

- **Message from Dr. Sundwall:** The President's budget proposal spares most providers from "cuts" in Medicare reimbursement.
- **Billing and Reimbursement:** The ABN form and instructions have been sent to OMB for final review.
- **CPT:** We achieved consensus on most lab issues prior to the CPT Editorial Panel meeting.
- **ESRD:** ACLA wrote to CMS concerning possible changes to the 50/50 rule for ESRD laboratory testing.
- **FDA:** We discussed the status of FDA's proposed draft guidance related to in vitro HIV drug genotyping assays.
- **Negotiated Rule Making Implementation:** The first phase of implementing "national coverage and administrative policies for clinical diagnostic laboratory tests" is imminent.

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Congress has returned after a week long break for President's Day, and health issues are again emerging as national problems meriting attention. After having been pushed down the list of legislative priorities by the terrorist attacks on 9/11, and subsequent anthrax bioterrorism through the mails, health care now seems to be moving up on the agenda.

The President's budget proposal for 2003 spares most providers from "cuts" in Medicare reimbursement and seeks instead to "modernize" the program - through some new initiatives, and by improving the efficiency of payment processes. Specifically, the President is proposing a prescription drug benefit, but limited to low income beneficiaries and to be phased in over time. He also proposes to enhance Medicare + Choice [the managed care option] by adding more funds to this program, hoping it will attract more insurance companies to participate.

The good news for clinical labs is that once again this Administration has not proposed funding of its priorities by seeking "savings", or offsets from future outlays for lab services covered by the Medicare program. As we know all too well, this had become a familiar pattern in recent years. This is not to say, however, that we can relax. Not only does Congress share the President's interest in adding a prescription drug benefit to the Medicare program but most Democrats, and some Republicans, would like to see it much more generous and therefore more costly than the President has proposed. Furthermore, physicians are vigorously seeking a legislative correction to the statutory formula which sets their level of reimbursement by Medicare. Last year they suffered an across the board cut of 5.4% because the "update" in their fee schedule relies heavily on estimates of eco-

nomie growth (which, of course did not do too well, overall). And other health care providers are seeking more public dollars - nursing homes, teaching hospitals, etc. So, even though the President's team has not yet asked for cuts from specified provider groups to finance the initiatives they have proposed, HHS Secretary Thompson has made clear they are prepared to "work with Congress" on all budget issues [also read - realign spending to ensure priorities are funded].

It remains to be seen how much Congress will get done related to health care issues inasmuch as this is an election year for all Representatives and a third of the Senators. Some say the drug cost debate is a prescription for gridlock. But whatever is done we cannot allow new initiatives, nor addressing financial grievances of other health care providers, to be funded at the expense of clinical lab payments. We will be calling on all of you to assist us at some time to make this clear to our elected officials, their staff, and those responsible for administering these programs in the public interest.

David N. Sundwall

Billing and Reimbursement

The Billing and Reimbursement committee met by conference call on February 28, 2002, to consider outstanding issues and new concerns. We reported that the ABN form and instructions have been sent by CMS to OMB for final review under the Paperwork Reduction Act. While many, if not all of the issues that ACLA has identified as concerns have been resolved, the effective date by which the new ABN form must be used remains unclear. ACLA will seek clarification of that date.

We also discussed the status of the draft program memoranda on carrier enrollment of out-of-jurisdiction laboratories and clarification that purchased diagnostic test price information is not required for Part B laboratory claims.

CPT

ACLA participated in the recent meeting of the CPT Editorial Panel meeting in Phoenix (February 8-10). This was a critical meeting in that it the Panel considered proposed changes for CPT codes for clinical lab tests to be included in the 2003 Manual, including ones made by ACLA. Thanks to collaboration with representatives from the College of American Pathologists (CAP), and particularly Dr. Mark Hilborne, the CPT Panel member responsible for reviewing lab proposals, we achieved consensus on most lab issues prior to the Panel meeting. While we didn't get everything we wanted with respect to new codes, we are pleased that ACLA will be able to participate in two new "workgroups" - collaborative efforts to address general coding issues and policies related to nucleic acid tests for microbiology, and molecular genetic/oncology tests.

ESRD

On February 19, 2002, ACLA wrote CMS to follow up on a day-long meeting, held January 14, 2002, of the ACLA ESRD committee and staff from CMS. During that meeting we discussed possible changes to the 50/50 rule for ESRD laboratory testing. In our letter, we provided written comments

on possible changes to the rule including: clarification of the rule's application; definition of modifiers; medical necessity denials; profiles; and the need for additional modifiers. We urged CMS to establish an intensive education effort concerning the 50/50 rule, directed not only at providers but at carriers and fiscal intermediaries as well.

Representatives of ESRD member companies have expressed serious concerns about the need to update several of the national policies developed during the negotiated rulemaking. ACLA will convene a working group to develop the changes we believe need to be made in the policies and the scientific information justifying the changes.

FDA

The FDA committee met by conference call on February 4, 2002. We discussed the status of FDA's proposed draft guidance document related to in-vitro HIV drug resistance genotyping assays. We agreed that our next step will be to seek a meeting with the appropriate individuals at FDA to express our concerns about the impact the guidance could have on the the development of in-house laboratory tests that provide physicians with vital health information and contribute to the health of patients.

Negotiated Rule Making Implementation

Although more than three years behind schedule, the first phase of implementing "national coverage and administrative policies for clinical diagnostic laboratory tests under part B" of the Medicare program is

imminent. A Program Memorandum (PM) will be published within a week informing carriers of the new policies, developed by a negotiated rule making process and published as a final rule November 23, 2001. The notice will clarify that carriers are *not to review lab claims* unless they have been detected as meriting attention by a pre-determined electronic edit, that frequency screens cannot be used without prior publication, that physician signatures are not required, and the appropriate use of certain modifiers, e.g. "59" and "91". [The PM should be available on the CMS website after March 1, www.cms.gov]

These directives apply primarily to Medicare carriers and contractors. Clinical labs will have until November 23 of this year to comply with the rule and adapt their information systems to meet the new uniform coding requirements. It has been a long, hard process, but notwithstanding the delay and some obsolescence [see ESRD Report] it still feels like a major victory - simplified, uniform and national Medicare coverage policies for 23 of the most commonly ordered lab tests!

ACLA member companies, and particularly their employees who worked so hard to see this become a reality, deserve a great deal of credit for this constructive change in policy.

ACLA To Be Represented at CLIAC

Dr. Sundwall has been selected by Mr. Tommy G. Thompson, Secretary of Health and Human Services, to serve on the [Clinical Laboratory Improvement Advisory Committee](#) of the Centers for Disease Control and Prevention (CDC).

Calendar of Events — March 2002

March 4	Laboratory Budget Coalition Meeting	<i>Washington, DC</i>
March 7	HLC Confidentiality Coalition Meeting	<i>Washington, DC</i>
March 13	CMS Open Forum on HIPAA	<i>Baltimore, MD</i>
March 14	ACLA Billing and Reimbursement Committee Meeting	<i>Baltimore, MD</i>
March 14	National Committee for Quality Health Care Annual Conference	<i>Washington, DC</i>
March 14	CMS Open Forum on Labs/ESRD	<i>Baltimore, MD</i>
March 22-24	National Conference of Primary Care Access	<i>Bethesda, MD</i>
March 28	Billing and Reimbursement Committee Meeting	<i>Conference Call</i>
