

• **Message from Dr. Sundwall:**

When Congress returns to work this week they face tougher choices.

• **Advanced Beneficiary Notice:**

We urged that laboratories be given a year from the date of publication of the final PM before requiring use of the new ABN form.

• **CPT:** Consideration of the hematology codes has been rescheduled for the November CPT meeting.

• **CMS New Code Payment:**

CMS plans to publish this fall a proposed rule outlining the process by which they will establish payments for new tests.

• **State Issues:** ACLA wrote to Rhode Island in response to a recent proposal to amend regulations regarding HIV-1 testing.

What a difference a month (or two) makes. Not long ago we had a big surplus in federal funds and the economy was humming along, producing more tax revenues for federal and state governments. However, upon returning from Maine a couple of weeks ago I found a decidedly different tone in Washington — much more sober and less optimistic about the future of our economic welfare. Budget analysts now say the surplus is less than half of what it was thought to be just this past the Spring, and some analysts have already stated that the President's proposed budget for 2002, which includes new spending for a Medicare prescription benefit, a missile defense system, and education cannot be financed without using Medicare Trust fund dollars [which of course the Administration has said are off limits]. Congressional Democratic leaders have sent President Bush a letter asking him to put forward a plan reconciling his budget with the rapidly dwindling surplus. A series of meetings between the White House and Congressional leaders has been scheduled over the next two weeks to discuss these issues. Furthermore, concerns about the federal budget are compounded by a slowing economy in general, here and abroad, which at this time is being reflected in the stock market.

This all means that when Congress returns to work this week they face tougher choices than prior to their August recess. And partisanship is surely to increase — House Minority Leader, Dick Gephardt, has already implied the current situation is due to the President's tax cut, stating "We [Democrats] told you so." This new circumstance of perceived austerity may not last in that some feel the economy is not as bad off as portrayed, and that the tax cuts take time to stimulate economic growth. Nonetheless, it is going to be much harder to get additional funds

for anything out of this Congress at this time. It also means that significant reforms of Medicare may be put off until next year. Conventional wisdom in Washington is that the popular drug benefit will not be added to the Medicare program now because of a growing recognition of how costly it could become.

The current environment means that our efforts to seek improvements in the payment and regulatory climate are more important than ever. Other providers of health services are sure to redouble their efforts to seek improved reimbursement, so we need to make clear that whatever Medicare amendments are passed [likely as part of a budget resolution] include the Medicare Patient Access to Preventive and Diagnostics Test Act (H.R.1798/S1066). This will restore a degree of fairness to payment for lab services, and enable Medicare beneficiaries the benefit of new technologies on a more timely basis. We look forward to working with all of you to see that this happens.

David N. Sundwall

Advanced Beneficiary Notice

On August 14, 2001, ACLA and representatives from member companies met with Denis Garrison at CMS to discuss remaining concerns about the draft program memorandum (PM) that will accompany the new advanced beneficiary notice (ABNs) forms. We pointed out that, at least for several of the larger laboratory companies, rolling out the new form will be a logistical challenge requiring a substantial lead time. For most clients, laboratories will need to replace existing requisition forms with new customized forms and customized ABNs, change software to accommodate the form and educate their own workforce as well as their

clients on the proper use of the new form. We urged that laboratories be given a year from the date of publication of the final PM before requiring use of the new form.

On August 30, 2001, Mr. Garrison circulated a draft revised program memorandum for review and comment. The revised draft, while it doesn't address the timing question, does respond to several concerns we had about the earlier version. Most notably, it recommends that laboratories should preprint the list of tests most likely to be subject to the ABN in a "readable" font in the size range of 10 point to 12 point.

Finally, a website for frequently asked questions about ABNs was posted on August 31, 2001. In response to the hypothetical beneficiary question whether an ABN that was not on the approved ABN form (CMS-R-131) was a legitimate ABN, CMS stated that "[t]he CMS-R-131 came into use in June 2001 and is expected to be the only ABN in use by September 2002. In the meantime, you may receive ABNs using the old approved model language...." You may access the website at www.hcfa.gov/medlearn/refabn.htm.

CPT

Pat Maloney and David Sundwall represented ACLA at a meeting of the CPT Editorial Panel in Chicago on August 3. It was crucial meeting in that the Panel was to consider a proposal put forth by the College of American Pathologist (CAP) for revisions in several codes for hematology tests. ACLA was given an opportunity to review this particular proposal when it was in development and we expressed several serious concerns. Over the past six months we have worked closely with CAP, who in the process significantly modified their proposal to address our concerns.

Nonetheless, the revised proposal still would have proven problematic, and as a consequence we had a "last minute" (literally) conference with CAP representatives at the Panel meeting which resulted in further modifications. The changes we agreed upon were then put before the Panel, but they felt they needed more time to review the revised proposal before action was taken. Consequently, consideration of the hematology codes has been rescheduled for their November meeting. ACLA is now developing a package of proposed new codes for the CPT Editorial Panel to consider for inclusion in the 2003 Manual.

CMS New Code Payment Meeting

ACLA and representatives from ACLA member companies attended the August 6, 2001, Centers for Medicare and Medicaid Services (CMS) meeting to discuss payment recommendations for new clinical laboratory tests. Twelve organizations made presentations, including ACLA, the College of American Pathologists, the American Society of Microbiology, the Clinical Laboratory Management Association, and several manufacturers of test kits.

With a couple of exceptions, most presenters were in general agreement about whether to gapfill or crosswalk a particular test and the appropriate code to crosswalk. The two exceptions were c-reactive protein and hepatitis C virus (HCV). With respect to c-reactive protein, most presenters agreed it should be crosswalked, but differed as to which code to crosswalk. Several presenters wanted to gapfill rather than crosswalk HCV; ACLA and others recommended it be crosswalked instead. This meeting was in-

tended to be a "listening" session on the part of the CMS participants, and, consequently, they gave no reaction to any of the presentations. CMS plans to publish this fall a proposed rule outlining the process by which they will establish payments for new tests. A summary of the recommendations from the August 6 meeting appears on the CMS website at www.hcfa.gov/medicare/clinlabs.htm.

State Issues

On August 27, 2001, ACLA wrote to the director of the Rhode Island Department of Health in response to a recent proposal to amend regulations regarding HIV-1 testing and reporting. In our letter we made two points. First, we urged the state not to amend their regulations to limit HIV testing to tests "currently approved by the federal Food and Drug Administration." Current regulations permitting "medically accepted" HIV tests allow the use of more precise testing opportunities. We also objected to the proposed amendment to the regulations that would limit HIV testing to Rhode Island-licensed hospital laboratories.

ACLA Board Member, **Craig Dawson**, announced his resignation from Fresenius Medical Care, N.A. in August. He has recently joined AML Laboratories. ACLA wishes him the very best in his new position.

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

Calendar of Events — September 2001

September 6	Meeting with Greg Critchfield, President and CEO of Myriad Genetics Laboratory	<i>Salt Lake City, UT</i>
September 11	Laboratory Coalition Fly-In Meeting	<i>Washington, DC</i>
September 17	Practicing Physicians Advisory Council	<i>Washington, DC</i>
September 17	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
September 18	Meetings: ACLA Board and with Thomas Scully, Administrator of CMS	<i>Washington, DC</i>
September 19	ACLA Billing and Reimbursement Committee Meeting	<i>Washington, DC</i>
September 19	Meeting with Craig Dawson, American Medical Laboratories (AML)	<i>Chantilly, VA</i>
September 25	National Exploring Health Careers Committee Meeting	<i>Washington, DC</i>