



RESULTS

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President's Message

June is turning out to be a good month for ACLA with encouraging developments in Congress, progress in educating policy makers about the value of genetic testing, and even welcoming an old friend back to ACLA's membership.

The inclusion of the repeal of the laboratory competitive bidding demonstration project in both Democrat and Republican Senate Medicare legislative packages this month was a major milestone. This is the first time either Senate Finance Committee Chairman Baucus (D-MT) or Ranking Republican Senator Grassley (R-IA) has included repeal in legislation, let alone in a "must pass" bill.

The repeal provision was included in both Democrat and Republican bills that would stop the 10.1% reduction in the physician fee schedule otherwise scheduled to occur on July 1st. The bills also include an important 18 month extension of the technical component (TC) grandfather clause

Democrats and Republicans will have to work out other differences in the two versions, but prospects for passage of legislation are strong given the July 1 deadline.

Genetic testing -- and the public policy issues surrounding genetic testing -- continues to grow in importance as an ACLA issue. I am becoming increasingly concerned about misleading information spread by some groups and picked up by the media challenging the value and oversight of genetic testing. It is imperative that ACLA and the **Results for Life** Campaign educate policy makers and the media about the value of genetic testing, its growing importance in medicine, and that it is regulated.

I was reminded of this again in June when ACLA participated in a Roundtable on direct-to-consumer genetic testing held by the Senate Aging Committee. Dr. Elaine Lyon from ARUP Laboratories did a terrific job representing ACLA at the Roundtable and educating the Committee on the value of genetic testing. She also used the opportunity to discuss ACLA's model for

improving oversight of genetic testing that will ensure public safety while avoiding policies that would stifle innovation.

ACLA and the **Results for Life** Campaign are stepping up our efforts with new materials and ways of communicating with policy makers and the media.

Finally, I am pleased to welcome back to ACLA our friends at Myriad Genetic Laboratories. Myriad Genetic Laboratories and its President, Dr. Greg Critchfield -- a former ACLA Board member -- have rejoined ACLA. I look forward to again working with Greg and his superb team at Myriad. Ron Weiss and I had the opportunity to meet with Greg and his team at Myriad at their headquarters in Salt Lake City earlier this year.

Baucus, Grassley Introduce Respective Medicare Bills, Both Include Demo Repeal

On June 6th Senate Finance Chairman Max Baucus (D-MT) introduced the Medicare Improvement for Patients and Providers Act of 2008 (S. 3101). The legislation includes a repeal of the Medicare demonstration project to competitively bid clinical laboratory services. Also included in S. 3101 is an 18-month extension of the technical component (TC) grandfather provision and positive updates to the Medicare Physician Fee Schedule in 2008 and 2009. Senators Gordon Smith (R-OR), Olympia Snowe (R-ME) and John Rockefeller (D-WV) joined Chairman Baucus as original co-sponsors of the bill. A few days later Senate Finance Committee Ranking Member Charles Grassley (R-IA) introduced the Preserving Access to Medicare Act of 2008 (S. 3118). Like Senator Baucus' bill, S. 3118 includes the demo repeal and an 18 month extension of the TC grandfather. The major differences between the two bills are how they propose to pay for the underlying bill: Baucus

uses cuts to Medicare Advantage; Grassley phases out indirect medical education.

Democrats brought Senator Baucus' bill to the floor for a procedural vote on June 12th. S. 3101 fell 6 votes short of the necessary 60 votes needed to proceed with the final vote of 54 yeas to 39 nays.

Chairman Baucus will likely now return to bipartisan negotiations with his Senate GOP colleagues to enact a smaller Medicare bill that will pass the Senate and be signed by the President. Unless Congress acts by June 30th, a 10% cut of the Medicare Physician Fee Schedule will take effect and laboratories will no longer be permitted to bill Medicare directly for the TC of surgical pathology services provided to hospital patients.

ACLA has been working to enact repeal of the competitive bidding demonstration project since its inception. Legislation in the House (H.R. 3453) and the Senate (S. 2099) would permanently repeal the demonstration project and halt further progress on the ongoing effort in San Diego. To view a copy of either S. 3101 or S. 3118, ACLA's letters of support as well as letters of support from the Clinical Laboratory Coalition please visit ACLA's website at <http://www.clinical-labs.org/>.

In a related development regarding the status of the San Diego litigation, the government asked for and received a two month extension to file its response to the plaintiff laboratories' complaint. This delay will give the government until August 9, 2008 to answer the complaint at which point the case may be moot if legislation is enacted in the interim to repeal the legislative authority for the demonstration. The government did not meet the June 9 deadline to file an appeal of the preliminary injunction stopping all laboratory demonstration project activities.

LMI/Brookings Outline Details of AHIC SUCCESSOR, Transition

On June 4th LMI, in concert with the Brookings Institution, outlined the latest details of the forthcoming American Health Information Community (AHIC) Successor during the 3rd and final public meeting hosted by the transition team. Meeting participants learned that the transition from the current AHIC to the AHIC Successor will take place in six to seven months. The AHIC Successor Board will consist of 18 members, two of whom will

be represented by the government and a patient representative. The Board will be advised by standing committees, each chaired by a member of the Board. Regarding membership and dues, the federal government will make an initial investment of \$5 – 8 million dollars with additional funding resources coming from membership dues ranging from \$1,000 – 50,000. The next steps for the AHIC Successor include incorporating the organization, developing a health IT roadmap, and hiring a firm to find senior level management to run the AHIC Successor.

ACLA Well Represented at Senate Genetic Test Briefing

ACLA was well represented at the June 12th Senate Special Committee on Aging, Genetic Test Roundtable Discussion. Dr. Elaine Lyon, Medical Director of Molecular Genetics at ARUP Laboratories, was part of a panel that included representatives from FDA, CMS, the National Human Genome Research Institute, the Johns Hopkins Genetics and Public Policy Center and web based company 23andMe. The roundtable was organized by Senator Gordon Smith (R-OR), as a follow-up to a 2006 Congressional Hearing on Nutrigenetic Testing held by this committee. In his opening remarks, Senator Smith referred back to the 2006 Hearing which revealed questionable practices related to some direct to consumer genetic tests. He described the purpose of this briefing as an opportunity to revisit the safety and effectiveness of these tests and to determine whether additional protection is needed for consumers.

The panel discussion started with an inquiry to the government agencies represented on the panel to update their activities following the 2006 Hearing. CMS, as the agency responsible for CLIA, stated that much was in place or planned. This included considerable interagency coordination with CDC and FDA, hiring of a designated staff person for DTC genetic testing, a scheduled MMWR best practices publication, and a timetable has been set for a Notice of Proposed Rulemaking to expand and update CLIA requirements for Proficiency Testing (PT). The work on PT will be informed by the Clinical Laboratory Improvement Advisory Committee and the CLIA private accrediting organizations. The Federal Trade Commission, although not part of the panel, had a representative in the audience who updated their activities. An FTC Consumer Warning Alert was published shortly

after the 2006 hearing and he indicated that specific company investigations of deceptive advertising are underway. Dr. Lyon provided specific examples of test validation and quality control activities performed by laboratories that lent clear support for CLIA's systems approach to safe and effective testing.

Panelists were asked their opinion of the recommendations contained in the recently released Secretary's Advisory Committee on Genetics, Health and Society (SACGHS). The report was recognized as a valuable and comprehensive review that is under careful review by the agencies. One area of general consensus was support for the SACGHS recommendation for a publicly available genetic test data registry informed by stakeholder input. Concern for consumer's data disclosure, privacy, and confidentiality received considerable discussion. The FTC stated that they would consider any breach in security an immediate trigger for investigation.

Overall, the Roundtable served as an opportunity to communicate to Senator Smith the prevailing message that genetic testing has value, that there is tremendous innovation underway to further the promise of genetic testing, and because of the complexity of the issue, there is a need for smart, careful, and effective regulatory oversight that does not stifle innovation. ACLA's written comment – including a Genetic test Fact Sheet – can be downloaded from the ACLA web site and the web cast of the briefing will be on the Senate Special Committee on Aging web site as will a transcript of the briefing.

Results for Life Update

The *Results for Life* campaign has had a fully engaged and busy month. Following a meeting with Congresswoman Diana DeGette's office, information provided by *Results for Life* was published in the Congressional Diabetes Caucus monthly newsletter along with *Results for Life* website link as source attribution. The newsletter circulates to all members on the Diabetes Caucus, and *Results for Life* will continue to look for opportunities to contribute information and gain visibility with the caucus.

On May 29, The Salt Lake City Tribune published an Op-Ed written by Dr. Ronald Weiss, Chairman of the

Results for Life Committee, titled “Lessons from Landmark Legislation on Personalized Medicine”. The article highlights the importance of GINA, the recently passed Genetics Information Nondiscrimination Act. The act effectively removes barriers to genetic testing by providing individuals protection from health insurance and employment discrimination. The article also emphasizes how genomics will redefine medicine and the clear benefits of genetic testing that result. Benefits such as identifying individuals at high risk for diseases-- before the onset of the disease, and companion diagnostics, allowing relationships to be drawn between medications and certain lab tests, are at the forefront of this revolution.

Back in Washington, DC, **Results for Life** is now participating in The Hill's White Papers Portal, a recently launched program allowing organizations to post position papers and issue briefs on The Hill's website. These white papers are available to the public, with a large readership among our target audience on Capitol Hill. All five storyboards and two recent op-eds have been posted to kick-off what will be a continued stream of materials provided to their growing database. **Results for Life** will also be participating in the exclusive “Congress Blog”- a blog where members of congress and industry leaders can exchange ideas and discuss issues. A meeting with the Editor in Chief is scheduled to discuss further involvement in their new programs.

A “Personalized Medicine” Storyboard, focused on the value of genetic testing and the resulting earlier diagnosis and treatment, better prevention, and better-targeted therapy, releases by the end of the month. The body of this storyboard is a chart demonstrating that by identifying a patient's genetic profile, predicting, screening, diagnosing, selecting a treatment, and managing disease becomes personalized, less invasive, cost efficient, and more effective. Genetic tests for Breast Cancer, HIV, Leukemia, Cardiovascular Disease, and others, are outlined to demonstrate their potential for revolutionizing healthcare and to highlight the importance of development and innovation in this realm of laboratory testing.

Additionally **Results for Life** will be releasing a second, North American Precis Syndicate (NAPS) article on Personalized Medicine, focusing on genetic testing and the benefits arising from the ability to identify the unique genetic profiles of patients or their diseases- allowing physicians to tailor treatment to those specific character-

istics. Our previous NAPS article on the value of laboratory testing continues gaining placement, published in over 200 regional papers in 18 states and the radio spot broadcasted 596 times in 37 different states.

On June 12, ACLA had a seat at a Genetic Testing Roundtable before the Senate Special Committee on Aging. Dr. Elaine Lyon of ARUPLaboratories spoke on behalf of ACLA on DTC Genetic Testing. (See related article)

The next **Results for Life** Committee Call will be Friday, June 27, 2:00 PM ET.

Billing and Payment Issues

ACLA Receives Reply from CMS on the Physician Signature Issue

On May 8, ACLA received a written reply from CMS to its letter and follow-up meeting confirming that CMS policy does not require physician signatures on lab requisitions, that there are other mechanisms to demonstrate that the requisition is a valid one, and they would be issuing a corrected transmittal making it clear to the contractors that physician signatures are not required. The corrected transmittal has not been issued at press time.

ACLA Meets with Palmetto GBA J1 Contractor

On May 13, ACLA and representatives from 13 member companies met with the project manager, medical director and other officials of Palmetto GBA, the new J1 MAC for California, Nevada and Hawaii. The meeting was very productive as we learned how Palmetto intended to complete the transition to the new MAC including how the MAC planned to consolidate local coverage decisions. Because so many ACLA members will be submitting claims to the new MAC, we had an opportunity to raise a number of laboratory specific issues with the appropriate carrier officials. This meeting was the second in our series of “meet the new MAC contractor” visits.

ACLA Meets with CMS on Ionized Calcium Policy

ACLA and representatives of ACLA member ESRD laboratories met with CMS officials on May 21 to discuss our concerns with a recently issued transmittal addressing payment and coverage policy for ionized calcium. The transmittal provided instructions to carriers that, effective July 1, 2008, ion-

ized calcium would be paid as an automated multichannel chemistry (AMCC), based on the AMCC panel payment algorithm. It also stated that for ESRD dialysis patients, the new panel would be considered a composite rate test when the ionized calcium is ordered to replace serum calcium. Finally, it included ionized calcium in the calculation of the 50/50 rule applicable to ESRD patients.

We stated that it is incorrect to consider ionized calcium as an automated chemistry test since it doesn't meet the criteria for an automated chemistry and, therefore, it shouldn't be paid for on the basis of the AAMC algorithm. Further, we contended it is incorrect to pay for it as an ESRD test because it is not routinely ordered or commonly used to treat ESRD patients and is also not appropriate to include ionized calcium in the 50/50 rule. CMS agreed to review our concerns and contact us again. We have asked CMS to suspend the effective date of the ESRD provisions of the transmittal until their review is completed.

ACLA Urges Extension of Effective Date of Transition to New ABN Forms

Earlier this spring, ACLA wrote to CMS asking for at least a one year transition period from the date final instructions implementing the revised ABN form are published before laboratories are required to comply fully with the new form. CLMA and the Clinical Laboratory Coalition also corresponded with CMS making the same request. We have not received a response from CMS at press time. CMS did provide copies of the draft instructions for our review and comments, and we and other members of the coalition will be providing comments.

New ACLA Member

ACLA welcomes new member, Myriad Genetic Laboratories, and President, Dr. Gregory Critchfield!

Myriad, based in Salt Lake City, Utah, offers genetic testing for hereditary cancer.

More information about Myriad Genetic Laboratories can be found on its website, www.myriad.com

National Intelligence Report - May 26, 2008

President Signs Genetic Information Non-Discrimination Act

At a signing ceremony on May 21, President Bush signed into law the Genetic Information Non-Discrimination Act that prohibits employers and health insurers from discriminating against individuals based on their genetic information and test results. The signing is the culmination of a 13-year effort to get such a law on the books. The American Clinical Laboratory Association called GINA “a vote for the future.” President Alan Mertz said in a statement, “Genetic testing is already making great strides in cancer, HIV, heart disease, and other areas — and this is just a start. GINA protects that future by giving patients the confidence of knowing that their personal information will not be used against them.”

CMS to Clarify Physician Signature Policy for Lab Claims

The Centers for Medicare & Medicaid Services will correct problems that have recently occurred in the medical review by the Comprehensive Error Rate Testing (CERT) contractor of clinical laboratory test claims over requirements for the signature of the ordering physician. CMS was alerted to the problem by the American Clinical Laboratory Association (ACLA), which said many of its member labs had received documentation requests from the CERT contractor—AdvanceMed, a wholly owned subsidiary of Computer Sciences Corporation—for the physician’s signature on both paper and electronic claims. Without it, the contractor would recommend that the claim be rejected. In a March 14 letter to CMS, ACLA noted that labs routinely respond to CERT requests for medical records to determine whether claims were correctly paid. “However, in the past month, several ACLA member labs have reported that after the records are submitted, the CERT contractor has said they are inadequate because they do not include an original signed requisition slip. 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.”

G-2 Compliance Report - June 2008

Committee Recommends Additional Oversight of Genetic Tests - ACLA Responds

The American Clinical Laboratory Association (ACLA) says it shares the committee’s overarching goal to ensure that genetic technologies and test methodologies continue to keep pace with innovation and remain accessible to enhance and benefit individual personal health care. However, ACLA is concerned that the recommendations for regulatory oversight could have unintended consequences if interpreted to mean that FDA’s Food Drug and Cosmetic Act requirements should be applied to all laboratory diagnostic tests. “Any change in the regulatory oversight of these critically important tests has to be fully informed by the laboratory community to ensure interagency coordination, elimination of regulatory redundancies and duplications,” said Alan Mertz, ACLA president, in a statement. “Although there are many similarities between FDA’s and CLIA’s regulatory requirements, there are clear redundancies and duplications that, if not coordinated, harmonized, and streamlined, will stifle innovation in this area.” ACLA has proposed a regulatory model that it says builds on interagency coordination, is consistent with principles of least burdensome, 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, CMS, and FDA. The model also invokes public-private partnerships, thus avoiding significant new costs for the agencies, says ACLA.

CMS Mandates Switch to Single Medicare ABN by Sept. 1

The Centers for Medicare & Medicaid Services (CMS) has issued a revised Advanced Beneficiary Notice (ABN) that clinical laboratories and other providers billing Part B must use by no later than September 1 of this year. In a letter to CMS, the American Clinical Laboratory Association (ACLA) said its members “find this type of flexibility to be extremely problematic . . . particularly for clinical labs that are often the rendering provider and are forced to rely on the physician, or other ordering provider, to complete the ABN form appropriately. Therefore, contractors need to be instructed clearly that an ABN is not invalidated merely because it does not contain the estimated cost . . . It is very important that there be clear standards for what is and what is not permissible, particularly with respect to cost. Otherwise, there will be repeated disputes about whether or not the lab or other provider can bill for the service.”

Calendar of Events/Meetings

June 2	Clinical Laboratory Coalition Meeting	Conference Call
June 5	OIG Meeting with Mark Stiglitz	Conference Call
June 5	Health IT Data Standards Meeting	Conference Call
June 5	FDA Committee Meeting	Conference Call
June 5	OIAS Meeting	Conference Call
June 5	ACLA FDA Committee Meeting	Conference Call
June 6	ACLA Weekly Call	Conference Call
June 9	ABN Draft Instructions Call	Conference Call
June 10	Clinical Laboratory Coalition Meeting	Conference Call
June 12	Senate Aging Committee Roundtable Meeting	Washington, DC
June 16	2008 Health Reform Summit	Washington, DC
June 18	CPT Committee Meeting	Conference Call
June 19	Billing & Reimbursement Committee Meeting	Conference Call
June 23	Clinical Laboratory Coalition Meeting	Conference Call
June 26	OIAS Meeting	Conference Call
June 27	ACLA Weekly Call	Conference Call
June 30	Clinical Laboratory Coalition Meeting	Conference Call