The Hard Work of Advocacy

KATHY HANSEN, DON LAVANTY

Following the 2002 Legislative Symposium, the ASCLS Government Affairs Committee (GAC) has continued to work on the advocacy issues that we raised as they continue their respective journeys through the Congress.

There were five 'leave-behind' issue papers addressing legislative and regulatory issues of interest to the laboratory. We have had a great success on the Bioterrorism/Personnel Shortage legislation and some success on the Medicare Reimbursement. We also continue to work on the other three issues: specimen collection fee, Medicare simplification, and criteria for waived test classification.

Bioterrorism and the personnel shortage

As unfortunate as the events related to September 11th were, the memory of the threat of anthrax on Capitol Hill provided an effective vehicle to use to advocate for support to alleviate the laboratory personnel shortage. Legislative Symposium attendees generally found Senate and House offices to be sympathetic to concerns about allied health shortages and infrastructure. We were making our visits at a time when the conference committee was beginning to work on a compromise version of House and Senate-passed bills.

Ultimately, the conference committee of the House and Senate agreed upon the items found in the House-passed version of the bioterrorism bill that provide for financial support to train additional laboratory professionals. This support is in the form of loan forgiveness, grants to programs, scholarships, and other incentives. That compromise version was passed and signed into law by President Bush. A great success for those who worked so hard at Legislative Day and one we can be proud of!

The work has not ended, however. ASCLS is currently lobbying House members, particularly members of the House Subcommittee on Labor, Health and Human Services, and Education to include in the 2003 budget the appropriations for clinical laboratory science education funding that were authorized in the Bioterrorism bill.

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated jointly by Kathy Hansen, Chair of the ASCLS Government Affairs Committee, and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS (301) 657-2768 extension 3022; (301) 657-2909 (fax); or mail to ASCLS, 6701 Democracy Blvd., Suite 300, Bethesda MD 20814, Attention: Washington Beat.

Reimbursement for specimen collection

In 1984, the Medicare program established a rate of $3.00 for outpatient blood collection (includes hospital outpatients, clinic patients, and nursing homes). That fee has stayed the same for 17 years. Obviously, during that time salaries have increased and supplies have become more costly in order to meet current safety requirements. There was a bill introduced in the House (H3448), which would raise this fee to $5.25. There is not yet a companion bill in the Senate. If passed, this increase will result in $600 million in additional national laboratory revenue over five years. Current status of this bill is not optimistic.

Allow inflationary increase for clinical laboratory testing reimbursement

In 1997, the Balanced Budget Act imposed a freeze on Medicare fee schedule increases for clinical laboratory services. During that time the Consumer Price Index has increased 1.5% to 2.7% per year, but because of the freeze *laboratory* reimbursement did not increase. The clinical laboratory is the *only* segment of healthcare that has actually seen its reimbursement decrease (in real dollars) since 1984. If no Congressional action is taken, the five-year freeze will end at the end of this budget year, so that laboratories can receive an inflationary increase in 2003. However, Secretary Thompson of Health and Human Services suggested renewing current freezes in order to fund a prescription drug benefit.

Since the Legislative Symposium, the House Ways and Means Committee considered a bill that would have continued the freeze on the clinical laboratory fee schedule until competitive bidding for laboratory services could be established (potentially several more years). ASCLS members and members of other professional organizations in the Clinical Laboratory Coalition lobbied hard against this, and again were successful in that the freeze has now been taken out of the proposal. Unfortunately, there is still a provision calling for a competitive bidding demonstration project.

Medicare simplification

The House of Representatives has already passed the Medicare Regulatory and Contracting Reform Act of 2001 (HR 3391), which contains some of the recommendations that were made in the Institute of Medicine's December 2000 report on laboratory reimbursement. The provisions of most interest are:

- Improving the process for evaluating and pricing new tests, which is of critical importance with the explosion of genetic testing.
- Removing the burdensome requirement for hospital laboratories that serve as reference laboratories for clinics to determine whether Medicare is the patient's primary insurance. This is ex-

tremely difficult to do when the laboratory is receiving samples and not seeing the patient.

The companion Senate bill, S1545, is being considered by the Senate Finance Committee. We hope that bill will reach the full Senate in the fall.

Waived testing

Under Clinical Laboratory Improvement Amendments (CLIA) regulations, tests are categorized as waived, moderate complexity, or high complexity. Waived tests are unregulated, in the sense that laboratories that perform them are not inspected and need not perform and report proficiency testing. There are no standards for personnel performing waived tests.

The FDA has one set of standards for evaluating waived tests for home use, i.e. over the counter tests, and a more stringent set of criteria for evaluating waived tests intended for diagnostic use, such as in a physician office laboratory. However, once a test has been approved as waived it can be used in either setting. There is potential risk to patient safety if an incorrect result is obtained with the less accurate home use test.

The Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Centers for Disease Prevention and Control (CDC) have been charged with developing new criteria for waived test approval. We asked Congress to contact these agencies to advocate for more stringent and safer standards and many of our members received positive responses for support of our position on this issue. (See Winter 2002 *Clinical Laboratory Science* for more on waived testing.)

The advocacy work that our members do each year at the Legislative Symposium informs Congress about our issues and serves as a base for other forms of advocacy, e.g., letters and emails as well as follow-up calls by our Legislative Consultant, Don Lavanty. ASCLS provides this important service to its members as well as the larger laboratory community. We need to have everyone participate. See the roster for the GAC on the ASCLS Web site for contact information for the person who is GAC liaison to your state and region. Get involved!