

- **Message from Dr. Sundwall:** We have worked hard as we know many of you have, to educate Congress why labs must have the CPI update this year.
- **CPT:** The first step of a process to develop CPT codes for new genetic tests was taken by the CAP.
- **ESRD:** CMS representatives from the coverage and analysis group agreed to meet with ACLA and its ESRD members on our request.
- **FDA:** ACLA sent follow-up letters to Dr. Catherine Zoon and Steven Masiello at the FDA's CBER.
- **Genetic Testing:** Rapid growth in genomic medicine seems to be paralleled by government interest in oversight and regulation.
- **State Issues:** ACLA expressed our opposition to competitive bidding for laboratory services provided under Medi-Cal.

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

Congress is in recess (an extended Memorial Day Holiday), and I'm sure they are enjoying a break from the rancorous bickering related to health issues which developed over the past month within, as well as between, political parties. You will recall that last month's newsletter announced that an early draft of the House Republican Medicare package was leaked. This draft included a freeze on the CPI update for the lab fee schedule, and is coupled with a competitive bidding plan for Medicare to contract for lab services. These proposals seem particularly punitive to the clinical lab industry inasmuch as we are the only providers not to have received any relief from the BBA '97 freeze. Other provider groups have actively sought increases in outlays for their services – physicians, hospitals, nursing homes, etc. and seem to have gained some support for their plight. However, the over-riding political imperative is to add a prescription drug benefit to the Medicare program, but concern about the associated costs and configuration, were such a new benefit to be implemented, has slowed things down considerably.

We have worked hard, as we know many of you have, to educate Congress – key health staff and members – why labs must have the CPI update this year. We have also made the case that competitive bidding for lab services is no better idea now than it was when previously considered and rejected by Congress and the Administration. On the latter issue we think we have made some headway, and that if anything is enacted it will only be a requirement that CMS conduct a demonstration project related to competitive bidding for lab services. But, pressure on the budget remains and is likely to intensify. Perhaps the best we can hope for is continued stalemate over the

prescription drug benefit during this election year, and that a sense of fairness might prevail over taking from one health care provider to give to another, thus leaving the scheduled CPI update for lab services in tact.

Prior to recess Congress did succeed in passing a \$4.6 billion bioterrorism bill, which the President will sign into law. This includes significant funds to upgrade public health laboratories, but also some controls on laboratories and universities that “possess dangerous pathogens”. One very welcome aspect of the bill related to the lab industry is that it attempts to address shortages in the clinical lab workforce by providing incentives through public health programs to train more lab personnel.

We will continue our advocacy of your interests in legislation – in statute, and in committee report language accompanying bills considered. As always, we will call on you to support our efforts through your respective contacts and friends among our elected officials.

David N. Sundwall

CPT

The CPT Committee convened via teleconference on May 23. We discussed preparations for the now annual CMS meeting in August to discuss how best to establish fair payment for new CPT codes, i.e. “cross-walk” or “gap-fill.” Once a list of new codes under consideration is received from CMS, we will share with the Billing and Reimbursement Committee and seek their recommendations.

The first step of a process to develop CPT codes for new genetic tests was taken by the College of American Pathologists (CAP) con-

vening a call among interested parties on May 29, to discuss related issues and challenges. ACLA was represented by Dr. Sundwall, Pat Maloney (Quest Diagnostics Incorporated), and Dr. Myla Lai Goldman (Lab Corp). We agreed to start by identifying commonly ordered genetic tests, report on volume, and identify experts in technologies of molecular testing within our respective organizations. It was agreed that ongoing deliberation was essential, including broader representation than present on this initial teleconference, and that we would attempt to have consensus on recommendations prior to the CPT Editorial Panel meeting in November, 2002.

ESRD

At the May 10, 2002, CMS ESRD/Clinical Laboratory Open Forum, ACLA presented a request from ESRD laboratories that CMS work with the laboratories to develop consistent nation-wide reimbursement policies for ESRD laboratory services. Specifically, those policies would be based on test utilization edits specific to the ESRD population and standardized requirements for medical necessity documentation requirements. CMS representatives from the coverage and analysis group agreed to meet with ACLA and its ESRD members on our request.

FDA

On May 17, 2002, ACLA sent follow-up letters to Dr. Catherine Zoon and Steven Masiello at the FDA Center for Biologics

Evaluation and Research. We reiterated our concerns about the impact their Draft Guidance for Premarket Notifications for In Vitro HIV Drug Resistance Genotype Assays will have on access to this vital testing by this vulnerable patient population. We promised to work with them to ensure that physicians continue to have access to all available testing methodologies that they and their patients rely on for treatment decisions.

ACLA participated in the quarterly FDA Professional IVD Roundtable on May 22, 2002. The Roundtable is a group of professional societies and associations concerned about issues associated with IVD testing; FDA, CMS, and CDC officials are invited to update relevant activities and listen to our concerns. At the May meeting, the College of American Pathologists presented a preliminary conceptual proposal for oversight of genetic testing which, while it led to a lively discussion, may be a possible alternative to FDA regulation. ACLA will co-host the next meeting of the Roundtable next fall.

Genetic Testing

Rapid growth in technology and interest in genomic medicine seems to be paralleled by government interest in oversight and regulation. At the Secretary's Advisory Committee on Genetic Testing (SACGT) meeting in Baltimore, May 14 - 15, a draft of their proposed report, "Coverage & Reimbursement of Genetic Testing Services: Challenges to Achieving an Ideal System", was presented to the committee. The draft document addresses several issues of great importance to the clinical lab industry, but

also seems to presume a significant role of the FDA in the regulation of such tests. SACGT plans on convening a public "roundtable" to address these issues sometime later this year, and ACLA will request an opportunity to present our views before the committee at that time. ACLA has also written to Dr. Eve Slater, Assistant Secretary for Health - DHHS, and senior medical advisor to Secretary Thompson. We have requested an opportunity to discuss pending proposals related to genetic testing regulation and to share with her our views on what might constitute appropriate federal oversight.

State Issues

ACLA wrote to members of the California Senate and Assembly to express our strong opposition to Governor Gray's May revisions to his budget that call for competitive bidding for laboratory services provided under Medi-Cal. We pointed out that for more than a decade the Federal Government has discussed a possible demonstration project to test competitive bidding for laboratory services under Medicare and has come face-to-face with the complexity of the task, the start-up costs involved and the numerous thorny questions that needed to be addressed. We concluded that competitive bidding would threaten the quality of and access to laboratory services for a very vulnerable population but will not result in a cost-effective reform of Medi-Cal.

Calendar of Events June 2002

June 5	ACLA Billing Committee Meeting with CMS Officials	<i>Baltimore, MD</i>
June 11	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
June 11	HHS HIPAA	<i>Conference Call</i>
June 11	National Exploring Health Careers Committee Meeting at USUHS	<i>Bethesda, MD</i>
June 12	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
June 17	Meeting with NY State Laboratory Officials	<i>Albany, NY</i>
June 18	Washington Institute for Health Policy Leadership Meeting	<i>Washington, DC</i>
June 25	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
June 26	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
