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• **Message from Dr. Sundwall:**

The battles of the budget are being waged behind scenes between Congress and the Administration.

• **ABN:** ACLA filed comments regarding the final version of the new ABN.

• **Billing and Reimbursement:**

ACLA filed comments with CMS regarding identification and return of overpayments and technical amendments to the Medicare and Medicaid programs.

• **ESRD/Clinical Laboratory Service Open Forum:**

ACLA expressed strong support for CMS to designate a single Medicare carrier to process clinical laboratory claims for ESRD.

• **HHS Advisory Committee on Regulatory Reform:**

ACLA filed comments regarding ways to reduce current burdens imposed by existing regulations.

Congress is in recess and while the Hill seems relatively quiet at the moment, the battles of the budget are being waged behind scenes between Congress and the Administration. There is a tug of war going on - key Congressional leaders are pressing the Administration on what should be "cut" in order to finance within the constraints of the current budget parameters the new health initiatives the President has recommended. The President's men, Secretary Tommy Thompson and Mitch Daniels (Director of the OMB), have responded by simply sticking to their original proposals and not giving in to demands that they should tell Congress how to balance the budget. One indication of the Administration's willingness to negotiate, however, gives us concern about the fate of the CPI update for clinical labs, now scheduled to be restored in 2003. The Administration's letter to Congresspersons Bill Thomas and Nancy Johnson (House Ways and Means Committee) states, "...we recognize that some provisions in law that, in the past, have restrained growth in payments are about to expire and extension of these provisions is one potential way to ensure a budget-neutral package of reforms". This leaves us with no doubt how important it is to make certain Congress does not turn to the clinical lab fee schedule, once again, to find funds to pay for other services covered by the Medicare program.

Notwithstanding the ongoing debate over spending priorities, this seems a particularly positive time for the clinical lab industry. The Washington Post recently cited two developments - one a public health initiative, another a scientific breakthrough - each based on clinical laboratory services. The first article reports the federal government is calling for millions of overweight Americans to be tested for "pre-diabetes" as a preventive measure. If the tendency for developing diabetes mellitus is present, then it is hoped that through diet and

exercise untold expenses might be saved by delaying the development of costly complication of clinical diabetes. The second article is about the discovery of a common genetic variation which may help doctors predict which patients can lower their risk of heart disease by taking estrogens. This could be of great value in tailoring treatment for patients - limiting risk to those unlikely to benefit from hormone replacement therapy, and recommending such for those who most need it.

The services ACLA member companies provide are essential for public and personal health. These kind of newsworthy events and scientific developments will help us in our efforts to ensure a more healthy regulatory environment and payment policies for the clinical laboratory industry.

[F.Y.I. - My wife, Cathy Hammon Sundwall, is running for Congress in Utah's 1st Congressional District.]

David N. Sundwall

ABN

ACLA also filed comments with the Office of Management and Budget and CMS regarding the final version of the new Advance Beneficiary Notice (ABN) and Program Memorandum applicable to clinical laboratory services. ACLA praised CMS's efforts thus far to design a form that serves the needs of patients, physicians, and laboratories, but made several specific recommendations designed to introduce even more utility, clarity, and compliance to the process as a whole. ACLA recommended that: laboratories be permitted until at least September 2002 to become compliant with the new form and instructions; laboratories be permitted to adjust the typeface for the text of the ABN so that all necessary tests can be included on the

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form; the instructions be clarified to explain that in situations where the identifying information on the ABN form relates to another health care provider that obtained the ABN rather than the laboratory that is billing for the service, the ABN form is still valid so long as it was properly executed; the instructions be clarified to state that there are a variety of factors that determine whether or not an entity provides ABNs and not every failure to furnish an ABN constitutes a fraud and abuse violation; and CMS take into consideration that implementation of the new ABN form and instructions will create a significant burden on laboratories.

Billing and Reimbursement

On March 26, 2002, ACLA filed comments with the Centers for Medicare and Medicaid Services (CMS) on Proposed Rules regarding identification and return of overpayments and technical amendments to the Medicare and Medicaid programs. The first Proposed Rule would require providers, suppliers, individuals, and managed care organizations contracting with CMS to return overpayments to CMS, and establish the timeframe and process for making reports and returning the overpayments. In particular, ACLA expressed its concerns about this proposal because it creates a new legal mandate that providers report and return overpayments within 60 days. ACLA recommended that CMS withdraw the proposal, but also made the following suggestions for changes if CMS decides to pursue the proposal: clarify what constitutes an "identification" of a Medicare overpayment; establish a more reasonable time frame for identification and return of overpayments; simplify the procedures for returning overpayments; create exceptions

for de minimis overpayments and good faith disputes; and revise the Regulatory Impact Statement to more accurately reflect the actual time required to identify and return overpayments to the Medicare Program. In addition, ACLA filed comments making various suggestions for clarification of the Proposed Rule for technical amendments to the terms, definitions, and addresses in the Medicare and Medicaid programs.

ESRD/Clinical Laboratory Service Open Forum

ACLA participated in another CMS-sponsored "Open Forum" at headquarters in Baltimore on March 14th. These sessions are designed to promote dialogue between the providers of Medicare services with senior CMS staff. ACLA had the opportunity to express strong support for CMS moving to designate a single Medicare carrier to process clinical laboratory claims for ESRD patients. We were pleased to hear unanimous support for this policy - from the ESRD community, physician groups, and the National Kidney Foundation. This "single carrier policy" was felt to promote more fair reimbursement, and also appropriate utilization of services based on clinical guidelines.

At this forum, ACLA also encouraged CMS to provide an option for any independent laboratory to elect to use a single carrier to process Medicare Part B laboratory claims. We presented this as a constructive and inexpensive alternative to CMS complying with the statutory mandate to designate "not more than five" regional carriers to process clinical laboratory claims (BBA '97). After this meeting, we wrote Jeffrey L. Kang, M.D., M.P.H., Chief Clinical Officer and Director

of the Office of Clinical Standards and Quality, reiterating our position and encouraging him to facilitate, if possible, these new policies through a regulatory process. Tom Scully, Administrator of CMS, was also informed of ACLA's position on single carrier policies, for ESRD labs, and as an option for all others.

HHS Advisory Committee on Regulatory Reform

ACLA filed comments with the Secretary's Advisory Committee on Regulatory Reform regarding ways to reduce current burdens imposed by existing regulations of the Department of Health and Human Services (HHS) that inhibit the delivery of high quality, timely, and efficient health care. In particular, ACLA made the following recommendations for reducing the unnecessary and unreasonable burden of existing HHS regulations: multistate labs should choose, or be assigned, a single carrier for clinical laboratory claims processing; a single national fee schedule governing payment for clinical laboratory claims should be implemented; the Centers for Medicare and Medicaid Services (CMS) should develop a better and more efficient system for determining payment for new laboratory tests; and regulation of the clinical laboratory industry should be targeted through the existing regulatory framework of the Clinical Laboratory Improvement Amendments (CLIA). The Secretary's Advisory Committee is accepting these written public comments as well as conducting various sessions across the country to receive input from the health care industry and consumers.

Calendar of Events — April 2002

April 2	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
April 2	Coordinating Council on the Clinical Lab Work Force Meeting	<i>Chicago, IL</i>
April 4	ACLA Billing and Reimbursement Committee Meeting	<i>Conference Call</i>
April 4	Confidentiality Coalition Meeting	<i>Washington, DC</i>
April 10	Council on Graduate Medical Education Meeting	<i>Bethesda, MD</i>
April 15	CPT Advisory Committee Meeting	<i>Conference Call</i>
April 15-16	John Hopkins' Conference - Clinical Care of HIV	<i>Baltimore, MD</i>
April 17	Meeting with Dr. Kathryn Zoon, FDA	<i>Rockville, MD</i>
April 18	ACLA Summit on New Technologies	<i>Washington, DC</i>
April 22	National Exploring Health Careers Committee Meeting	<i>Washington, DC</i>
April 25-27	International Health Work Force Conference	<i>Ottawa, Canada</i>
