

## VOLUME 7 • NUMBER 8

•**Message from Dr. Sundwall:**

ACLA participated in a press conference commemorating the introduction of **The Medicare Patient Access to Preventive and Diagnostics Tests Act**.

•**Advanced Beneficiary Notice:**

ACLA believes the new proposed ABN is a substantial improvement over previous proposals.

•**Billing and Reimbursement:**

We discussed the status of our proposal to HCFA to amend the technical component of pathology services PM.

•**Genetic Testing:**

ACLA met with Dr. David Feigal, Jr., FDA's representative to the HHS Secretary's Advisory Committee on Genetic Testing.

•**Medicare Patient Access to Preventive and Diagnostics Test Act:**

It establishes a single national fee schedule for laboratory payments and restores the CPI update.

**W**ow - what a great time to be in Washington! That is if you thrive on political drama, the likes of which haven't been seen around here for some time. Whoever would have thought we could witness a change of leadership in the U.S. Senate without an election? But that is exactly what happened last week with Vermont's Senator Jeffords bolting the Republican Party to become an Independent, thus shifting the ever so slight margin of power to the Democrats. Pundits have wasted no time in speculating what this will mean during this 107th Congress, but I think it is far too early to tell how the agenda of President Bush or Congress will be affected.

ACLA's big news for the month was our participation in a press conference on Capitol Hill on May 24, commemorating the introduction of **The Medicare Patient Access to Preventive and Diagnostics Tests Act of 2001 (H.R. 1798)**. [Unfortunately, we were *some-what* eclipsed by Senator Jefford's announcement he was changing parties, which occurred on the very same day.] This press event was spearheaded by AdvaMed - the trade association representing the medical devices and diagnostics industry - and was held outside, near the House of Representatives. It was attended by representatives of all the major clinical laboratory industry and professional organizations, as well as several trade publications (but alas, not the "big three" networks). Congresswoman Jennifer Dunn (R-WA), and Congressman Jim McDermott (D-WA) jointly introduced the bill and gave statements indicating their awareness and appreciation of the value of clinical lab data and testing services. Their bipartisan legislation will, if enacted into law, translate into national policies some of

the key recommendations of the Institute of Medicine's report, Medicare Laboratory Payment Policies: Now and In the Future. Former ACLA Board member, Dr. John M. Matsen, who served on the IOM lab study committee gave a succinct summary of their work of this project and urged support for this legislation. I was honored to make a statement on behalf of ACLA, and the other lab organizations present, in support of this bill (copy of ACLA press release enclosed).

I also attended a meeting - Genetic Testing and Screening in the Age of Genomic Medicine - at New York University School of Medicine on May 30, where experts discussed recommendations of the New York Task Force on Life and the Law. While the potential for revolutionizing medicine with our new understanding of genes is clearly apparent, much of the discussion centered on legal and bio-ethical problems. I had an opportunity to raise our concerns with Dr. Antonia Novello, Commission of Health for New York State, about inappropriate oversight and regulations that might be imposed on clinical laboratories conducting genetic testing. It is clear these issues will be high priority for ACLA for the foreseeable future.

We hope to meet with the new Administrator of the Health Care Financing Administration, Thomas Scully, in the near future, and will be inviting representatives of the Board to attend this meeting to discuss issues of importance to the clinical laboratory industry. In the meantime, we will be vigilant in monitoring what is going on in Congress and the Administration during this time of great change and uncertainty .

*David N. Sundwall*

## Advanced Beneficiary Notice

ACLA filed comments and recommendations on HCFA's new version of its advanced beneficiary notice on May 18, 2001. Overall, ACLA believes the new proposed ABN is a substantial improvement over previous proposals. The design eliminates many of the previous drafts' defects and solves a variety of the administrative and operational concerns. We did offer several specific proposals for minor revisions to the proposed ABN.

Among other points, we suggested that the name, address and other identifying information for the laboratory be printed at the top of the notice rather than the notifier of the beneficiary. We also suggested that the form be amended to require only one date to be identified and that should be the date the beneficiary signs the form. We asked that laboratories be given the flexibility, in customizing the form, to use a slightly smaller font to preprint information about limited coverage tests. Finally, we recommended that laboratories be provided at least one year to implement the new ABN form requirements.

## Billing and Reimbursement

The Billing and Reimbursement Committee met on May 17, 2001, to discuss pending and ongoing issues. We discussed the status of our proposal to HCFA to amend the technical component of pathology services program memorandum (PM.) Our proposal would permit laboratories to submit attestations to carriers that arrangements between hospitals and laboratories were in place by July 1999 in lieu of providing origi-

nal documentation of the arrangement. We agreed to develop alternative PM language to share with HCFA.

## Genetic Testing

On May 7, 2001, ACLA and representatives from ACLA member companies met with Dr. David Feigal, Jr., Director of FDA's Center for Devices and Radiological Health and FDA's representative to the HHS' Secretary's Advisory Committee on Genetic Testing. The purpose of the meeting was to discuss FDA's current position with regard to the regulation of home brew testing for genetic diseases and whether FDA proposed to require some sort of government approval for these tests before they can be offered. We raised a number of concerns about FDA singling out home brew testing for genetic disease for special treatment. We agreed to work with the agency to try to develop a workable solution that met public concerns about perceived lack of control over genetic disease testing without stifling research advances.

## Medicare Patient Access to Preventive and Diagnostic Tests Act

On May 10, 2001, Congresswoman Jennifer Dunn (R-Wa) introduced H.R. 1798, the Medicare Patient Access to Preventive and Diagnostic Tests Act. The bill establishes a process for public comment and consideration of payment rates for new technology and provides some guidance to HCFA as to when to "crosswalk" a test to an existing test and when to "gap fill" when a test represents new technology. It also

establishes a single national fee schedule for laboratory payments under Part B at the national limitation amount and restores the CPI update for 2002.

The bill enjoys bipartisan support in the House of Representatives. A Senate version is expected to be introduced by Senators Orrin Hatch (R-UT) and John Kerrey (D-MA) in early June. ACLA is working with a coalition of other laboratory organizations and representatives of diagnostics manufacturers to seek additional cosponsors and support for the legislation.

## Welcome Erin Lewis Darling!

ACLA is pleased to announce that **Erin Lewis Darling**, an associate at Mintz Levin, will be assisting us on legal issues. She replaces Colin Roskey who has taken a professional staff position with the Senate Finance Committee. Erin's legal experience includes health information privacy and confidentiality, health care fraud and abuse policy and litigation, and Medicare reimbursement law and policy. She is admitted to practice in North Carolina and the District of Columbia. She received a BA in political science from the University of North Carolina at Chapel Hill and earned her JD, cum laude, from Georgetown University Law Center.

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## Calendar of Events — June 2001

<b>June 7</b>	National Exploring Health Careers Committee Meeting	<i>Washington, DC</i>
<b>June 8</b>	AACC Evidence Based Medicine Conference	<i>Crystal City, VA</i>
<b>June 13</b>	Quest Diagnostics Incorporated Government Affairs Conference	<i>Washington, DC</i>
<b>June 19</b>	University of Maryland Health Policy Institute Meeting	<i>College Park, MD</i>
<b>June 20</b>	ACLA Billing and Reimbursement Committee Meeting with Thomas Gustafson, Director of Plan and Provider Purchasing Policy Group, at HCFA	<i>Baltimore, MD</i>
<b>June 21</b>	ACLA CPT Advisory Committee Meeting	<i>Washington, DC</i>

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