



RESULTS

American Clinical Laboratory Association

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President's Message

No Time to 'Rest on Our Laurels!'

At this year's "Lab Institute," I had the opportunity to speak to the laboratory community about lessons learned from our effort to repeal competitive bidding and applying those lessons learned to future advocacy battles. I also talked about what threats and opportunities are likely to present themselves next year.

The key "lessons" from competitive bidding were that a unified and focused laboratory community stands the best chance of success. We were also reminded about the power of "grassroots" advocacy, where laboratory folks back home get involved, and communicate with their members of Congress. Finally, we developed some great champions in Congress who fought for the laboratory industry – we need to continue to work with these members and find more champions.

I emphasized that while we had tremendous victories this year on competitive bidding and our inflation update, this is no time to rest on our laurels. In fact, the threats to laboratory reimbursement may be even more pronounced in coming years. The need for cost savings is going to grow exponentially next year as we face a Physician Fee Schedule cut that is twice as large as this year's, and the budget squeeze in the Medicare program in general intensifies.

A unified and focused ACLA and the laboratory community must focus on educating members about the value of laboratory services, and the need for adequate reimbursement. ACLA will push for the community to keep the grassroots advocacy efforts moving ahead, and developing more champions for our cause!

While the competitive bidding battle is mostly over, ACLA has been very busy on a number of other fronts. We are fighting for reasonable changes to the new ABNs, for more transition time for the ICD-10, for fixing the 'date of service' rule, and many other issues.

Finally, please mark your calendars for three future ACLA meetings/events. First, **Results**

for Life will hold a "Primer on Genetic Testing" on October 28. Then, ACLA hosts a special "LABLine" audio conference for November 12. Also, for a little longer term planning, the ACLA 2008 Annual Meeting has been scheduled for May 6-7, 2008 in Washington, DC. More information can be found on the ACLA website, www.clinical-labs.org.

ACLA Comments on 2009 Physician Fee Schedule Proposed Rule

On August 28, ACLA filed extensive comments on the Physician Fee Schedule Proposed Rule for 2009. Our comments addressed the following issues: (1) the proposed revisions to the physician self-referral and anti-markup provisions; (2) the independent diagnostic testing facility enrollment requirement for physicians and nonphysician practitioners (NPPs); (3) the enrollment of physicians and NPPs; (4) the billing of the technical component and professional component of physician pathology services; (5) the clinical laboratory fee schedule update factor; (6) coding issues relating to new G-codes for prostate saturation biopsies; and (7) issues relating to the date of service rules. Our comments are posted on the ACLA website.

With respect to the physician self-referral and anti-markup provisions, ACLA urged CMS to act decisively and recognize that groups should only be able to bill for services that are truly ancillary to the specialty of the physician furnishing the service. Multi-specialty group practices should not be permitted to use employment or independent contractor arrangements to bring pathology services in-house and claim the referral is exempt from the Stark self-referral law.

CMS Issues Manual Instructions for the Revised ABN Form

On August 18, CMS published website final instructions for the revised ABN form with the final implementation date for use of the new

RESULTS is a monthly report to ACLA member companies

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form established as March 1, 2009. Regarding the requirement for providing a cost estimate for the services subject to the ABN, the website instructions stated the ABN would not be considered valid without a good faith attempt to estimate cost but CMS would be “flexible in defining what a good faith estimate is, particularly in consideration of cases where the ordering and rendering providers may be different.”

When the official manual instructions were issued on September 5, the language above was not included, was deleted from the website instructions, and replaced by language providing for a complicated and essentially unworkable calculation with respect to laboratory services. ACLA has expressed our concern to CMS about the elimination of the reference to good faith efforts particularly where the laboratory is not the provider obtaining the ABN. We plan to communicate formally with CMS on this and several other issues raised by the new manual instructions.

CMS Publishes Revised Transmittal on Physician Signature

Almost four months after CMS had written to ACLA confirming our position that CMS policy does not require physician signatures on lab requisitions, CMS issued Transmittal 94, instructing contractors that signatures are not required. The transmittal does stipulate that the physician must clearly document, in the medical record, his or her intent that the test be performed.

The language that the signature was not required was inadvertently dropped from instructions in the web-based version of the Medicare manual in January 2008, causing Medicare contractors to challenge reimbursement for lab claims where requisitions did not have physician signatures. ACLA met with CMS in late winter to challenge the signature requirement. CMS agreed that we were correct and promised to change the manual instructions and would communicate with the contractors that signatures were not required. However, until the issuance of the revised instructions, several contractors continued to challenge claims without the requisite signatures.

ACLA Has Second Meeting with CMS on Ionized Calcium Policies

On September 16, ACLA and representatives of ACLA member ESRD

companies met with CMS hospital and ambulatory policy officials to press our concerns about a CMS transmittal issued in April regarding payment and coverage policies for ionized calcium. We reiterated our challenge to the appropriateness of paying for ionized calcium as a panel test based on the automated multichannel chemistry panel payment algorithm, since ionized calcium in a commercial laboratory setting can only be performed on a separate piece of equipment and not as part of an automated panel. We also stated that ionized calcium should be considered a composite rate test as it is not routinely ordered nor commonly used to treat ESRD patients. We asked CMS to pay for ionized calcium at the existing fee schedule payment rate, when it is ordered with other chemistry tests and to amend the existing transmittal to delete the provisions classifying ionized calcium as a composite rate test.

ACLA had met with CMS officials in the chronic care policy group in May to discuss these issues and addressed the payment issue during a CMS meeting this summer on payment rates for the 2009 Clinical Laboratory Fee Schedule.

ACLA Joins Payers and Providers to Oppose Proposed HIPAA Timeline

ON August 22, CMS proposed two sets of rules, one implementing HIPAA standard 5010 and a second that would modify the medical data code set standards to adopt ICD-10-CM and ICD-10-PCS, with October 21 as the target date for final implementation of both sets of changes. Comments on the proposed rules must be submitted by October 21, and HHS has indicated that it intends to promulgate final rules before the end of this calendar year.

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 primary providers who must provide 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.

ACLA has joined a coalition representing the payer community, provider groups including the AMA, and others in seeking

a more reasonable five year time frame (to 2013) for accomplishing the completion of HIPAA standard 5010 and the labor-intensive shift from ICD-9 to ICD-10. The coalition is asking for at least two years to implement 5010 followed by a year of external testing. Under the coalition timeline, the health care system would be given three years to shift from ICD-9 to ICD-10, work that would start during the period of external testing of 5010. The coalition has met with Congressional leaders and White House, OMB and senior HHS officials to build support for a more realistic timeline.

Results for Life Update

This fall is a robust time for the *Results for Life* Campaign. We kicked off the season with the roll out of the Personalized Medicine Story Board -- distributed to over 250 targeted offices on Capitol Hill and followed with personal phone calls and meetings.

Dr. Ron Weiss, Chairman of the *Results for Life* Campaign, was published on the Health Affairs blog, making “The Case for Personalized Medicine”. The highly respected health policy journal ran the article in September, outlining the role that personalized medicine will play in the health reform debate through the upcoming election.

Results for Life recently posted a response to Time Magazine in response to the article, “Should Genetic Tests be Regulated?” In a continuing effort to push back on recent media attention lumping the Direct to Consumer Genetic Testing market as ‘all genetic tests’, the letter highlighted the importance of recognizing the benefits of genetic testing and medical breakthroughs it’s facilitated.

Also on the forefront, a Media Primer event titled “A Primer on Genetic Testing: What Is It? How Does It Work? Why Does It Matter?” is scheduled for October 28th at the National Press Club in Washington. John Iglehart, Washington correspondent with the New England Journal of Medicine, will be joining us as the moderator for the event, as well as an impressive lineup of molecular and genetic expert speakers. The audience will be primarily media and press contacts, as well as a number of Capitol Hill Staff and key organization representatives. The speakers will cover everything from the basics of how

genetic testing works, to the science, economic and policy issues surrounding the tests.

We continue to use North American Precip Syndicate and USA News placement services for short articles in regional papers. There are currently two articles in circulation: "Get a Test, Stop a Killer" running 228 times in 20 states, "Personalized Medicine: It's All About You" running 168 times in 19 states, in addition to our 60 second radio spot, "Lab Tests Save Lives", airing 645 times in 39 different states.

Additionally an Op-Ed authored by Representative Ciro Rodriguez (D-TX) was published in The Hill health section September 24th. The article "Time to Hit the Brakes on an Epidemic – the Deaths of 7 out of 10 Americans" notes that diabetes, kidney disease, cancer, and heart disease have become an epidemic-- in terms of both prevalence and healthcare costs in the United States. The Congressman touches on the devastating effects of these chronic diseases and emphasizes the need for education, early detection and prevention. The article ran next to a **Results for Life** campaign ad.

ACLA Comments on Phase VIII Medically Unlikely Edits

ACLA submitted comments on Phase VIII of the Medically Unlikely Edits (MUE) program to Correct Coding Solutions on September 9th, the contractor for the Centers for Medicare and Medicaid Services (CMS). 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 defined group of services that cannot be medically justified to have been performed on a single date of service for the same patient. They are meant to identify claims with obvious or negligent errors such as typographical errors, transcriptional errors, or duplicative services. The examples given by CMS supporting this definition are vasectomy on a female, hysterectomy of a male or two 24 hour urine samples. ACLA's comments reiterated that MUEs should not dictate medical policy or in any way interfere with clinical ordering and judgment.

ACLA's CPT Committee took the lead in preparing the comment response. The comments identified codes which ACLA did not agree with the proposed MUE and therefore provided an alternative MUE and/or identified a number of codes which should not be subject to an MUE. For codes which should not be subject to an

MUE, ACLA provided examples where these codes are driven by the professional judgment of the clinician and therefore not possible to set a limit for testing performed in a single date of service. Another reason that some codes should not be subject to an MUE is because the AMA description of the CPT code states its use is "each".

Because of the many unresolved issues and concerns associated with this phase of MUEs, ACLA requested a meeting with CMS, the contractor and other stakeholders prior to final decision making.

Institute of Medicine Invites Comment from ACLA on Emergency Preparedness

Dr. Hawazin Faruki, V.P. Laboratory Corporation of America and representing ACLA, presented on September 23rd to the Institute of Medicine (IOM) Committee tasked to explore the Effectiveness of National Biosurveillance Systems in the event of biological terrorism or other biothreats to human health. Dr. Faruki specifically addressed the important role the clinical laboratories can play in the event of a public health emergency.

Dr. Faruki's power point presentation can be found on the ACLA web site. The presentation stressed the complementary roles of the clinical and public health labs and noted the recent progress in better understanding and forging agreements between the two lab sectors in emergency preparedness. Details were given elaborating on the specific areas of clinical laboratory contributions in testing and logistics assistance as well as specific clinical laboratory considerations in advance of a threat.

Following the presentation, an IOM Committee member commented on the robust clinical laboratory transportation networks and information technology connectivity as a plus for critical communication. The IOM project is sponsored by the U.S. Department of Homeland Security with the final report in prepublication form in June 2009.

CLIAC Approves Good Laboratory Practices for Molecular and Genetic Testing

The Clinical Laboratory Improvement Advisory Committee (CLIAC) approved a workgroup report at their September 10th, 11th meeting on Good Laboratory Practices for Molecular and Genetic Testing. The guidelines will be published in the CDC Morbidity and Mortality Weekly Report (MMWR) sometime in early 2009.

CLIAC approved the report as voluntary guidelines; not intended to be new CLIA regulatory requirements. The scope of this guidance is limited to molecular tests for heritable disorders or conditions. CLIAC endorsed a recommendation to pursue additional future guidelines which could address biochemical and somatic testing.

To meet the MMWR publication schedule, CDC staff plan to submit a revised draft of the report to MMWR by November 2nd. They indicated they will try to post the report on the CLIAC web site before the 2nd - <http://wwwn.cdc.gov/cliac/>.

ACLA In The News

National Intelligence Report

September 29, 2008

Lab Industry Urged to 'Get Ahead of the Wave'

At the Institute's Capitol Hill Buzz session, Alan Mertz, president of the American Clinical Laboratory Association, noted that clinical lab and pathology groups scored on three top legislative priorities this year:

- Repeal of the Medicare competitive bidding demonstration for independent lab services that the government had planned to launch July 1 in San Diego.
- Increase in Medicare fees. Congress canceled a 10.6 percent cut in physician fees and guaranteed a 0.5 percent increase through 2009. Lab fees got a Consumer Price Index (CPI) update for the first time in five years; however, Congress reduced the update by 0.5 percent from 2009 through 2013. The update for 2009 is 4.5 percent.
- Extension of the "grandfather" protection that allows certain independent labs to bill Part B for the technical component of anatomic pathology services for hospital patients.

The nation's financial picture only adds to the squeeze on Medicare spending, Mertz said, and urged labs to remain vigilant against any legislative move to cut lab spending to pay for increases elsewhere. He emphasized the importance of a solid front to safeguard lab spending, noting the industry's success in persuading Congress to scuttle the lab bidding demo. Advocacy campaigns must continue to educate members of Congress and their staff on the value of lab testing in clinical practice and the need for better reimbursement for new genetic tests and technologies, he said.

National Intelligence Report

September 15, 2008

HHS Proposes Transition to ICD-10 Diagnosis Codes by October 2011

"The American Clinical Laboratory Association, which along with the Blues is part of the

ACLA in the News (continued)

33-member ICD-10 coalition, agrees that the transitions should not overlap. They involve a vastly expanded number of codes and different nomenclatures, ACLA senior vice president JoAnne Glisson told NIR, and this poses a host of administrative and educational complexities to surmount. "You can't make the switch to both during the same time span. This would require you to simultaneously support two systems for payers, Versions 4010 and 5010, and two systems for diagnosis codes, ICD-9 and ICD-10, during the turnover. And at the same time, you would be dealing with physicians and other trading partners at various stages of readiness for the transitions."

Is It Time to Consider Overhauling the Lab Fee Schedule?

"The American Society for Clinical Laboratory Science (ASCLS) and the Clinical Laboratory Management Association (CLMA) think so and last month secured the introduction in the House of a bill (H.R. 6761) that would require a negotiated rulemaking process to revamp the Medicare lab fee schedule based on the value of the testing, the resources required, and geographic cost differences." "Alan Mertz, president of the American Clinical Laboratory Association, told NIR that ACLA is reviewing H.R. 6761 and talking to proponents. But it is clear that there is not a consensus within the lab industry on key questions, he said. Should there be an overhaul of the current lab fee schedule? If there is a need to do it, how should it be done? Is this the approach we should ask Congress to take? As the competitive bidding battle demonstrated, Mertz said, "We need to focus and set our priorities for lobbying our cause on Capitol Hill. We need to emphasize the upside of laboratory testing, its vital role in treatment and prevention, while making sure lawmakers see the downside of cutting lab spending. We also need to lobby for better reimbursement for prevention and genetic testing." Labs need to remain vigilant that we are not tapped to pay for other priorities. We are getting a healthy fee update in 2009, so we could again become a target as has happened often in the past."

CAPTODAY - August 2008

Wins, Worries on Reimbursement Battlefields

ACLA President, Alan Mertz, was extensively quoted in an article acknowledging recent reimbursement victories but recognizing that major challenges remain. A few quotes are provided below – the entire article can be found at: <http://www.cap.org>. "Repeal of competitive bidding represented a major, collaborative advocacy effort by the industry, Mertz says. And the "silver lining to the effort," he adds, is that Congress now has a much better understanding of the complexity of lab services. "It's not just a widget that everyone can bid on—it's a service." "Repeal of competitive bidding came at a price, however. It was important for labs to provide some savings for the competitive bidding demonstration repeal, estimated to cost labs \$10 million to \$20 million over five years, says David Mongillo, ACLA's vice president for policy and medical affairs. Thus, under HR 6331, he says, labs will give up 0.5 percent of the scheduled update over the next five years—\$600 million less overall." "Mertz says the lab community reached a "unanimous consensus" that the \$600 million was worth it because labs hadn't had an update except for one year out of the last 10. For 2009, in fact, the inflation adjustment will result in labs getting about a 4.5 percent update, Mertz noted in a July 23 ACLA-sponsored LabLine audio conference on the Medicare legislation."

G-2 Compliance Report - October 2008

Lab Groups Support Additional Efforts to End Incentives for Ordering Tests

Groups representing pathologists and clinical laboratories are urging the Centers for Medicare and Medicaid Services (CMS) to do more to limit the ability of physician groups to bill for pathology services under the auspices of an exception to the Stark law. In comments on the 2009 Medicare physician fee schedule (MPFS) proposed rule, submitted August 28, the American Clinical Laboratory Association (ACLA) notes that despite efforts to stop physicians from profiting from their referrals, abusive arrangements have continued to proliferate.

Calendar of Events/Meetings

October 1	CPT Committee Meeting	Conference Call
October 2	Health IT Data Standards Meeting	Conference Call
October 3	ACLA Weekly Call	Conference Call
October 3	5010 and ICD-10 Meeting	Conference Call
October 6	Clinical Laboratory Coalition Meeting	Conference Call
October 9	ACLA FDA Committee Meeting	Conference Call
October 9	IOAS Meeting	Conference Call
October 10	ACLA Weekly Call	Conference Call
October 15	CPT Committee Meeting	Conference Call
October 16	Billing and Reimbursement Committee Meeting	Conference Call
October 17	ACLA Weekly Call	Conference Call
October 23	IOAS Meeting	Conference Call
October 24	ACLA Weekly Call	Conference Call
October 24	Results for Life Committee Meeting	Conference Call
October 28	Results for Life Media Primer on Genetic Testing	Washington, DC
October 31	ACLA Weekly Call	Conference Call