

ASHI Prepares 2025 Advocacy Efforts

Now that the 118th Congress has concluded, ASHI is preparing for another active year of advocacy during the 119th Congress and with the incoming Trump Administration. We anticipate continued interest and actions from lawmakers interested in issues impacting clinical laboratories, including Medicare reimbursement and regulation of laboratory developed tests (LDTs).

ASHI successfully worked to once again prevent Medicare laboratory reimbursement cuts beginning in January of 2025. In late September, as part of the *Continuing Appropriations and Extensions Act, 2025*, delayed *Protecting Access to Medicare Act* (PAMA)-related reimbursement reductions and reporting requirements until 2026. While staving off these cuts represents a significant victory, ASHI remains committed to working with Congress and stakeholders towards achievement of a sustainable and predictable pathway forward for laboratory reimbursement, with support for the *Saving Access to Laboratory Services Act* (SALSA; H.R. 2377 / S. 1000) forming the foundation of these efforts.

ASHI anticipates the new year will bring renewed focus on the issue of LDT regulation. In addition to the multiple lawsuits pending against the Food and Drug Administration's (FDA) Final Rule making explicit that in vitro diagnostic products are devices under the Federal Food, Drug, and Cosmetic Act [Docket No. FDA-2023-N-2177], it is possible that the Trump Administration will take steps to repeal the Final Rule. Further, we anticipate that Congress will continue examining the issue of LDT regulation, and ASHI stands ready to continue its steadfast advocacy against any efforts to grant misguided and unnecessary FDA oversight of Histocompatibility testing. ASHI will continue working with lawmakers and like-minded stakeholders to achieve optimal regulation of LDTs.

In addition to these priorities, ASHI is poised to work on new and emerging advocacy issues as we continually work to elevate our Society and ensure our members' voices are represented at the federal level.