

The ACLA Annual Membership Meeting convened here in Washington, D.C., on January 14, 2003. We had an excellent group of speakers representing the Administration, Congress, science, public health, and industry. Through the course of the day we learned about current and proposed changes in public policy that could affect the clinical laboratory industry.

The ACLA Board met subsequent to the Membership Meeting and developed a list of priorities for ACLA during the coming year. Board Chair, Kenneth Freeman, presented the following summary at the close of our meeting:

• **Message from Dr. Sundwall:** The ACLA Board met and developed a list of priorities for ACLA during the coming year.

• **CMS Open Forum:** An internal working group is developing a carrier change request that would tell carriers to load the fee schedules.

• **LHCC:** A joint research project with the National Committee on Quality Assurance (NCQA) designed to identify laboratory-specific data in HEDIS measures was approved.

• **OSHA:** ACLA met with OSHA to discuss our concerns about their interpretive letter forbidding the reuse of reusable needleholders.

1. **Reimbursement** - Protect the annual CPI update, ensure there will be no co-payment required for lab services, and oppose competitive bidding. Also, work closely with CMS and contribute to the development of any alternative they might consider to the current clinical lab fee schedule, i.e. a "charges-based" relative value scale to determine level of payment.. [ACLA will convene a workgroup of representatives from member companies to develop consensus on "principles" on which we believe any alternate fee schedule should be based.]

2. **FDA** - Closely monitor regulatory policies related to clinical lab testing services, and to the extent possible contribute to the development of revised or new regulations of lab tests.

3. **Quality of Lab Testing Services** - Promote public understanding of the quality of lab testing services provided by independent clinical laboratories. Seek opportunities to promote improved quality measures of lab testing, including indicators that illustrate

distinctions between labs providing such services.

4. **Bioterrorism** - Monitor government activities related to prevention, detection, and management of possible terrorists' attacks using biochemical or biological agents. Work with the Centers for Disease Control (CDC) to facilitate a coordinated public/private sector response from clinical laboratories to such attacks.

5. **Medical Malpractice and Liability Reform** - Vigorously support legislation requiring federal tort reforms related to medical malpractice. Make certain protections for clinical laboratories are included in such legislation.

6. **Clinical Laboratory Workforce** - Participate in the Coordinating Council on the Clinical Lab Workforce (CCCLW), a national collaborative effort to monitor and address shortages of clinical laboratory personnel. Also, monitor efforts underway by the Public Health Service's National Center for Health Workforce Information and Analysis, to identify regional shortages of clinical lab personnel and related problems with access to lab testing services.

7. **ACLA Membership** - Continue efforts to expand membership in ACLA, building a broader base for representation of the clinical laboratory industry in Washington D.C., with state governments, other health professional organizations, and the general public.

8. **Collaboration** - Promote further collaboration and joint representation of common interests among a variety of organizations involved in the clinical laboratory industry. These include all entities directly involved with the provision of lab testing, those developing of new technologies, manufacturers, professional organizations, etc.

9. **ACLA Members Advocacy** - Each ACLA member will identify key contacts in Congress,

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elected officials and staff, in order to promote ACLA's policy agenda. Representatives of each company should meet with such individuals in Washington D.C., in their respective home town offices, and if possible invite them to tour lab facilities in their jurisdictions.

10. **OSHA** - Work with the Occupational Safety and Health Administration (OSHA) to revise current regulations related to reuse of blood tube holding devices. Establish clear lines of communication to facilitate more appropriate policies related to the regulation of clinical lab testing work sites.

I look forward to working with all ACLA member companies to ensure we succeed in addressing these priority policy issues during the coming year.

*David N. Sundwall*

## **CMS Open Forum**

On January 31, ACLA attended and participated in the Centers for Medicare and Medicaid Services ESRD/Clinical Laboratory Open Forum. The open forum is an opportunity to seek clarification, redress, and guidance from CMS officials on issues of importance to providers. At the forum ACLA asked if there had been an opportunity to follow up on a request made at the November meeting to require Medicare carriers to load all of the carrier fee schedules. This would simplify claims processing by

permitting a laboratory to submit claims that include lab-to-lab referrals to one carrier for payment. A CMS official responded that an internal working group is developing a carrier change request that would tell carriers to load the fee schedules. ACLA asked if representatives of laboratory providers could meet with that working group, and CMS agreed. We also asked CMS to instruct Medicare carriers to advise Medicare beneficiaries that laboratories may seek routine Advanced Beneficiary Notices when there is a national coverage decision or published local medical review policy limiting frequency of laboratory testing. CMS agreed to our request.

Earlier in the day, representatives of ACLA companies providing services to ESRD patients met with CMS officials in Baltimore to seek resolution of payment for dialysis-related laboratory services to ESRD patients in skilled nursing facilities. CMS offered to develop a list of dialysis-related CPT codes for our review and comment. CMS would send the list to carriers as clarification of their earlier program memorandum on this issue. A code on the list coupled with the CB modifier identifying the patient as an ESRD beneficiary should be sufficient for the carrier not to deny claims for these services.

## **LHCC**

The Laboratory Health Care Coalition (LHCC), consists of ten national organizations who work together to promote public awareness and appreciation for clinical labo-

ratory services. During a meeting held on January 15, two new projects were approved: (1) distributing an article about LabTestsOnline ([www.labtestsonline.org](http://www.labtestsonline.org)) to the nation's newspapers using the North American Precis Syndicate (NAPS). We will follow over time the media pick-up of this article, and determine if this service helps us in meeting our public relations objectives; (2) a joint research project with the National Committee on Quality Assurance (NCQA) designed to identify laboratory-specific data in HEDIS measures, used to monitor the quality of health care provided by health plans. This project is considered timely in that it complements efforts underway by the CDC to highlight the role of clinical laboratories in health care quality and the utility of lab data in reducing medical errors.

## **OSHA**

On January 16, 2003, ACLA and representatives of ACLA member companies met with Mr. Gary Visscher, Deputy Assistant Secretary of Labor in the Occupational Safety and Health Administration, and Mr. Richard Fairfax, Director of the OSHA Office of Enforcement, to discuss our concerns about their interpretive letter forbidding the reuse of reusable needleholders. A copy of ACLA's white paper, which was presented to Mr. Visscher and Mr. Fairfax, has been posted on the ACLA website under "What's New."

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## **Calendar of Events -- February 2003**

|                     |   |                        |
|---------------------|---|------------------------|
| <b>February 1</b>   | 2003 Health Policy Ball                             | <i>Washington, DC</i>  |
| <b>February 3</b>   | Privacy State Study Project Meeting                 | <i>Washington DC</i>   |
| <b>February 4</b>   | National Exploring Health Careers Committee Meeting | <i>Bethesda, MD</i>    |
| <b>February 4</b>   | AdvaMed Meeting on Medicare Reform                  | <i>Washington, DC</i>  |
| <b>February 4</b>   | Healthcare Liability Alliance Meeting               | <i>Washington DC</i>   |
| <b>February 4</b>   | CPT Advisory Committee Meeting                      | <i>Conference Call</i> |
| <b>February 6</b>   | Clinical Laboratory Coalition Meeting               | <i>Washington, DC</i>  |
| <b>February 6</b>   | Confidentiality Coalition Meeting                   | <i>Washington, DC</i>  |
| <b>February 7-8</b> | CPT Editorial Panel Meeting                         | <i>Orlando, FL</i>     |
| <b>February 10</b>  | CPT Advisory Committee Meeting                      | <i>Conference Call</i> |
| <b>February 13</b>  | Billing and Reimbursement Committee Meeting         | <i>Washington, DC</i>  |
| <b>February 14</b>  | Privacy State Study Work Product Demo               | <i>Washington DC</i>   |
| <b>February 21</b>  | FDA/IVD Roundtable Meeting                          | <i>Washington, DC</i>  |

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