

•**Message from Dr. Sundwall:** ACLA continues to move our legislative and regulatory agenda forward.

•**CPT:** ACLA has received an invitation to participate in the new Pathology Coding Caucus (PCC).

•**ESRD:** ACLA submitted to CMS a proposal making recommendations for testing frequencies for certain laboratory tests.

•**FDA:** ACLA met with FDA to discuss issues related to analyte specific reagents and laboratory developed testing.

•**HIPAA Standard Transactions Working Group:** ACLA has established a working group to determine if we should seek changes to the requirements.

•**State Issues:** ACLA has written to the New Jersey Medicaid program requesting a meeting.

For more information regarding ACLA, please call 202-637-9466, or visit our website - www.clinical-labs.org

Our country is now at war with Iraq, and each day of the conflict brings additional challenges to our nation's leaders. While we have been engaged in battle for only a few weeks, it now seems clear we will not achieve victory swiftly nor easily. Consequently, business in Washington is decidedly not as usual, but ACLA continues to move our legislative and regulatory relief agenda forward.

The Senate passed a 2004 budget bill on March 28, surprisingly on schedule (unusual even in times of peace). It includes the President's requested \$400 billion over the next ten years for Medicare reform, incorporating the funds needed for a needs-based prescription drug benefit. It also includes \$50 billion for health insurance for the uninsured, and another \$5.75 billion for bioterrorism protection efforts.

The focus of concerns of a variety of health advocates about the budget is scheduled cuts in Medicaid funding (\$93 billion) included in the House-passed bill. Differences between the bills need to be reconciled, but given the growing course of pleas from states for financial relief, it is not going to be an easy conference.

As always, clinical laboratories need to be visible and pull together to advocate for policies and payments essential to the health of our industry. Progress is being made on several regulatory issues (see reports below), but we are also counting on each of our member companies to advocate ACLA's agenda to your elected representatives. *[Enclosed is a copy of ACLA Health Policy Priorities - 2003]*

David N. Sundwall

CPT

ACLA has received an invitation to participate in the newly established Pathology Coding Caucus (PCC). Dr. Tracy Gordy (Chair - CPT Editorial Panel) and Dr. Paul Raslavicus (President - College of American Pathologists) informed Dr. Sundwall in a letter dated March 20, 2003, that the PCC has been created to "foster a greater degree of participation from non-physician stakeholder in the CPT process while maintaining a predictable systematic process for revising and updating CPT codes". ACLA welcomes this development, and will be represented at the first meeting of the PCC on May 1, in Los Angeles by Dr. Sundwall, and Kaye Jones [LabCorp], Chair of the ACLA CPT Advisory Committee.

ESRD

ACLA submitted to CMS a proposal making recommendations for testing frequencies for certain laboratory tests that are routinely ordered for ESRD patients to monitor dialysis treatments and to properly diagnose and treat the co-morbid diseases and conditions that commonly accompany ESRD. It is our hope that CMS will adopt these recommendations to standardize payment policies and medical necessity documentation requirements for laboratory tests on ESRD patients across the United States.

On March 28, ACLA wrote to CMS to express our serious concerns about the proposed new program memorandum and accompanying claims processing changes that the agency is considering to enable it to better monitor compliance with the 50/50 rule. The 50/50 rule applies to automated chemistries furnished to

Medicare beneficiaries receiving ESRD services. We pointed out that the proposed solutions will not really solve concerns about the 50/50 rule, that it is likely to be time consuming and expensive for labs to implement, and that it will increase claims and complicate claims processing issues. We urged CMS to delay implementation of the proposal and meet with affected stake holders to develop alternative solutions.

FDA

On March 24, 2003, ACLA and representatives of ACLA member companies met with officials of FDA's Center for Devices and Radiological Health to discuss issues related to analyte specific reagents (ASRs) and laboratory developed testing. FDA representatives stated that they have not decided what, if any, course of action to take in this area. They stressed that they do not intend to slow innovation but are looking for ways to get more "transparency" into the development of laboratory developed testing. At the conclusion of the meeting, they reiterated their desire to work with the laboratory community to meet our mutual concerns. We agreed to coordinate a meeting of those members of the FDA Professional Roundtable interested in discussing the issue further.

HIPAA Standard Transactions Working Group

The requirements related to standard transaction sets mandated by the Health Insurance Portability and Accountability Act

of 1996 go into effect in October 2003. Because of concerns about how the requirements will apply to laboratories and whether labs will be able to obtain all of the information required, ACLA has established a working group to examine the issue more closely and to determine if we should seek changes to the requirements. The working group met by teleconference twice in March and has scheduled a "live" meeting in the ACLA offices in early April.

Lab to Lab Referral

On March 26, 2003, representatives of the ACLA Billing and Reimbursement Committee met with CMS officials to discuss issues related to lab-to-lab referrals. After long and diligent efforts by ACLA, CMS has now agreed that the most appropriate way to deal with this issue is to require that all carriers load the fee schedules for all jurisdictions. For any lab services that includes a -90 modifier (indicating that the services were referred out), CMS will require the CLIA number of the reference laboratory; the address of the performing laboratory, including the zip code; and the local PIN number for that laboratory (i.e., the PIN number that the reference laboratory's own carrier has given to it for submission of claims.) Eventually, carriers who have enrolled out of state laboratories will be required to eliminate the PIN numbers for those laboratories so that only laboratories with a physical presence in the carrier jurisdiction would be able to bill the carrier.

While there are still a few issues to be resolved, CMS is hopeful that the implementing PM will be finalized by May 1, 2003, with an October 1, 2003 effective date. If not, the likely effective date will be delayed to April 1, 2004.

State Issues

ACLA has written to the director of the New Jersey Medicaid program requesting a meeting to discuss any progress the state has made in addressing the lab-to-lab referral issue so that one laboratory within a corporate structure could bill for all tests performed by authorized laboratories within that corporate structure. ACLA has met with New Jersey Medicaid in the past on this issue, and we were advised that they were willing to make the systems adjustments necessary to resolve this issue. In our letter, we also asked the state to revisit the original physician signature requirement under Medicaid.

If you would like to receive RESULTS electronically, please send your email address to Cheryl Hawkins at chawk@clinical-labs.org

Calendar of Events -- April 2003

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| April 3 | HCLA Public Relations Committee Meeting | <i>Washington, DC</i> |
| April 3 | Clinical Lab Coalition Meeting | <i>Washington, DC</i> |
| April 9 | ACLA Standard Transactions Working Group Meeting | <i>Washington, DC</i> |
| April 10 | ACLA Billing and Reimbursement Committee Meeting | <i>Washington, DC</i> |
| April 10 | Confidentiality Coalition Meeting | <i>Washington, DC</i> |
| April 11 | DNA Diagnostics Roundtable Meeting with Secretary Tommy Thompson | <i>New York, NY</i> |
| April 13 | National Health Council Briefing The Agency for Health Care Quality (ARHC) | <i>Washington, DC</i> |
| April 13-15 | CDC's Quality Institute Conference - 2003 | <i>Atlanta, GA</i> |
| April 14 | HIPAA State Study Steering Committee Meeting | <i>Washington, DC</i> |
| April 16 | NIH - Symposium on Genetic Variation in Human Health and Disease | <i>Bethesda, MD</i> |
