

•**Message from Dr. Sundwall:** Just how much can get done with relatively narrow margins of majority in each house remains to be seen.

•**ABN:** CMS agreed that if a laboratory receives a signed model-language ABN, the laboratory may submit its claim with the GA modifier indicating that it has a signed ABN on file.

•**ESRD:** CMS says that carriers will pay claims using ICD-9 code 585 plus 285.21.

•**FDA:** The dialogue at the FDA/IVD Roundtable meeting was open and constructive.

•**Federal Affairs:** The Administration has delayed publication of the 2003 physician fee schedule.

•**National Policies Transition Period:** ACLA met with CMS to discuss the challenges labs will face during the transition period.

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The elections are almost over (just a few races still undecided as I write this), and the GOP seems to have won big time – taking back control of Congress and winning some unexpected Governor’s races. The pundits will have a hey day trying to make sense of what these results mean, but already it seems there is consensus that President Bush’s energetic campaigning for Republican candidates throughout the country paid off, indicating general support for his leadership. He is now likely to have more success with his legislative agenda, but just how much can get done with relatively narrow margins of majority in each house remains to be seen.

Not much has been accomplished (yet) by the 107th Congress, as predicted last month and itemized below in the Federal Affairs report. When they reconvene in mid-November they will likely limit their agenda to essential business – passing necessary budget bills, but not tackling outstanding health legislation. However, House Majority Dennis Hastert has already announced, “health care will be a top priority in the GOP controlled House”. We will continue to promote ACLA’s legislative during the upcoming “lame duck session”, and guard against any efforts to reduce Medicare payments.

REMINDER: ACLA’s Annual Membership Meeting is scheduled for January 14, 2003. This is when with your help we develop our legislative and regulatory agenda for the coming year, so please plan to attend now (registration form and draft agenda included).

David N. Sundwall

ABN

On October 29, 2002, we received a response to our September 17, 2002, letter to CMS seeking clarification of certain requirements related to the new Advanced Beneficiary Notice (ABN) forms. We expressed our concern that after October 1, 2002, when the new ABN instructions are to be implemented, laboratories and other types of providers will continue to receive the older ABNs that were previously in use. We made it clear that all ACLA members are distributing the new ABN form and are making conscientious efforts to educate physicians and ensure that physicians use the new form. Nevertheless, we took the position that if a laboratory receives an old ABN form after the October 1 implementation date for the new ABNs, it may continue to submit a claim with the GA modifier, indicating that it received an ABN for the services, and may continue to bill the beneficiary for those services.

In its response, CMS agreed that, for a short transitional period (to be determined,) if a laboratory receives from an ordering physician a signed model-language ABN that otherwise contains sufficient information to properly notify the beneficiary consistent with the ABN program memorandum, the laboratory may submit its claim with the GA modifier indicating that it has a signed ABN on file. The response goes on to state that [a] laboratory receiving an obsolete ABN should, of course, immediately educate the physician who furnished the ABN to use the proper form.

ESRD

ACLA and several members of the ESRD committee participated in an October 31, 2002, conference call with CMS to discuss the rationale behind several of our recommendations for changes in three of the national coverage poli-

cies. We focused most of our attention during the call on the need to amend the iron studies panel to include ICD-9 code 285.21, anemia in end-state renal disease, a new ICD-9 code as of October 2001. CMS agreed with us and proposes to use an expedited procedure to reach a national coverage decision by not requiring medical evidence and relying on the narrative of the national policy. They hope to have the amendment finalized and incorporated into the policy by April 1, 2003. In the interim, they advise that carriers will pay claims using ICD-9 code 585 plus 285.21. This promises to be a problematic resolution since carriers are now paying 285.21 which is a more specific code and physicians are used to using just 285.21. Instructing physicians to add 585 for an interim period will be confusing at the very least. ACLA intends to ask CMS for an alternative interim instruction.

FDA/IVD Roundtable

ACLA co-hosted with the Association of Public Health Laboratories (APHL) an FDA/IVD Roundtable on October 17. The meeting was well attended by representatives from a broad spectrum of organizations, and senior staff from the FDA. An update was presented by FDA's Center for Diagnostics and Radiological Health (CDRH) - Dr. Steve Gutman, and by the Center for Biological Evaluation and Research (CBER) - Dr. Jay Epstein, including an explanation of recent reorganizations within these centers. ACLA representatives - Dr. Hawazin Faruki (LabCorp), Dr. Joyce Schwartz (Quest), and Dr. Nick Hellman (Virologic) - made a joint presen-

tation on how and why independent laboratories develop new tests, how they assure the quality of in-house developed reagents, and how they validate their clinical utility. The dialogue between attendees and FDA was open and constructive, enabling government officials to hear first hand from laboratory experts about the impact and effectiveness of current regulatory oversight.

Federal Affairs

Congress recessed for the election without passing Medicare reform, prescription drug coverage, provider updates, legislation establishing a national homeland security department, and eleven of thirteen appropriations bills. They passed a short term funding measure on October 17, 2002, that will keep the government running through November 22 and agreed to return to Washington on November 12 to attempt to finish up unfinished business. Priorities in unfinished business include amending the formula in the physician fee schedule to restore some, if not all, of the expected reductions in the 2003 fee schedule. To simplify that effort, the Administration has delayed Federal Register publication of the 2003 physician fee schedule for several weeks.

National Policies Transition Period

On October 9, 2002, ACLA and representatives of ACLA member companies met with CMS officials to discuss the challenges labs will face during the period from Novem-

ber 25, 2002, when the national Medicare lab coverage policies become effective, and the date on which the software edits for processing claims under the new policies are installed by the carriers (scheduled for January 1, 2003). Carriers have been instructed to make sure their local medical review policies (LMRPs) don't conflict with the national policies by the November 25 effective date. Carriers were given two options - eliminate all LMRPs for the national policies, or to process claims by hand according to the national policies. Since many carriers are opting for the former, we pointed out that a substantial number of claims will be processed and paid during the transition that would not be paid under the new policies. This would require retrospective review with the new software or post-payment review, thus burdening the carriers and laboratories, as well as confusing beneficiaries and physicians. We agreed to provide information to CMS on a sampling of volume of claims that would be involved in the transition. We are particularly concerned that, if the January 1, 2003, date for the installation of the software is missed, that CMS not wait until the next scheduled date for carrier software updates (April 1, 2003) to install the edits.

*ACLA would like to welcome
its newest member,
Specialty Laboratories,
located in Santa Monica, CA.*

Calendar of Events -- November 2002

November 4	CMS Briefing on Final Rule on CLIA Quality Standards	Washington, DC
November 5	ACLA CPT Advisory Committee Meeting	Conference Call
November 7	ACLA CPT Editorial Panel Meeting	New Orleans, LA
November 7	HIPAA Confidentiality Coalition Meeting	Washington, DC
November 8	California Clinical Laboratory Association Annual Meeting	San Diego, CA
November 12	CDC Quality Institute Steering Committee Meeting	Conference Call
November 12	Health Care Liability Alliance Meeting	Washington, DC
November 13	Clinical Laboratory Coalition	Washington, DC
November 20	RSPA Meeting on International Transportation	Washington, DC
November 22	CMS Open Forum - ESRD/Clinical Labs	Baltimore, MD
November 25	National Exploring Health Careers Committee Meeting	Washington, DC
November 26	Health Care Liability Alliance Meeting	Washington, DC
November 27	Clinical Laboratory Coalition Meeting	Washington, DC