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•Message from Dr. Sundwall:
The new administration is slowly taking shape and form, but too slowly for some.

•ESRD: ACLA has written to HCFA to express our concerns about the way in which the agency intends to eliminate the "50/50 rule."

•Legal: ACLA filed comments on "Stark II."

•Privacy Comments: On March 30, 2001, ACLA filed supplemental comments on the HHS final rule establishing privacy standards

•State Issues: ACLA urged Georgia to promulgate regulations restricting phlebotomists.

It has been interesting to observe the new administration in action here in Washington. President Bush initially enjoyed considerable success in promoting good will and collaboration with Congress; however, as he attempts to obtain legislative approval for a large tax cut and his 2002 federal budget, tensions have mounted. Differences are inevitable between branches of our government at any time, but just how "different" things will be during this unusual era - with an almost evenly divided legislature, and a president without a majority mandate - remains to be seen. Some pundits have pointed out that in spite of these historically unique circumstances, our elected representatives are not that far apart philosophically, and that after jockeying for position and attention, consensus will be achieved on taxes and budget priorities. But even so, it may not be a time when significant new policies can be agreed upon, e.g. "Medicare reform".

The new administration is slowly taking shape and form, but too slowly for some. Secretary Tommy Thompson was confirmed by the Senate on January 24, and sworn in on February 2, 2001. Now almost two months later, only a handful of political appointments have been made. Dr. Claude Allen, the Secretary of Health and Human Resources in Virginia, has been nominated to serve as the Deputy Secretary of H.H.S. Tom Scully, currently President and C.E.O. of the Federation of American Hospitals, has been nominated to serve as Administrator of the Health Care Financing Administration (HCFA), but no date has been set for his Senate confirmation hearing. A Deputy Administrator for HCFA has been appointed, Ruben Jose King-Shaw, Jr., who has served as Secretary of Florida's Agency for

Health Care Administration. No appointments have yet been made to key positions in the Public Health Service, although most Clinton appointees have been asked to leave their posts, leaving these positions in the hands of "acting" career employees.

ACLA has co-signed a letter to Secretary Thompson urging him to publish the proposed rule for adoption of national, simplified and uniform payment policies for clinical lab services covered under Medicare Part B (as required by law in the Balanced Budget Act of 1997). We participated in a lengthy "negotiated rule making" process to develop this proposal, which if implemented would eliminate carrier variation for coverage and payment policies for 23 commonly ordered clinical lab tests, thereby significantly reducing the "hassle factor" for doctors and labs alike. [According to statute, this should have been done by January, 1999.]

ACLA continues to promote our legislative and regulatory agenda - individually and with others by participation in various coalitions. We are seeking meetings with key officials in Congress and the administration and will be calling on you to join us for these all important educational opportunities.

David N. Sundwall

CPT

The Committee met via conference call on March 19, and reviewed a study done by Joan Logue for Abbott Laboratories, a "Cross Walk Analysis of 2001 Laboratory CPT Codes". This report documents serious problems with HCFA price setting for several new lab codes. For 56 of 58 new codes, prices seem to have been established by cross walking the new code to an existing code, rather than establishing payment more appropriately through a gap fill method.

ACLA is reviewing our collective experience with these new codes and will write HCFA and request a meeting to address these issues. ACLA has been given the CAP final application for new CPT hematology codes, which incorporated some recommended changes we offered to their draft proposal. We will carefully review this document and determine if we will make formal comments and request further modifications when these codes are considered by the CPT Editorial Panel meeting in August.

ESRD

ACLA has written to HCFA to express our concerns about the way in which the agency intends to eliminate the "50/50 rule." While we have long advocated eliminating the complex and confusing rule, we strenuously object to HCFA's plans to apply a significantly discounted reimbursement rate to all automated chemistries furnished to ESRD patients, regardless of whether or not other composite rate chemistry tests are ordered and performed at the same time. We urged HCFA to consider a fairer and more appropriate approach which takes into account whether or not composite rate chemistries were furnished on the same day.

Legal

On April 4, 2001, ACLA filed comments in response to Phase I of the final regulations implementing the physician self-referral law, usually referred to as Stark II. In its comments, ACLA supported many of the clarifications made in the regulations, although it also expressed concern about provisions that could permit physicians to establish "shared

laboratories," laboratories where the physicians practice in the same building, but not as part of a group practice. Further, the comments looked at a new exception covering "indirect compensation arrangements," which, while potentially helpful, is defined in a manner that is very confusing. Finally, ACLA expressed support for most of the provisions that clarify the types of items and supplies that a laboratory may provide to a physician as part of the testing process.

Privacy Comments

On March 30, 2001, ACLA filed supplemental comments on the HHS final rule establishing privacy standards for individually identifiable health information. The final rule was published on December 28, 2000, and is scheduled to go into effect on April 14, 2001, although the requirements do not have to be implemented for two years. HHS Secretary Tommy Thompson reopened the comment period for 30 days at the request of the provider community. At this point, it is unknown what action, if any, HHS will take with regard to the rule's implementation.

In its comments, ACLA echoed the position of many other health care groups by seeking significant changes in the law, and requesting a significant delay in the date for compliance. In addition, ACLA sought further clarification of the relationship between the HIPAA provisions permitting patient access to medical information and state laws that limit to whom test results can be given. ACLA's comments also addressed the enormous cost impact that the privacy rule would have on clinical laboratories, especially given the way that laboratories keep and maintain patient information. That is, because labora-

tories typically treat each patient encounter as a separate testing and billing event, it is impossible to link all patient data together. Patients seeking information will likely have to provide additional identifying information, if errors are to be avoided.

ACLA will continue to monitor developments in this area and will, of course, keep members apprised of any further changes in the rule or its effective date.

State Issues

ACLA submitted a proposal to the Georgia Department of Human Resources Board urging the promulgation of regulations to prohibit independent clinical laboratories and all other entities that operate clinical laboratories from placing lab employees or contractors in physician offices. Our proposal would cover hospital labs and non-Georgia licensed laboratories. We recommended that the regulations include provision for loss of license and civil fines for offending labs and civil fines for physicians who permit the placement of lab employees or contractors in their offices.

Results is a monthly newsletter to educate ACLA member companies about the association's involvement in issues and activities that affect the clinical laboratory industry. Please feel free to distribute this newsletter to colleagues throughout your companies who would be interested in knowing what we are doing in Washington.

Calendar of Events — April 2001

April 5	Lab Budget Coalition Meeting	<i>Washington, DC</i>
April 6	Specialty Laboratories, Inc. Meeting	<i>Santa Monica, CA</i>
April 9-10	National Conference on Primary Health Care Access	<i>San Diego, CA</i>
April 12	National Exploring Health Careers Committee	<i>Washington, DC</i>
April 19	ACLA Billing and Reimbursement Committee Meeting	<i>Washington, DC</i>
April 24	New Jersey Department of Health Meeting	<i>Trenton, NJ</i>
April 27	ACLA Policies/Positions on Genetic Testing	<i>Conference Call</i>