



RESULTS

American Clinical Laboratory Association

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President's Message

As ACLA heads into 2008, Washington is a buzz with speculation about the most open Presidential election race in at least 40 years. Yet, no matter who wins the Presidency and controls Congress, ACLA is well positioned to make gains on its key advocacy agenda items. The repeal of competitive bidding, working to make sure all laboratory tests receive adequate reimbursement, and promoting oversight of genetic tests that ensures both safety and innovation continue to be our priorities.

On repealing competitive bidding, we came within a whisker of crossing the finish line at the end of 2007. We now have a dedicated team of runners who have already taken a few laps and are ready to try to finish the race in 2008. The unprecedented education campaign that ACLA, its members, and the Clinical Laboratory Coalition waged has laid an important foundation for future action on competitive bidding and laboratory reimbursement in general.

In 2007, ACLA took our positioning and advocacy on the issue of oversight of genetic testing up several notches. We forged an important new plan for enhanced oversight of genetic testing. This proposal will address some gaps in current oversight, while avoiding excessive and duplicative regulation that would threaten existing critical tests and future innovation. This month we will have an important meeting with CMS and FDA to discuss our proposal.

In addition to these advocacy issues, ACLA has been working on other important issues that do not always garner as much publicity, but are vitally important to our members. Heading this list was CMS recent decision to revise Change Request 5743 in January by deleting the standing order language. ACLA acted quickly to raise this issue with CMS last fall.

We are also putting the finishing touches on the upcoming 2008 ACLA Annual Meeting (April 17-18, Washington, DC). We have another stellar line up of speakers you won't want to miss. If you have not registered

yet, I encourage you to do so (www.clinical-labs.org) soon as this meeting will sell out.

Finally, I wanted to thank ACLA's members, Board, Chairman, and staff for making 2007 a banner year for ACLA!

Competitive Bidding – CMS Moving Ahead with Implementation

CMS convened the once postponed competitive bidders' conference in San Diego, the site of the first demonstration, on December 5 and announced the proposed deadlines for implementation of the project. Bids must be submitted by February 15th, CMS will announce the winning bidders and the bid fee schedule on April 11th and begin paying the bid fee schedule on July 1, 2008.

ACLA and representatives of ACLA member companies as well as those of laboratories located in the San Diego area participated in the bidders' conference. CMS and RTI, the contractor responsible for developing the parameters of the bidders' package, described how the demonstration would work and answered questions from prospective bidders about how the bidding process would work and how bids would be evaluated. Many of the responses left the prospective bidders with more questions than definitive answers and wondering whether they had sufficient information in which to prepare complete bids. Attendees were concerned about the terms and conditions that would be imposed on winning bidders and not known until after bids are submitted and CMS' statements that bid parameters might be amended after bids were submitted.

RESULTS is a monthly report to ACLA member companies

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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

Competitive Bidding 2008 – Legislative Strategy

The 2008 legislative agenda begins much like calendar year 2007 with the focus on repealing Medicare's competitive bidding demonstration project for clinical laboratory services. However, there is a stark contrast between last year and this year. The industry has growing congressional support from lawmakers who seek to repeal the demo project's authority. Bipartisan bills in the House (HR 3453) and Senate (S 2099) which would repeal the demo project have been introduced and have a number of co-sponsors. A hearing was held last summer before the House Small Business Committee which helped raise awareness about the issue. In addition, House and Senate lawmakers from the greater San Diego area wrote the Chair and Ranking Members of the Committees of jurisdiction urging them to repeal the demo project. At the outset of 2007 we were only beginning to realize the opportunity before us to repeal the demonstration project given the rise in power by Democrats.

Having done so much 'right' in 2007 our approach to 2008 isn't all that different. ACLA plans to concentrate our efforts on solidifying support for the repeal effort we already enjoy with several influential lawmakers: Senators Ken Salazar (D-CO) and Pat Roberts (R-KS); Senate Finance Chairman Max Baucus (D-MT) and Chuck Grassley (R-IA); Ways & Means Health Subcommittee Chairman Pete Stark (D-CA) and Ranking Member Dave Camp (R-MI); Small Business Committee Chairwoman Nydia Velazquez (D-NY) and Energy & Commerce Health Subcommittee Chairman Frank Pallone (D-NJ). In addition, ACLA will be working to expand the list of co-sponsors for both the Community Clinical Laboratory Fairness in Competition Act of 2007 (which currently has 30 co-sponsors) and the Senate version of the repeal, the Preserving Access to Laboratory Services Act of 2007 (6 co-sponsors). ACLA will meet with Members of Congress to further educate them about the dangers the demo project poses for not only the beneficiaries and laboratories of San Diego, but eventually, the nation itself.

The most likely vehicle to attach the repeal legislation is a comprehensive Medicare package, the basis of which is an extension of the current six

month update to physician payments. Medicare legislation enacted in December 2007 averted a 10% cut to Medicare physician payments for six months. Congressional lawmakers have agreed to pass more comprehensive legislation before that extension expires on July 1, 2008 – the same day CMS has tentatively scheduled to begin paying laboratories in San Diego, CA the new competitively bid laboratory fee schedule.

Standing Orders Change Request Rescinded

On December 19, 2007, CMS announced that it was rescinding Change Request 5743, which would have eliminated payment for all standing orders. ACLA had written to CMS in November asking them to delete this new authority that appeared in a transmittal which CMS stated "incorporates language inadvertently omitted from the Medicare Carriers Manual when the Internet Only Manual was published." ACLA discussed this provision during a meeting with CMS Deputy Administrator Herb Kuhn. ACLA also met with CMS officials directly involved with the standing order issue on December 18, 2007. We pointed out that not only was this new language but there are many legitimate uses for standing orders including the monitoring of drug regimens, in nursing home settings and in the care and treatment of ESRD patients.

On January 11, 2008, CMS issued a revised Change Request 5743 which deleted the standing order language. In correspondence ACLA received from CMS, a CMS official indicated that they would be revising the standing order language and would reissue it at a later date.

CMS Indicates Labs Can Modify the New ABN Form

ACLA met with CMS Deputy Administrator Herb Kuhn on December 11 to discuss our concerns about replacing the existing Lab ABN form with the new "one size fits all" generic ABN form. We explained that beneficiaries and physicians were very familiar with the existing form and that changing the form would unnecessarily confuse them. We also described and provided examples of the customized forms our members had developed to address national and local coverage decisions and ordering practices of medical specialties. CMS advised us that they intended to move forward with the new form but would work with us to try to address

our concerns within that framework.

On January 10, CMS did provide us with a mock-up of the ABN which appears to address some of our concerns about being able to customize the form, and we will work with the agency going forward to attempt to resolve our outstanding concerns. We remain very concerned about the legal status of an ABN for which the ordering provider did not include the cost or provided an incorrect cost for a test for which the beneficiary might be liable for payment.

Results for Life Update

The *Results for Life* campaign for 2008 is off to a resounding start. ACLA Board Chairman Dr. Ron Weiss and ACLA President Alan Mertz participated in a very successful media tour in Salt Lake City Utah. They met with local editorial boards from TV, radio and print outlets to promote the value of laboratory services and communicate the message that laboratory services save lives and save dollars. This regional media communication experience will serve as an example for other regional media events.

On January 23rd, *Results for Life* will host a luncheon in Washington for employer and payer groups. The event will communicate the role of laboratory services in an effective, cost-effective health care system and discuss ways to work together in advocating forward-thinking steps to improve health care delivery. As part of the luncheon, an exciting collaboration with the National Kidney Foundation will be announced. This will include a joint press release announcing a consumer brochure focusing attention on the impact of chronic kidney disease and the important role of laboratory tests in early detection. A Capitol Hill Event is tentatively scheduled for March 25th with the Diabetes/Kidney Caucus to promote the value of laboratory testing for chronic kidney disease to coincide with kidney disease month.

In addition, we are working with the North American Precipitation Syndicate (NAPS) service to place print article and radio spots nationwide and have a number of new web site enhancements.

The next *Results for Life* Committee conference call meeting is January 25th where many other activities will be discussed with the sponsors.

ACLA Submits Additional Comment on IVDMA Oversight: Meeting with FDA/CMS Scheduled

ACLA submitted additional comments regarding the Food and Drug Administration's ("FDA") *Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays*. The comments represent an evolution in ACLA thinking and propose a regulatory model for IVDMA oversight. An important aspect of the model is an interagency Memorandum of Understanding (MOU) defining a significant consultative role for the FDA while maintaining the Centers for Medicare and Medicaid Services (CMS) and CLIA as the exclusive regulatory authority for laboratory test services. The comments are posted on the ACLA web site.

ACLA will meet with both FDA and CMS officials on January 24th to present this model. The key elements of the proposal are summarized below.

- It is consistent with principles of least burdensome regulation thus avoiding overlapping and potentially conflicting regulatory oversight by maintaining CMS as the sole regulator under CLIA while identifying a significant FDA role.
- Intended to remedy known concerns by including:
 - A mandatory IVDMA test registry of standard data maintained by CMS or by a public-private entity and accessible by the public
 - CLIA enhancements that would be informed by interactive stakeholder and agency workshops to identify any gaps in CLIA quality programs and to resolve overlaps
 - Independent review of clinical validity and use claims by CMS/FDA or by a 3rd party review funded through user fees.
- Can be implemented under law as it exists today through the MOU process and use of interpretive guidelines.
- Is a participatory approach that draws on the expertise of industry stakeholders, CMS, FDA and others.
- Does not involve significant new costs for the agencies to build internal expertise or fund a parallel laboratory regulatory oversight structure. User fees would fund third party review of validation packages.

ACLA Comments to SACGHS on Genetic Test Oversight

ACLA submitted comments on December 21st to the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) on the draft report, *U.S. System of Genetic Testing: A Response to the Charge of the Secretary of HHS*. The comments stressed ACLA's shared commitment to maximizing the benefits of genetic testing by continuing to promote innovation responsibly and to integrate these technologies into clinical practice. ACLA's comments acknowledged support for many of the SACGHS recommendations in the Draft Report, and particular support for the Committee's overarching recommendation, which appropriately recognizes the need for enhanced interagency coordination. ACLA agreed as well with the need for greater funding and research into ways of utilizing this information and developing appropriate standards, and strongly supported the recommendation for better education of key decision makers, providers and other users of this information.

ACLA further recognized the Committee's attention to reimbursement-related issues, and endorsed its recommendation that HHS should take action on the recommendations made by the Committee in a previous report. ACLA urged the Committee to recommend that CMS continue to be the lead agency in the regulation of clinical laboratories, and fully supported the recommendation in the draft report that the development of new regulations and policies in this area should be done with better interagency coordination. ACLA emphasized that we share the Committee's goal of ensuring continued access to innovative, safe, and effective laboratory services and offered to work with the Committee, the agencies, and other stakeholders to ensure that these goals are achieved. The comments are on the ACLA website.

CMS Publishes 2008 Clinical Laboratory Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) published the 2008 Clinical Laboratory Fee Schedule on their web site at http://www.cms.hhs.gov/Clinical-LabFeeSched/02_clinlab.asp#TopOfPage. This provides the CMS payment for new codes effective January 1, 2008.

Prices for new CPT codes added to the Medicare lab fee schedule in 2008 are established by CMS following a public

meeting. CMS elected to use the cross-walk method, which matches payment rates to existing codes. There are no new test codes to be gap-filled, a method based on local pricing patterns. For all other codes, the lab fee schedule is frozen at their 2003 levels through 2008.

State Issues

On January 17, ACLA wrote to the Florida Medicaid agency requesting a meeting to discuss reductions in payment for certain CPT codes as well as developing an ongoing more formal relationship with the agency on laboratory policy issues.



Preliminary Agenda

- Presidential & Congressional Election Outlook; What Will The Agenda Be With A New President In 2009?
- View From The Hill
- The Presidential Campaigns & The Health Care Agenda
- The Laboratory Advocacy Agenda
- Inside CMS
- Oversight of Genetic & Molecular Testing — Perspective From The Agencies And The Hill
- Laboratory Best Practices And Other Quality Standards
- Where Is Clinical Laboratory Medicine Heading?

To obtain a registration form, please visit ACLA's website, www.clinical-labs.org. Hotel reservations can be made directly with the Grand Hyatt Hotel (202-582-1234). Be sure to identify yourself as attending the ACLA Annual Meeting.

For more information, please contact Cheryl Hawkins via telephone, 202-637-9466 OR email, chawk@clinical-labs.org.

ACLA in the News

National Intelligence Report – December 17, 2007

CMS Forging Ahead with Lab Bidding Demo in San Diego

The Centers for Medicare & Medicaid Services took another big step toward the launch of its Part B lab competitive bidding demonstration with a December 5 bidder's conference for clinical labs in San Diego, the first of two sites for the pilot project. The fact that major questions raised by the industry remain unanswered at this late stage "only reinforces the need to repeal the demo," said Alan Mertz, president of the American Clinical Laboratory Association.

Advisory Panel Prescribes Changes for CMS, FDA in Genetic Test Oversight

The recommendations are contained in the new draft report that the HHS Secretary's Advisory Committee on Genetics, Health & Society (SACGHS) has released for public comment through December 21. The initial reaction of the American Clinical Laboratory Association and the College of American Pathologists to the SACGHS recommendations for CMS and the FDA was generally favorable, but with some caveats. Both groups insist that CMS should be the lead federal agency to oversee genetic testing services, and both contend the FDA should take a "go slow" consultative approach to regulating genetic test products.

ACLA elaborated on what that role should be in additional comments submitted December 11 to the FDA regarding its IVDMA guidance. ACLA advocates a regulatory model for IVDMA oversight that addresses industry concerns "while avoiding overlapping and potentially conflicting regulation." A key aspect of the model is "an interagency Memorandum of Understanding (MOU) defining a significant consultative role for the FDA while maintaining CMS and CLIA as the exclusive regulatory authority for lab test services." The FDA role would include defining a risk classification for IVDMA's and validity criteria.

The model also includes:

- "CLIA enhancements ... to identify any gaps in CLIA quality programs" and to resolve overlaps between CLIA quality control rules and the FDA's quality system requirements.
- A mandatory IVDMA test registry of standard data maintained by CMS or a public-private entity and accessible by the public.
- Independent review of clinical validity and use claims by CMS/FDA or by a third-party review funded through user fees.

The model "can be implemented under current law through the MOU process and use of interpretive guidelines," ACLA said. "If regulatory changes are needed, the industry would be committed to making consensus standards happen in a timely fashion."

ACLA also warns against an overly broad regulatory definition "that could sweep in many tests which have some genetic component but not necessarily an inherited one, including routine cholesterol or glucose checks, basic blood counts, and DNA-based tests for non-inheritable abnormalities."

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Calendar of Events/Meetings

January 14-18	Salt Lake City Results for Life Media Tour	Salt Lake City, UT
January 21	ACLA Office Closed -Dr. Martin Luther King Holiday	
January 22	ACLA Ad Hoc Board of Directors Meeting	
January 22	AHIC Meeting	Conference Call
January 23	Results for Life Payor/Provider Business Luncheon	Washington, DC
January 24	CMS/FDA Meeting	Washington, DC
January 25	ACLA Weekly Call	Rockville, MD
January 25	Results for Life/PR Committee Meeting	Conference Call
January 30	Alan Mertz and JoAnne Glisson visit AcuLabs	Conference Call
January 30	AHIC Meeting	Brunswick, NJ
February 1	ACLA Weekly Call	Washington, DC
February 5	ACLA Board of Directors Meeting	Conference Call
February 7	Chairman Pete Stark (D-CA) Fundraiser	Washington, DC
February 8	ACLA Weekly Call	Washington, DC
February 8		Conference Call
April 17-18	SAVE THE DATE - ACLA's 13th Annual Meeting	Washington, DC