

VOLUME 8•NUMBER 1

•**Message from Dr. Sundwall:**

The over-arching health care challenge at present is dealing with anthrax bio-terrorism.

•**Billing and Reimbursement:**

We urged CMS to address the chronic difficulties laboratories face in splitting claims.

•**CPT:** Dr. Sundwall will present ACLA's position at the CPT Editorial Panel meeting in San Diego.

•**Genotyping Guidance:** ACLA submitted comments to FDA on the Draft Guidance.

•**Laboratory Healthcare Coalition:** The Coalition agreed to finance the publication of an article based on research conducted by Dr. Michael Pine.

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

Life has changed since September 11, perhaps more so here in Washington D.C. and New York City than elsewhere. The analogy may not be fair, but I sometimes feel as though we are living in London during World War II prior to the blitz - periodically there are helicopters buzzing overhead (I imagine doing surveillance of the White House), and frequent sirens (I'm not sure why). And with almost daily announcements of anthrax being discovered in federal buildings and post offices and more documented cases of exposure, one gets the sense that we are indeed under siege. So all of us are on alert, meaning we are anxious and wondering what, where, and when the next assault might be.

Notwithstanding the fact that America is engaged in an unfolding war against terrorism - here and abroad - ACLA has had a busy month representing the interests of our member companies. While Congress has been focused almost entirely on our response to terrorism, the various agencies of government continue with their respective responsibilities. Consequently, we have been alert to monitor proposed regulations and have made formal comment when necessary (see reports below).

The notice of greatest interest throughout the clinical laboratory community was a document titled "Draft Guidance for Industry - Pre-market Notification [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays", published by the FDA for comment. ACLA has been contacted by several non-member companies, soliciting our views of this particular proposal and seeking to collaborate with us in making public comment. The consensus is that the FDA intends to regulate in some fashion "homebrew" HIV resistance tests. Our collective challenge is to ensure that they do not impose unnecessarily burdensome requirements, and that they not extend their reach to regulate homebrew reagents in general.

The over-arching health care challenge at present is dealing with anthrax bio-terrorism. I attended a lecture given by HHS Secretary Tommy G. Thompson on October 17, where he provided an overview of the government's efforts to date, and stressed the burden on public health laboratories. I told him that our member companies had provided assistance in various ways in response to the terrorist attacks, and collaborated to ensure the ongoing availability of clinical lab services. While much of the burden on the public health labs seems to be testing for environmental contamination by anthrax and reassuring the "worried well." I asked him how our member companies might compliment efforts by the public sector to deal with the current crisis. He then invited us (ACLA) to meet with him as soon as possible to discuss these issues (see copy of October 19 letter to Secretary Thompson on ACLA website). ACLA Board member, Ken Freeman, underscored our responsibilities in his address to the WG-2 Annual Lab Institute on October 26, by stating, "As an industry we need to reach out collectively to support public health agencies during this challenging period in any way we are able."

And finally, there is some good news to report. After representatives of the ACLA Board met with Tom Scully, CMS Administrator, in New York City on September 26, he sent me an e-mail with the following message: "When I got back from our meeting I was stunned to learn that it [the final negotiated rule for uniform Medicare coverage policies for clinical lab services] had been lying around and no one had a real problem with it. I was angry - with the process - and pushed it through". The rule went to OMB for review on October 9, 2001, and we hope for speedy approval. So, life goes on and the wheels of government turn - sometimes moving forward!

David N. Sundwall

Billing and Reimbursement

The committee met in the ACLA offices on October 24, 2001, joined by phone with Glenn Kendall, Dan Layne and others from the CMS Central Office Lab and DME Claims Processing Group. Mr. Kendall offered his group as a pointer for the lab industry, to channel inquiries and issues to the appropriate office within CMS. He asked for the top few laboratory claims processing issues that his team could address. ACLA members responded with two system-wide concerns. First and foremost, we urged CMS to address the chronic difficulties laboratories face in splitting/forwarding claims for referrals into other carrier jurisdictions. We would greatly prefer that this problem be resolved by assigning a single carrier to each laboratory company for all its Medicare claims processing. Second, we pointed out that many carriers do not understand that claims for services on the clinical laboratory fee schedule are not subject to purchased diagnostic service requirements. Thus, many carriers erroneously require a "purchase price" on claims for lab-to-lab referrals, typically indicated with a "90" CPT code modifier. We recommended that a program memorandum be issued to Part-B carriers to clarify this issue.

CPT

The committee met via teleconference on October 11 and 23. We agreed to develop an ACLA position statement for presentation to the CPT Editorial Panel regarding the College of American Pathologists' (CAP) proposal for revised CPT codes for hematology tests. Dr. Sundwall will present ACLA's position at the Panel meeting in San Diego on November 8, 2001 - supporting most of the proposed revisions, but vigorously opposing adoption of a new code for a "partial CBC", and for a new code for an

already existing test, the automated platelet count. ACLA obtained permission to submit after the published deadline one more code to be considered for inclusion in the 2003 CPT Manual. We have agreed to share these proposals with CAP, with the understanding they will give us an opportunity to review any proposals they might submit for new clinical lab codes. ACLA has forwarded to the committee a Program Memorandum sent to all Medicare Contractors on October 26, related to Medicare coverage and coding for anthrax - related testing.

Genotyping Guidance

On October 29, 2001, ACLA submitted comments to the Food and Drug Administration (FDA) on the Center for Biologics Evaluation and Research's "Draft Guidance for Industry Premarket Notifications for In Vitro Drug Resistance Genotype Assays: Special Controls." In our statement we emphasized the fact that the draft guidance will stifle innovation in the rapidly changing scientific area and negatively affect the quality of treatment for patients. We also made the point that the guidance represents a sudden change in current medical practice, which is unnecessary and which contradicts the existing regulatory framework governing the classification and reclassification of ASRs. We stated that it would be more logical and reasonable to address in-house laboratory testing through the CLIA regulatory process. Finally, we concluded that the draft guidance would create an undue burden on manufacturers of ASRs and the laboratories that depend on these products for use in in-house laboratory testing. The proposed change would interfere with the relationship between physicians and laboratories, disrupt current medical care, and could lead to dire consequences for patients and the public health.

A copy of ACLA's comments is available on the ACLA website.

Laboratory Healthcare Coalition

Johnson and Johnson hosted a meeting of the Coalition on October 31. We considered several options for new initiatives to promote public awareness of the value of clinical lab testing, including: 1) preparing general interest articles for distribution to the popular press by a news service, 2) a joint project with the American Association of Health Plans and the National Committee on Quality Assurance to identify clinical lab tests used in HEDIS quality measures and barriers encountered in extracting such data, and 3) collaboration with the Agency for Health Care Research and Quality related to utilizing clinical lab data in medical outcomes research. The Coalition also agreed to finance the publication in a peer reviewed journal of an article based on the research conducted on our behalf by Dr. Michael Pine. His report documented the value of clinical lab data in risk-adjusted cost models for hospitalized patients with acute myocardial infarction, pneumonia, or congestive heart failure.

ACLA to co-sponsor an AACC
Audioconference:

**"What Every Laboratory Needs to
Know About Chemical and Bio
Terrorism"**

Wednesday, December 12, 2001
1:00 - 2:30 pm (EST)

We encourage all ACLA members to participate. You may register on-line at www.aacc.org, or by downloading the registration form from our website.

Calendar of Events — November 2001

November 5	ACLA Briefing - Robert Wood Johnson Health Policy Fellows
November 8	CPT Editorial Panel Meeting
November 9	California Clinical Laboratory Association (CCLA) Conference
November 13	ACLA CPT Committee Meeting
November 13	Waiver of OTC Tests Meeting
November 14	Lab Coalition Meeting
November 15-16	Secretary's Advisory Committee on Genetic Testing (SACGT)
November 15	AACC Conference on Reforming Lab Payments
November 20	ACLA Billing and Reimbursement Committee Meeting

Washington, DC
San Diego, CA
San Diego, CA
Conference Call
Baltimore, MD
Washington, DC
Bethesda, MD
Alexandria, VA
Conference Call