

• **Message from Dr. Sundwall:**

Significant Medicare reform will not be considered in what remains of this election year.

• **Billing and Reimbursement:**

We agreed to seek a CMS meeting to discuss claims processing concerns.

• **CPT:** ACLA has been collecting information for the CAPWork Group on Genetic Test Coding.

• **Environmental/Occupational Health:** ACLA submitted comments to CDC on their Proposed Data Collection regarding Notification of Possession of a Select Agent.

• **Legislative Affairs:** ACLA has been meeting with Senate staff to discuss our priorities, including the single carrier option.

• **State Issues:** ACLA communicated with the California Senate expressing our opposition to legislation related to reporting blood lead testing result.

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The Senate finally focused on health care legislation over the past couple weeks, debating a generics drug bill, the Greater Access to Affordable Pharmaceutical Act. This legislation was designed to prevent brand-name drug firms from blocking generic drugs from entering the market; however, Senate Majority Leader Tom Daschle allowed amendments, and the bill then served as a vehicle for discussion of various legislative versions of a new Medicare prescription drug benefit. The popularity of such a benefit makes this a compelling political imperative for both parties, but profound differences between Republicans and Democrats remain over two issues - the costs associated with providing pharmaceuticals for a growing senior population, and the role of the federal government in administering the benefit.

The price tag for the various bills range from \$380 billion - \$500 + billion over eight years, with varying co-payments and deductibles, making this popular new benefit risky across the political spectrum. Senators struggled to find a compromise on the level of spending and consensus seems to be developing that only a scaled back version, focusing on beneficiaries with limited resources, would be possible at this time. More difficult to work out, however, may be the way in which the benefit is administered, the Republicans preferring private sector insurance programs, and Democrats insisting it be part of the traditional federally run Medicare program. But when all was said and done, a lot was said and nothing was done - at least not to add prescription drugs as a Medicare benefit. The generics drug provisions did pass, however, with a big boost from a timely FTC report supporting the potential cost savings.

ACLA has been focusing our efforts on the Senate, meeting with and informing key staff about provisions of importance to the clinical lab industry. When Medicare amendments are considered, either as amendments to the generic drug bill or separately

on the Senate floor, we are doing all we can to ensure that: the clinical lab fee schedule is protected; that the annual CPI update to the fee schedule is implemented for 2003 and beyond; that co-payment lab services are not required; and that competitive bidding for all Part B Medicare services is not adopted.

Significant Medicare reform will not be considered in what remains of this election year, but limited Medicare amendments likely will be considered and may pass sometime in September, including some provider "giveback" provisions. We'll be there to make sure the clinical lab industry is understood, appreciated, and supported - if not with much deserved "give back" funds to compensate for past cuts in Medicare reimbursement, at least with sustained and updated payments.

David N. Sundwall

Billing and Reimbursement

The Billing and Reimbursement Committee met in the ACLA offices on July 18, 2002. We discussed the proposed Physician Fee schedule changes for 2003 for pathology services and the impact on independent laboratories and agreed to work with other interested parties to seek revisions in the calculations. We also discussed continuing claims processing issues, particularly the on going problem of carriers refusing to enroll out-of-jurisdiction laboratories and the status of the program memorandum directing carriers to do so. Apparently, carriers have raised objections to the program memorandum. We agreed to seek a CMS meeting to discuss this and other claims processing concerns.

CPT

ACLA representatives of the CPT Advisory Committee have been busy preparing information for the College of American Pathology (CAP) Work Group on Genetic Test Coding. This College is working with us, the American College of Medical Genetics, the American Society for Clinical Pathology and others to achieve consensus on how best to develop CPT codes for genetic tests. This collective effort is considered by all parties to be essential, anticipating there will be an exponential increase in such testing and a need for conventions related to how to apply for, and how the CPT Editorial Panel should assign specific codes.

ACLA has been asked to provide data related to volume of such testing, i.e. the "18-20 most commonly ordered genetic tests" during 2002. We are also documenting problems encountered in the process of billing and being reimbursed for such testing. It is anticipated we will have a report related to these issues ready for review by the CPT Editorial Panel prior to their meeting in November, 2002.

Environmental/Occupational Health

On July 14, 2002, ACLA submitted comments to the Centers for Disease Control and Prevention on their Proposed Data Collection regarding Notification of Possession of a Select Agent. We supported the efforts of the agency to address the potential threat of dangerous biological agents and toxins but expressed our concerns about the proposal's lack of clarity on several points, including the

exemption of clinical laboratories from the notification requirement. Specifically, we recommended that the agency: (1) clarify what constitutes a dangerous biological agent or toxin, (2) provide a definition of "facility" and clarify which facilities are required to submit an Application for Notice of Possession of a Select Agent, and (3) clarify that clinical laboratories are exempt from the notification requirement.

Legislative Affairs

Congress has adjourned for the August recess without finalizing Medicare prescription drug coverage/provider payment reform legislation. As discussed in detail in the July issue of Results, the House passed its version in late June. (That bill did not contain provisions affecting laboratory payment rates. It did include several provisions of interest to laboratories: it required a competitive bidding demonstration project for lab services, coverage for a number of screening services, and a GAO study comparing laboratory payment rates in Medicare and the private sector.) The Senate limited its July efforts to passing Medicare prescription drug coverage, postponing consideration of provider payment reform to the fall.

As has been widely reported, the Senate failed in four attempts to pass Medicare prescription drug coverage. Instead, they passed a bill that would (1) make it more difficult for pharmaceutical companies that manufacture brand-name drugs to stave off competition from manufacturers of generic versions once their original patent expired; (2) allow Americans to reimport US-made

drugs from Canada; and (3) provide an additional \$9 billion to state Medicaid and social service programs. In the waning hours before adjournment, Finance Committee members were attempting to reach agreement on Medicare provider payment reform legislation for passage as a separate vehicle but ran out of time. While it may be difficult if not impossible for Congress to agree on prescription drug coverage before the election, they will be heavily lobbied to address provider payment reform this fall. ACLA has been meeting with Senate staff to discuss our priorities, including the single carrier option, and will continue to do so over the August recess.

State Issues

ACLA communicated with members of the California Senate expressing our opposition to legislation developed by the State health department related to reporting blood lead testing results. The legislation, SB 622, would require testing laboratories to report detailed, patient-specific information to the Department of Health, information that laboratories that do not see the patient in question are not able to provide. We proposed that the reporting requirements be amended to ensure that the medical laboratory, office or other facility directly in contact with the patient be the entity responsible for the collection of the patient-specific information required by the Department. We are also collaborating with the California Clinical Laboratory Association in its efforts to amend the legislation.

Calendar of Events August 2002

August 1-3	National Exploring Health Careers Exposition	<i>Bethesda, MD</i>
August 2	Alliance to Improve Medicare Congressional Briefing	<i>Washington, DC</i>
August 5	CMS 2003 CPT Payment Recommendations Meeting	<i>Baltimore, MD</i>
August 6	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
August 7	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
August 8	CAP Genetic Tests Coding Workgroup	<i>Conference Call</i>
August 20	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
