

JULY 2004



# RESULTS

American Clinical Laboratory Association

VOLUME 10 • NUMBER 6

RESULTS is a monthly report to ACLA members companies

## In This Issue

- President's Message (page 1)
- AmeriPath Joins (page 1)
- ACLA Writes AHCA (page 2)
- Stark II Comments (page 2)
- State Issues (page 2)
- Information Technology Update (page 2)
- ACLA Joins WEDI (page 3)
- CDC Meeting (page 3)
- Infectious Disease Subcommittee (pg 3)
- CPT (page 4)
- ACLA in the News (page 4)
- SACGHS (page 4)
- Calendar of Events (page 4)
- ACLA Calendar of Events

### ACLA Staff

**Alan Mertz**, *President*

**JoAnne Glisson**, Senior Vice President

**David Sundwall**, M.D., Senior Medical & Scientific Officer

**Jason DuBois**, Vice President, Government Relations

**Cheryl Hawkins**, Membership Coordinator

**Peter Kazon**, Legal Counsel

202-637-9466  
www.clinical-labs.org

## President's Message

ACLA's ability to be an effective advocate for the clinical laboratory industry is only as strong as its membership base. This is why I am so pleased to report that our membership base continues to expand with one of the nation's largest laboratories, Ameripath, Inc., joining our ranks. That brings ACLA membership to 19 companies, up from 14 less than one year ago. I expect more good news about at least two other prospective members in the near future.

In June I had the opportunity to tour three of ACLA's member laboratories in the San Francisco area, as well as meet with prospective members. I want to thank ACLA members Rina Wolf and her colleagues at Genomic Health, Inc., Paul Beyer at Satellite Laboratory Services, and Bill Young at Virologic for hosting me.

I was very pleased with the great turnout for our new weekly conference calls for ACLA members, which began June 18. Each Friday at 11 a.m., ACLA members and staff are invited to participate in the 30 minute call in which we share information and ideas on our key advocacy issues. Given the positive response to the calls, we will definitely continue these calls.

While we continue to work hard on our top two issues – the OIG proposed rule and competitive bidding – we also had some real progress on other issues. We filed excellent comments on the Stark II Rule with the help of Peter Kazon and many ACLA members. JoAnne Glisson's testimony before state legislatures and boards in New Jersey and Florida turned out to be very successful. In New Jersey, a Senate committee amended a problematic cytotech bill, and in Florida, the Board of Laboratory Personnel decided not to change standards for cytotechs. Dr. Sundwall

coordinated a productive ACLA-hosted CDC meeting on public/private partnerships. ACLA was also very actively involved in a wide range of meetings on health care information technology. More about all of these efforts in this Results.

If you have not seen ACLA's web site ([www.clinical-labs.org](http://www.clinical-labs.org)) lately, take a look. We have greatly expanded the "Issues Section," and added several new features. Thanks to Jason DuBois for his work here.

The ACLA Board meets by conference call on July 15<sup>th</sup>, and I will be reporting on that meeting in the next Results.

*Alan Mertz*

## AmeriPath, Inc. Joins ACLA

ACLA welcomed its newest member, Ameripath, Inc. in June. AmeriPath, Inc. is a leading national provider of cancer diagnostics, genomics, and related information services. The company's extensive diagnostics infrastructure includes over 400 pathologists and doctorate-level scientists providing services in over 40 independent pathology laboratories, more than 200 hospitals, the Center for Advanced Diagnostics (CAD) and DermPath Diagnostics, a division of AmeriPath. CAD provides specialized diagnostic testing and information services including Fluorescence In-Situ Hybridization (FISH), Flow Cytometry, DNA Analysis, Polymerase Chain Reaction (PCR), Molecular Genetics, Cytogenetics and HPV Typing. AmeriPath has over 60 board-certified dermato-pathologists supporting DermPath Diagnostics, one of the country's leading providers of dermatopathology services.

## ACLA Writes Florida AHCA

In a June 15 letter, ACLA followed up on its recent meeting with Florida Agency for Health Care Administration (AHCA) Director Alan Levine with a letter spelling out concerns about a capitated, single-winner competitive bidding scheme.

"We believe that the assumptions underlying AHCA's [capitated, single-winner] approach are seriously flawed and that AHCA's plan ultimately will: increase rather than reduce reimbursement for clinical laboratory services; lead to longer turnaround times and create significant access issues that will ultimately harm Medicaid beneficiaries, and; drive up health costs in other parts of the Florida Medicaid program."

In the letter, ACLA expanded on three key problems with such a competitive bidding proposal: "(1) A capitated contract for clinical services will not be in the best interest of AHCA, Medicaid beneficiaries, or the citizens of Florida; (2) A "successful" RFP will reduce the already low margin received on Medicaid testing and place the entire financial burden on a single laboratory; (3) The ultimate result for Florida is theoretical short-term gain in return for certain long-term pain."

The ACLA letter to AHCA can be found on ACLA's website ([www.clinical-labs.org](http://www.clinical-labs.org)) on the "Issues" page under competitive bidding.

## CMS Demo

ACLA has continued discussions with CMS about the competitive bidding demonstration project and has expressed to CMS the importance of broad laboratory industry representation on the technical expert panel (TEP) that will be formed by an outside contractor (see CMS RFP

language below). ACLA also participated in a Clinical Laboratory Coalition meeting specifically on competitive bidding.

*"The contractor shall be responsible for organizing and operating a Technical Expert Panel (TEP). Activities involve selecting members, and coordinating work and work products, organizing and managing the members and meetings as appropriate. Requirements under the Federal Advisory Committee Act (FACA) are not applicable. Members should include expertise from major areas of the stakeholder community, (e.g., the laboratory industry, providers, and beneficiaries). Some of the meetings may take place via teleconference. The contractor will offer to pay an honorarium to the TEP members who are not employed by the government. The contractor shall submit proposed TEP membership, meeting agendas, and draft meeting summary notes and/or reports to CMS for approval.*

*During the design and startup of the operational phase of the demonstration, the TEP will provide a forum for raising and resolving technical, operational, and laboratory performance issues. The TEP shall review design options prior to the panel meeting. During the session the panel members will discuss the issues presented, discuss any additional design options, and provide advice on the specific model(s) to test."*

## ACLA Files Comments on Stark II Interim Final Rule

ACLA filed comments on the Interim Final Rule regarding Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships ("Stark II")

on June 24, 2004. ACLA stated that, in general, it supports the Interim Final Rule and believes that CMS has made great strides in accommodating the demands faced by health care providers attempting to comply with the Stark law. However, ACLA emphasized special concern that, as currently defined, the in-office ancillary services exception could be subject to abuse, including spurring new so-called "Pod" arrangements that could lead to the overutilization of pathology services. ACLA also recommended further clarification of the scope and applicability of several other exceptions to the law. A copy of our comments is posted on the ACLA website.

## Florida Board of Lab Personnel Decides Not to Change Standards for Cytotechs

On June 18, 2004, ACLA testified before the Florida Board of Clinical Laboratory Personnel in opposition to a proposed rule that would require cytotechnologists obtain a baccalaureate degree in cytotechnology. In the testimony, ACLA urged the Board to adopt the cytotechnologist requirements of CLIA: obtain a baccalaureate degree, graduate from an accredited program in cytotechnology and be qualified to sit for the certification examination of the American Society for Clinical Pathology (ASCP); and to apply appropriate "grandfather" requirements for individuals already certified by ASCP. ACLA pointed out that there are no institutions in Florida offering a baccalaureate degree in cytotechnology or accredited programs in cytotechnology. The Board decided to reject the proposed new rule and keep the requirement of the existing rule that a cytotechnologist be certified by ASCP. A copy of the testimony is posted on the ACLA website.

## NJ Senate Committee Amends Cytotech Bill Following ACLA Testimony

On June 7, 2004, ACLA testified before the New Jersey Senate Committee on Health in opposition to legislation that would require pathologists to review and certify as accurate all cervical cancer screening specimens, including negative results. In the testimony, ACLA pointed out that regular screening examinations

What's New on the ACLA Website in June?

([www.clinical-labs.org](http://www.clinical-labs.org))

- June 24 Comments on Stark II Self Referral Rule
- June 18 ACLA Testimony on Florida Cytotechnologist Licensure
- June 17 Statement on Information Technology to House Ways and Means Subcommittee
- June 15 ACLA Comments to AHCA Secretary Alan Levine
- June 7 ACLA Testimony on Cytotechnologist Legislation

and advances in technology are the most effective approach to reducing the incidence of cervical cancer. Following the hearing, the committee voted unanimously to replace the provision requiring pathologist review of all specimens with language that would require random rescreening of at least 20 percent of negative results. The rescreening could be performed by a cytotechnology supervisor. A copy of the testimony is posted on the ACLA website.

## **ACLA Meets with Government IT Experts, Attends e-Health Initiative Forum**

ACLA staff and members representing LabCorp, Quest Diagnostics Incorporated, and US LABS met with James Sorace, MD, a pathologist and lead staff with the Centers for Medicare and Medicaid Services (CMS) working on the integration of electronic health care records (EHRs). The meeting featured presentations by representatives of ACLA member companies as well as the Department of Veteran Affairs, the DC Department of Health, and the California Healthcare Foundation focusing on the rate of adoption and the utility of EHR systems as they relate to laboratory services with an emphasis on laboratory data interfaces. This meeting was the first in what will be a continuing dialogue with the Administration in the development and implementation of standards for laboratory services into EHR systems.

ACLA also attended the first annual "Connecting Communities for Better Health" Conference sponsored by the eHealth Initiative. The two-day meeting provided an in-depth look at ongoing efforts in the development of health information technology (IT) standards, the current utilization of IT in select communities nationwide, creating incentives for providers, among other issues. Breakout sessions featured topics such as the legal and regulatory impact of IT in health care; the role of the consumer in delivery systems; and the long-term value of transitioning to EHRs. ACLA is a member of the eHealth Initiative, also known as E-HI.

## **ACLA Joins WEDI as Voting Member**

ACLA has joined the Workgroup for Electronic Data Interchange (WEDI) as a voting member. WEDI is one of the data

content committees that, under HIPAA, must be consulted prior to the adoption or modification of standards for electronic health care transactions. The organization, whose current membership is dominated by payers, has established a policy advisory group concerning ongoing implementation issues regarding standard transactions sets. More recently, WEDI convened a second policy advisory group meeting to discuss issues involved in moving to the national provider identifier (NPI) required by HIPAA. During the NPI meeting, it became obvious that no one wanted to revisit the implementation difficulties of standard transactions. As an active participant in WEDI, ACLA will have an opportunity to provide the laboratory provider perspective and concerns associated with the various aspects of HIPAA implementation.

### **ACLA Member Companies**

Acadiana Medical Laboratories Ltd.  
AmeriPath, Inc.  
ARUP Laboratories  
DCI Laboratory  
Fresenius Medical Care  
Focus Technologies, Inc.  
Gambro HealthCare Services  
Genomic Health, Inc.  
Laboratory Corporation of America  
Myriad Genetic Laboratories, Inc.  
Oncotech, Inc.  
Quest Diagnostics Incorporated  
RenaLab  
Satellite Laboratory Services  
Specialty Laboratories  
Total Renal Laboratories  
US LABS  
Virco Labs, Inc.  
ViroLogic, Inc.

## **CDC Meeting on Public/Private**

ACLA hosted a meeting convened by the CDC on June 29 that also included representatives of the CAP, ASCP, and the APHL. The purpose was to discuss ways the "laboratory community" (both public and private laboratories) and the CDC could work more effectively together. Dr. Toby Merlin, Associate Director of Laboratory Medicine, represented the CDC and reported on CDC's Futures Initiative, an ambitious reorganization of the agency that includes a concerted effort to promote partnerships with private sector "clients" of the CDC.

A number of issues of mutual concern to the organizations attending were discussed, including consideration of various mecha-

nisms to address them. ACLA's highest priority issues relate to: 1) timeliness of information and materials from the CDC, in the event of emerging infectious disease agents or bio-terrorism, to facilitate our member companies contribution to an appropriate response; and 2) development of a standard form and procedures for reporting public health laboratory data to various public health entities (regional, state and federal).

The group felt some of the issues related to "preparedness" would be best addressed by the CLIAC; however, in order to respond to pressing public health concerns it was felt that a new entity was necessary to convene the interested parties on an urgent, ad hoc basis. Dr. Merlin agreed to investigate how this might be accomplished by the CDC within legal constraints governing such meetings. There was little interest in creating another standing committee or advisory group, whether sponsored by public or private sectors. Nonetheless, a workgroup was established to develop a template for a standard public health reporting form, and it was agreed that this group would meet again, likely here in Washington, to facilitate ongoing collaboration of clinical laboratories and the CDC.

## **ACLA Participates in APHL Infectious Disease Subcommittee**

Dr. Sundwall has been appointed to APHL's Subcommittee on Infectious Diseases, and was invited to attend a meeting of this group on June 28, along with Dr. Joyce Schwartz, Vice President and Chief Medical Officer of Quest Diagnostics Incorporated. The purpose of our participation in this meeting was to explore how public and private sector laboratories might improve their collaboration to address public health threats posed by emerging infectious disease agents. A number of issues were discussed, including how laboratories might improve and simplify current public health reporting requirements for clinical laboratory data. A primary barrier identified was the lack of electronic capability of many public health laboratories, as well as the "interconnectivity" of laboratories that do have computerized systems. It was acknowledged that standards need to be developed for how to report data, but not necessarily for what specific

information is deemed necessary for various geographic regions. All those in attendance expressed some confusion about CDC's two laboratory networks, the National Laboratory Response Network (NLRN), and the National Laboratory Network (NLN), a demonstration program that is intended to promote better collaboration among private and public sector laboratories. Representatives from Michigan, Wisconsin, and Minnesota presented examples of integration models that are working well.

## CPT

The ACLA CPT Advisory Committee met via teleconference on June 23, to review four proposals for new codes that have been submitted to the AMA for inclusion in the 2006 CPT Manual. The Pathology Coding Caucus (PCC) seeks comments from all participating members of this group and will collate comments prior to convening a teleconference in mid-July where the PCC will attempt to achieve consensus recommendations to the CPT Editorial Panel. The Panel next meets in Colorado August 12 – 14, 2004, and will consider these new proposals and possibly some revisions in existing laboratory codes. It seems that lab-coding issues have increased in volume and frequency over the past few years, requiring careful monitoring of these activities.

ACLA is also working with representatives from the Advanced Medical Technology Association (AdvaMed) to develop language that will be acceptable to clarify “multi-plex” as defined in CPT. ACLA had requested a change in this language at the May meeting of the CPT Editorial Panel but the proposal

**ACLA in the News**

From National Intelligence Report, July 5, 2004, "Controversy Flares over In-Office Ancillary Services"

"ACLA Takes Aim At 'Pod' Labs...(a)ccording to ACLA...(t)hese arrangements encourage overutilization, may increase the number of specimens biopsied and potentially adversely affect the quality of patient care."

From Laboratory Industry Report, July 2004, "Florida Labs May Form Network to Bid on Medicaid RFP".

"The American Clinical Laboratory Association (ACLA) continues to lobby against the coming RFP...In the case of this proposed capitated RFP, a winning bidder would simply win low or marginal Medicaid testing....physicians will be concerned about... turnaround times, quality..."

was not supported by the PCC. When consensus with AdvaMed on revised language is achieved, ACLA will resubmit the proposal to the PCC for their review, and hopefully, support.

The schedule for submission and review of new CPT codes recently has been revised, pushing back to November the deadline for new codes that can be submitted for consideration and subsequent inclusion in the 2006 Manual. Also, the Editorial Panel is now scheduled to meet only three times in 2006, instead of the customary four meetings. A revised schedule is available on the ACLA web site on the Issues page under "Coding".

## SACGHS

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) met on June 15 – 16, 2004, and addressed

issues related to: 1) genetics education and training of health professionals (not genetics specialists); 2) coverage and reimbursement of genetic technologies; and 3) a public health approach to genomics. The committee was also updated on stalled legislative efforts to outlaw discrimination of individuals based on genetic information obtained for health purposes. Draft position papers related to these issues were circulated for comment. The committee also heard a report from a workshop convened by the National Human Genome Research Institute on March 23, related to Direct to Consumer Advertising of genetic tests, and reviewed a draft “resolution” urging some regulation of such activities to protect the public from unnecessary and possibly invalid testing.

---

## Calendar of Events - July

<b>July 1</b>	Florida Competitive Bidding	<i>Conference Call</i>
<b>July 1</b>	ACLA Billing Committee Meeting	<i>Conference Call</i>
<b>July 6</b>	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
<b>July 7-8</b>	Agency for Quality Healthcare Research and Quality (AQRH) Grant Review for IT Demonstration Grants	<i>Rockville, MD</i>
<b>July 9</b>	ACLA Members Weekly Meeting	<i>Conference Call</i>
<b>July 13</b>	ACLA hosts National Exploring Health Careers Committee	<i>Washington, DC</i>
<b>July 13</b>	Pathology Coding Caucus (PCC) Meeting	<i>Conference Call</i>
<b>July 13</b>	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
<b>July 15</b>	ACLA Board of Directors Meeting	<i>Conference Call</i>
<b>July 20-23</b>	HHS Summit on Information Technology	<i>Washington, DC</i>
<b>July 23</b>	ACLA Members Weekly Meeting	<i>Conference Call</i>
<b>July 26</b>	CMS New Code Meeting	<i>Baltimore, MD</i>
<b>July 29</b>	FDA/DIA Pharmacogenomics Workshop	<i>Arlington, VA</i>
<b>July 30</b>	ACLA Members Weekly Meeting	<i>Conference Call</i>