

- **Message from Dr. Sundwall:** We will now focus our lobbying efforts on the Senate to make sure any Medicare legislation considered is favorable to the clinical laboratory industry and the beneficiaries we serve.
- **CPT:** We reviewed a draft of proposed edits to the NCCI.
- **ESRD:** ACLA and representatives met with CMS officials on June 28, 2002.
- **Legislative Affairs:** Labs should receive the full CPT update for years beginning 2003 and beyond.
- **Medicare Cholesterol Screening Benefit:** The House passed Medicare bill authorizes coverage for cholesterol and "other blood lipid screening tests."
- **State Issues:** ACLA met with Dr. Lawrence Sturman to discuss our concerns with respect to NY's proposed regulations governing assay approval.

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The Congress is in recess - our elected representatives have gone home for the Fourth of July Holiday. We will all be taking some time off to celebrate the birth of our nation, and to reflect on the challenges now facing America at a time when we are engaged in an ongoing international war against terrorism. Issues related to defense, trade, and bio-terrorism seem to have dominated the congressional agenda earlier, but in recent weeks domestic policy issues have moved up on the list. Concern about the economy is growing, which may account, at least in part, for why health-related legislation was finally addressed prior to recess.

The House narrowly passed legislation (pretty much along party lines), establishing a prescription drug benefit for Medicare beneficiaries, and increasing outlays for certain health providers - home health, physicians, skilled nursing facilities, teaching and "disproportionate share" hospitals, and allied health services - totaling about \$30 billion in "give-backs". (See Legislative Affairs below for lab-specific provisions in the Medicare bill).

The prescription drug plan developed by the Republicans is a voluntary program, providing 100% coverage for low-income seniors, but others choosing to participate would have varying co-payments and deductibles, until "catastrophic" coverage kicks in when expenses for drugs exceed \$3,700 in a calendar year. Reaction to the plan has been mixed, varying from: "progress made toward improving health care security for seniors" [Chip Kahn - Federation of American Hospitals], to a "major disappointment doomed to fail because its basic design is flawed" [Gail Shearer - Consumer's Union]. The Democratic leadership, however, was unanimous in denouncing the legislation

as insufficient and misleading to senior citizens regarding the extent of the drug benefit. At this point, with only 7 legislative weeks left on the Congressional calendar this year, the Democrat controlled Senate may not be able to pass their version of a drug benefit bill in the time remaining. And even if they were to do so, a compromise with the House passed legislation seems unlikely. If this is the case we will have to wait and see what voters make of such a stalemate - who gets blame (or credit) for a major campaign promise made in the 2000 election year not being kept.

We will now focus our lobbying efforts on the Senate to make sure any Medicare legislation considered is favorable to the clinical laboratory industry and the beneficiaries we serve. We encourage all of you to make your views known to your respective Senators, and also those serving on the Finance Committee. Medicare legislation in *some* form will be passed this year, with or without a prescription drug benefit, so we must be vigilant to ensure adequate payment and appropriate regulatory policies for clinical labs.

David N. Sundwall

CPT

The Committee met via conference call June 27. We reviewed a draft of proposed edits to the National Correct Coding Initiative (NCCI), sent to ACLA by Dr. Niles Rosen of AdminaStar Federal. We will recommend significant revisions based on the experience and comments of our members. The committee reviewed tasks assigned to ACLA by the CAP Genetic Coding Workgroup, specifically the request we provide information related to volume of genetic testing done by our member companies.

This information will be collected for the past year and provided in aggregate form to the CAP. The committee also discussed preparations for the CMS - Laboratory Public Meeting: Payment Policies for New Clinical Laboratory Tests (August 5, 2002). JoAnne Glisson is coordinating input from ACLA members to develop consensus recommendations regarding preferred methodologies to be used in setting payment rates for new CPT codes.

ESRD

ACLA and representatives of ACLA member ESRD laboratories met with CMS officials on Friday, June 28, 2002, to discuss our concerns in the areas of national and local medical review policies, frequency edits, and medical necessity documentation requirements. The CMS representatives acknowledged that the medical conditions of many ESRD patients required more frequent testing than for the general Medicare population but that the answers to more uniformity and developing a better system of edits and utilization screens are somewhat illusive. One suggestion was to revise the composite rate and allow CMS to establish the components of the composite rate by regulation; this would require a legislative change since the composite rate is established by statute. Alternatively, we could request national coverage decisions for any tests for which we sought uniformity. They did offer to set up a meeting between us and carrier medical directors during the next CMS carrier medical directors meeting this fall to elaborate on our concerns.

Legislative Affairs

The House of Representatives passed its Medicare prescription drug/provider payment reform bill on June 28, 2002, and promptly left for the July 4th recess. The bill does not contain provisions reducing or eliminating the CPI update for laboratory services; therefore, labs should receive the full CPI update for years beginning 2003 and beyond. Included in the legislation are: (1) a Part B clinical laboratory competitive bidding demonstration project; (2) a GAO study comparing laboratory payment rates in Medicare to the private sector; (3) a one year extension of the "grandfathering" of existing arrangements for the technical component of pathology services; (4) coverage of cholesterol and blood lipid screening; and (5) coverage of an initial preventive physical examinations with no applicable copay or deductible but excluding coverage of clinical laboratory tests. Staff says coverage of laboratory tests will be added in conference with the Senate. Opinion is divided as to whether the Senate will pass comparable legislation and, if it does, whether the two houses can agree on common language.

Medicare Cholesterol Screening Benefit

An amendment was accepted to the House passed Medicare bill authorizing coverage for cholesterol and "other blood lipid screening tests". The Secretary of H.H.S. would develop standards and frequency of such testing, in consultation with appropriate organizations. ACLA will strongly support

this provision being included in the Senate Medicare bill. This particular amendment sends an important message that screening for common medical conditions, which are treatable, merit coverage – by Medicare as well as private health insurers.

State Issues

On June 17, 2002, ACLA and representatives of ACLA member companies met with Dr. Lawrence Sturman, Director of the Wadsworth Center in New York, and his staff to discuss our concerns with respect to their proposed regulations governing assay approval. We noted that, based on our experience with the current approval process for genetic testing, we have serious concerns about expanding that process to cover other commonly-offered tests. Further, from a policy standpoint, the regulations impose an additional and unwarranted regulatory apparatus, which may adversely impact New York State residents because beneficial tests available to residents of other states will be unavailable to them. Finally, we proposed, as a reasonable alternative, that they establish an exemption process for laboratories that demonstrate that they had appropriate validation procedures in place. They did not dismiss our alternative and asked that we examine the proposed criteria for exemption and provide them with our suggestions for expanding the exemption category. We agreed to do so and forward our recommendations.

Calendar of Events July 2002

July 8	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
July 9	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
July 9	CDC Professional Laboratory Panel - Development of Hepatitis C Testing Guidelines	<i>Atlanta, GA</i>
July 11	National Exploring Health Careers Committee Meeting	<i>Washington, DC</i>
July 12	Clinical Laboratory Coalition Congressional Briefing	<i>Washington, DC</i>
July 12	CMS ESRD/Clinical Laboratory Open Forum	<i>Baltimore, MD</i>
July 18	ACLA Billing and Reimbursement Committee Meeting	<i>Conference Call</i>
July 18	ACLA CPT Advisory Committee Meeting	<i>Conference Call</i>
July 23	Health Care Liability Alliance Meeting	<i>Washington, DC</i>
July 24	Clinical Laboratory Coalition Meeting	<i>Washington, DC</i>
