would be based on gross revenues for services performed on specimens obtained in NY, would eventually be set at .8% for 2013 and thereafter. The proposed new tax would raise approximately \$36 million in the first year compared with less than \$20 million collected in budget year 2008-2009. A recent court decision ruled that the amount currently being collected by the Department of Health far exceeded the statutorily limited costs of CLEP and ordered the Department to recalculate their fees in accordance with the decision. The State has appealed the decision.

ACLA has formed a coalition with the New York State Clinical Laboratory Association (NSCLA) to fight replacing the existing tax with an assessment that would nearly double the tax on labs and that would far exceed the costs of CLEP, even if the State were successfully in overturning the court decision. The ACLA/NSCLA proposal would retain the CLEP tax and offer a one tenth of one percent tax on gross revenues for each of the next two budget years.

Health IT Update

While much has been made of the stimulus bill Congress is working to enact before the President's Day recess, unbeknownst to many this legislation includes major reforms to current federal privacy and security protections for health information. The American Recovery & Reinvestment Tax Act of 2009, scheduled for a final vote in the House of Representatives on January 28th includes the following reforms: a federal breach notification requirement for health information; the ability of patients to request an audit trail showing all disclosures made through an electronic record; a new prohibition precluding the sale of a patient's health information without their authorization; increased penalties for violations and providing greater resources for enforcement and oversight activities.

ACLA is working with the Healthcare Leadership Council's Confidentiality Coalition to raise our concerns where these new privacy provisions would represent either duplicative or burdensome reforms to the current framework of privacy protections.

Palmetto Agrees to Rescind LCDs on Flow Cytometry and Genetic Testing

The MAC J1 Contractor, Palmetto GBA, has agreed to rescind its Local Coverage Decisions on flow cytometry and genetic testing and will publish a new bulletin announcing that Flow studies should not exceed 20 units and immuno cyto chemical studies should not exceed 10 units. These criteria will be used in post payment review and not applied as a pre-payment edit.

Palmetto continues to have concerns about molecular diagnostic testing submitted with "stacked" and unlisted service codes with respect to the information necessary to determine clinical relevancy, proper coding for methodology and appropriate reimbursement. Palmetto medical directors have invited California laboratory representatives to meet with them in February to discuss the specifics of molecular diagnostic testing performed by their laboratories.

Results for Life Update

Results for Life kicked the New Year off with a bang. With the new President and New Congress, the campaign placed a full page ad in The Hill newspaper. It ran on January 20th, in a special inaugural edition and was passed out on the National Mall during the festivities. The full page ad congratulated President Obama and acknowledged his continuing efforts in the field of genetic testing and personalized medicine. The ad can be seen on the **Results for Life** website, www.LabResultsforLife.org.

On Capitol Hill, **Results for Life** has been working closely with Congresswoman Velázquez's office and the House Small Business Committee. We have learned that the Representative will author an Op-Ed, titled, "Disruptive Thinking: Let's Help Small Firms Help Us with the Big Battles". The article highlights the impact small emerging laboratories are having in the field of genetic testing and personalized medicine. The Op-Ed will run in the Special Health Section of The Hill next month. We will also hope to work with the Congresswoman's office to put together a briefing on Capitol Hill to raise awareness of underutilization of laboratory tests in high risk populations.

ACLA's newest consultant, Libby Mullin, of Mullin Strategies hit the ground running with the campaign. She is working with ACLA as well as **Results for Life** on patient group outreach and collaboration. While still in the nascent stages of development, initial meetings have been established to spark interest and cultivate future relationships. We are looking forward to working with these patient groups on a variety of activities in the future.

We are also pleased to report that a recent radio interview with Alan Mertz on behalf of **Results for Life** was covered on 2,063 stations in the last month. Various stations around the U.S. picked up the live interview broadcasting to an estimated 8.7 million listeners. A similar 2 minute radio spot was released in November that resulted in 3.4 million listeners with 1,515 airings on 665 stations. Both interviews were focused on the medical and economic benefits of laboratory testing.

We sent out our second e-newsletter this week to in effort to keep our extended audience up to date with the campaign's activities and plans. If you are not receiving the e-newsletter and would like to be on the list, please contact kbnet@clinical-labs.org.

Medically Unlikely Edits – CMS Responds

The Centers for Medicare and Medicaid Services (CMS), via their contractor Correct Coding Solutions, responded to ACLA comments on Phase VIII of the Medically Unlikely Edits (MUE) program. This group of MUEs comprised over 100 proposed edits - all codes related and utilized by the clinical laboratory and pathology community.

MUEs are a CMS unit of service limit based on medical practice and claims data and meant to identify claims with obvious or negligent errors such as typographical errors, transcriptional errors, or duplicative services. The examples given by CMS supporting the definition are vasectomy on a female, hysterectomy of a male or two 24 hour urine samples.

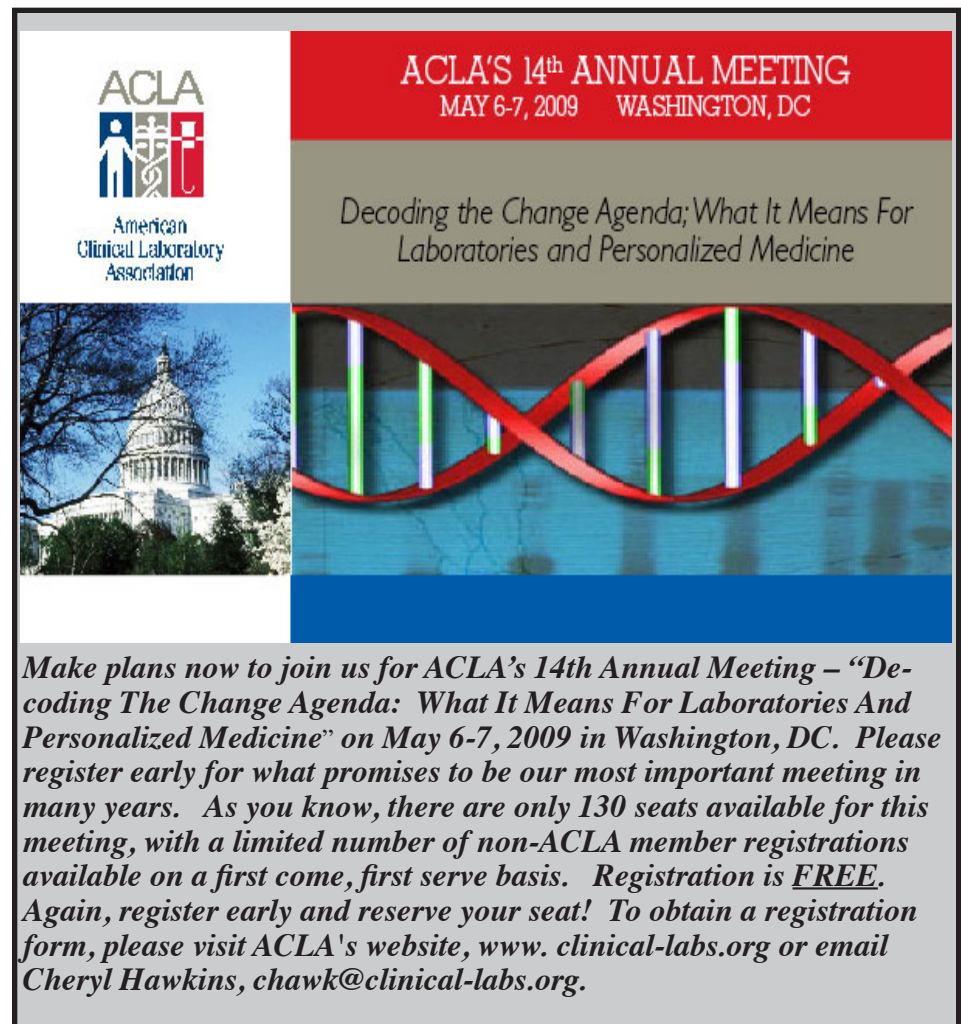
ACLA's CPT Committee took the lead in submitting comment on the proposed Phase VIII MUEs. ACLA provided clinical rationale and alternative MUEs for a number of proposed MUEs. ACLA's comments reiterated that MUEs should not dictate medical policy or in any way interfere with

clinical ordering and judgment. ACLA requested a meeting with CMS, the contractor and other stakeholders prior to final decision making on this phase of the MUEs.

In the December 18th response letter to ACLA, it was stated that "CMS does not publish some MUE values because of concerns about fraud and abuse. Since MUE values of four or more are not published at the current time, we are not providing the MUE values for the other codes. If your society/organization continues to disagree with the CMS decision, we invite your society/organization to send supporting documentation of your position."

ACLA is communicating a concern with this response to CMS and its contractor. Without knowing the final MUE above 4 (many of which are part of Phase VIII MUEs), there is no opportunity to challenge the CMS final MUE decision. The decision to not provide the MUEs of 4 or above to the organizations that commented on the MUEs is a new policy directive, not otherwise communicated or discussed.

ACLA is seeking a meeting to discuss and resolve this and related MUE issues.



The poster for ACLA's 14th Annual Meeting features a red header with the text "ACLA'S 14th ANNUAL MEETING MAY 6-7, 2009 WASHINGTON, DC". Below the header is a grey section with the title "Decoding the Change Agenda; What It Means For Laboratories and Personalized Medicine". The central image shows a DNA double helix with vertical bars of various colors (red, green, blue, yellow) representing data points. To the left of the DNA is a photograph of the U.S. Capitol building. The bottom section is a grey box with the following text: "Make plans now to join us for ACLA's 14th Annual Meeting – 'Decoding The Change Agenda: What It Means For Laboratories And Personalized Medicine' on May 6-7, 2009 in Washington, DC. Please register early for what promises to be our most important meeting in many years. As you know, there are only 130 seats available for this meeting, with a limited number of non-ACLA member registrations available on a first come, first serve basis. Registration is **FREE**. Again, register early and reserve your seat! To obtain a registration form, please visit ACLA's website, www.clinical-labs.org or email Cheryl Hawkins, chawk@clinical-labs.org.

ACLA in the News

National Intelligence Report - January 12, 2009

New Controversy Erupts Over FDA Regulation of Lab-Developed Tests

Genentech, based in South San Francisco, Calif., has filed a 32-page citizen petition with the FDA, asking it to “initiate rulemaking to exercise regulatory jurisdiction over all LDTs and use its current risk-based classification system to determine the level of regulatory oversight and review that is necessary and appropriate for these tests.”

The American Clinical Laboratory Association, which represents national and regional labs as well as test manufacturers, assailed Genentech’s move as posing a “chilling effect on innovation in patient care while stifling the promise of personalized medicine,” which tailors a particular treatment and therapy to an individual’s genetic profile. LDTs include commonly used tests for breast and colon cancer, AIDS, and other diseases that have a history of being safe and effective, ACLA said. “All health care-related lab tests are already either cleared by the FDA or are performed in a lab regulated by the Centers for Medicare and Medicaid Services under CLIA, or both. Also, labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight, often are also regulated by states, and most have further oversight via lab accrediting bodies.”

Laboratory Industry Report - December 2008

Genetic Testing Experts Say Future Promise in Multiplex and Array Analysis Lies in Reimbursement

Multiplex testing, genomic hybridization, and high throughput sequence analysis are leading the future of genetic testing, said leading experts from various areas of the genetic testing field at an October 28 panel discussion, “A Primer on Genetic Testing: What is It? How Does it Work? Why Does it Matter?” sponsored by the American Clinical Laboratory Association (ACLA) as part of their Results for Life educational campaign.

Days Before Historic Election, Pathologists Get 1.1% Medicare Fee Increase for 2009

In addition to this recent physician payment increase, the lab community should expect more reform initiatives by Congress, as well as by the incoming Obama administration, explained health care policy insiders during a recent audioconference, “The 2008 Election: What Will The Election Outcome Mean For Laboratories?.” The audioconference was sponsored by the American Clinical Laboratory Association (ACLA).

ICD-10-CM Expansion to 68,000 Codes Could Cost Labs and Providers Millions

HHS estimates that costs will total \$1.64 billion, which includes \$356 million related to training costs, \$572 million in lost productivity costs, and system change costs of \$713 million. But the American Clinical Laboratory Association (ACLA) argues that these estimates fail to include the costs that will be imposed on laboratories. Specifically, CMS has underestimated the number of coders necessary to be trained to use the ICD-10-CM codes. “According to ACLA members, there are approximately 150,000 certified professional coders that will require training and HHS has only accounted for approximately one-third of this number,” wrote ACLA’s counsel, Peter Kazon, an attorney with Alston & Bird (Washington, D.C.), in a letter to HHS. “The cost to train the remaining two-thirds of coders significantly increases the resources that laboratories and others will be forced to spend to transition to ICD-10-CM.”

Calendar of Events/Meetings

January 26	ACLA-Coalition Update Meeting	Conference Call
January 28	Results for Life Ambassador Training Session	Conference Call
January 28	ACLA Membership Committee Meeting	Conference Call
January 29	Weekly IOAS Meeting	Conference Call
January 30	ACLA Weekly Member Call	Conference Call
January 30	Results for Life Committee Meeting	Conference Call
February 2	ACLA Coalition Update Meeting	Conference Call
February 2	CLC Meeting	Conference Call
February 4	ACLA Board of Directors Meeting	Conference Call
February 4	Meeting with New Associate Members	Washington, DC
February 5	Health IT Data Standards Meeting	Conference Call
February 6	ACLA Weekly Member Call	Conference Call
February 9	ACLA Coalition Update Meeting	Conference Call
February 12	FDA Committee Meeting	Conference Call
February 12	Weekly IOAS Meeting	Conference Call
February 13	ACLA Weekly Member Call	Conference Call
February 16	ACLA Coalition Update Meeting	Conference Call
February 18	CPT Committee Meeting	Conference Call
February 19	Billing Committee Meeting	Conference Call
February 20	ACLA Weekly Member Call	Conference Call