

• **Message from Dr. Sundwall:** Of most interest to the clinical laboratory industry is the Medicare reform legislation under consideration.

• **Billing and Reimbursement:** ACLA will seek a meeting with CMS claims processing staff.

• **FDA:** ACLA's FDA Committee met with the Center for Biologics and Evaluation and Research.

• **HIPAA:** ACLA filed comments with HHS on the Proposed Rule modifying the HIPAA Privacy Regulation.

• **Summit on New Technology:** A group of ACLA representatives met here to discuss issues related to new technology approval.

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Health issues remain very much in the news in Washington. High profile political issues include adding a prescription drug benefit to Medicare, and more recently President Bush's support for mental health parity in health insurance benefits. Democrats are also insisting on adding federally subsidized health insurance for workers whose jobs are moved overseas. The latter issue is currently holding up the Administration's much wanted legislation granting them new international trade-negotiating authority. Because of a narrow margin of Republican leadership in the House, and razor-thin Democrat dominance in the Senate, votes related to these issues are predictably going to be close and highly partisan.

Of most interest to the clinical laboratory industry is the Medicare reform legislation under consideration. The most popular and the most difficult part of this bill relates to the prescription drug benefit, and while House Republicans passed such legislation two years ago, many fundamental differences remain to be ironed out in the House and then resolved in conference with the Senate.

ACLA has contacted every member of the Senate Finance Committee, and the House Ways and Means and Commerce Committees informing them of the importance of the CPI update to the fee schedule for clinical laboratory services. Your individual support for this provision and efforts you have made to contact your respective delegations is very much appreciated. It remains to be seen whether lawmakers will, as they have in the past, seek to balance the health care budget by taking from one provider to give to another. We certainly hope this is not the case this year. Interest in competitive bidding has once again surfaced in draft legislation under consideration in the House. A "competitive

acquisition program" would be established under which contracts would be awarded to entities successful in their bid to provide various services to Medicare beneficiaries: durable medical equipment, orthodontics, and lab services. As you know, this is not a new proposal, but remains of interest to certain policy makers as a means of promoting more "business-like" practices in the Medicare program. Notwithstanding its surface appeal, ACLA strongly opposes this competitive bidding. Previous experience with competitive bidding for lab services has resulted in unequal access and concerns about quality. ACLA is making our position known to members of Congress and we urge you to do the same

It is hard to govern with narrow margins of leadership, and only a month remains far until a floor vote on prescription drugs and Medicare reform legislation has been promised by the House leadership. Political pressure will likely result in *some* legislation, but I predict whatever is passed will constitute little constructive "reform."

David N. Sundwall

As we go to press, ACLA has learned that the draft House Republican Medicare prescription drug and Medicare amendments would continue the freeze on laboratory payments by suspending the CPI update -- again -- until the mandated competitive bidding system is in place. We are working independently and with the clinical laboratory coalition to get this provision deleted from the final House package. Please contact your own Member of Congress to express your opposition to suspending the CPI update for laboratory services.

Billing and Reimbursement

The committee met by conference call on April 25, 2002 to review new and pending issues. We reviewed correspondence ACLA received from First Coast, the Florida Medicare carrier regarding the status of its instructions for the use of two new modifiers, GY (item or service statutorily non-covered) and GZ (item or service not reasonable and necessary.) First Coast notified us that they had decided to rescind their instruction that providers use ICD-9 code 796.4 (other abnormal findings) to obtain a denial for these modifiers pending further instruction from CMS.

The committee agreed ACLA should seek a meeting with CMS claims processing staff to discuss the appropriate application of these modifiers and other ongoing billing and reimbursement issues.

FDA

On April 17, members of ACLA's FDA Committee met with Kathryn Zoon, Director of the Center for Biologics and Evaluation and Research at the FDA. The subject of the meeting was FDA's proposed guidance related to HIV genotyping assays. The members expressed their concerns about the guidance document and the impact that it could have on the availability of these crucial genotyping and phenotyping tests for HIV patients. The meeting also discussed alternatives that would address FDA's concerns about this testing. Members of ACLA's FDA Committee will meet to determine how to respond to the issues that were raised at the meeting and will follow up with a letter.

HIPAA

On April 26, 2002, ACLA filed comments with the Department of Health and Human Services on the Proposed Rule modifying the HIPAA Privacy Regulation. In general, ACLA expressed its support for the proposed revisions to the Privacy Regulation. For instance, ACLA strongly supports the provisions that would eliminate the consent requirement, consolidate the requirements for an authorization, allow covered entities to disclose protected health information for the treatment, payment, or health care operations purposes of other covered entities, and permit broader use of a limited data set for public health, research, and health care operations purposes. However, ACLA recommended additional clarifications on the minimum necessary and oral communications provisions, the business associate contract compliance extension, and the accounting for disclosures requirement. In addition, ACLA called for HHS to provide additional guidance on the intersection of the Privacy Regulation and state law. HHS is now in the process of reviewing the comments it received during the thirty day comment period and is expected to finalize the rule no later than October of this year.

Summit on New Technology

On April 18th a group of ACLA representatives met here to discuss issues related to new technology approval, CPT coding, and payment policies. Our discussion was facilitated by Eddie Allen, Esq. of Marc Associates. We discussed the current regulatory

landscape, identified barriers to the review and approval of new technologies, and the apparent trend in FDA of expanding its regulatory role. The group considered how CLIA may be strengthened in order to demonstrate accountability and quality control for ASR's for genetic testing and/or HIV testing. Our position is that this should be sufficient, and if implemented could substitute for applying medical device regulations to ASR's (an option FDA appears to be considering).

Representatives from CMS, Dr. Jeffrey Kang and Dr. Shawn Tunis, two high level officials responsible for coverage decisions, made a presentation to the group. They indicated that there is improved and more frequent coordination of CMS with the FDA (specifically the Center for Devices and Radiological Health) related to product clearance, coverage, and payment. However, it was recognized that the clinical laboratory industry has not had sufficient opportunity for comment and participation, particularly related to decisions determining payment levels. After a lively discussion, the group identified "ten steps to be taken" to address problems identified and to improve communication with federal agencies responsible for clinical laboratory services.

*ACLA would like to welcome
its newest member!*

Myriad Genetic Laboratories, Inc.
320 Wakara Way
Salt Lake City, UT 84108
(801) 584-3600

Calendar of Events May 2002

May 1	Clinical Laboratory Coalition Meeting
May 3	CPT Editorial Panel Meeting
May 3	HIV Genotyping Meeting
May 7	CDC National Laboratory Network Meeting
May 10	CMS/ESRD Clinical Laboratory Open Forum
May 14-15	Secretary's Advisory Committee on Genetic Testing Meeting
May 15	Clinical Laboratory Coalition Meeting
May 16	CPT Advisory Committee Meeting
May 22	FDA IVD Roundtable Meeting
May 23	CDC Quality Institute Steering Committee Meeting
May 30	CMS/Billing and Reimbursement Committee Meeting

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