ASHI Secures Year-End Legislative Victories

As the 117th Congress neared its conclusion in December of last year, ASHI's dedicated advocacy yielded significant results. Specifically, as Congress developed and passed comprehensive legislation to fund the government and advance numerous health care policies, ASHI successfully worked with allies in Congress to avert Protecting Access to Medicare Act (PAMA)-related cuts to HLA laboratory reimbursement and ensure that regulation of laboratory developed tests (LDTs) remained solely under the jurisdiction of the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

As a continuation of its multi-year effort to combat misguided PAMA-related reimbursement cuts, ASHI urged Congress to overhaul how CMS collects payment data and sets reimbursement rates. While ASHI will continue its efforts to secure this overhaul in the 118th Congress, ASHI was able to successfully work with Congress to avoid drastic reimbursement cuts that were slated to begin in January of 2023. This one-year delay of reimbursement cuts represents an important short-term solution that provides additional time to continue working with Congress on a long-term solution ensuring appropriate reimbursement for the tests ASHI members perform.

ASHI has also engaged in a multi-year advocacy effort to ensure that LDTs used in support of transplantation are not subjected to unwarranted FDA regulation, but rather remain solely under CLIA jurisdiction. The Verifying Accurate Leading-Edge IVCT Development (VALID) Act, which would subject LDTs used in support of transplantation to onerous FDA regulation, advanced further than it has in prior years. After working to avoid passage of the VALID Act as part of an FDA User Fee Reauthorization bill that passed last fall, ASHI worked tirelessly to successfully advocate for its exclusion from the year-end legislative package that became law. ASHI anticipates the VALID Act will once again be reintroduced in the 118th Congress and will continue working to ensure LDTs used in support of transplantation remain subjected to an appropriate and sensible regulatory regime. Additionally, FDA Commissioner Robert Califf has signaled that FDA may engage in rulemaking in an effort to regulate LDTs in the absence of congressional action, and ASHI will continue to monitor any related developments closely.

The 118th Congress formally began on January 3, 2023, and as policy conversations surrounding laboratory reimbursement, regulation, and other issues impacting HLA labs progress this year and beyond, ASHI will continue its steadfast advocacy work and aim to achieve additional policy victories important to ASHI members.