

## **119<sup>th</sup> Congress; New Administration Underway**

The first quarter of 2025 has brought another chapter in the ever-shifting federal landscape, with President Trump assuming office and Republicans now having majorities in both chambers of Congress. The Administration has been building out its staff, the Senate has been busy confirming the President's nominations, several of which are relevant to ASHI, and both chambers of Congress have been busy working to implement the President's legislative agenda. ASHI is working to build new and maintain existing relationships with these federal policymakers as we work to advance our federal policy priorities.

While it remains early in this Congress, ASHI and other clinical laboratory stakeholders once again face the specter of up to 15% Medicare reimbursement reductions without additional Congressional intervention before the end of 2025. ASHI has advocated for a long-term solution to *Protecting Access to Medicare Act* (PAMA)-related reimbursement reductions and is continuing this work. We anticipate advocacy on this issue to remain a major focal point of ASHI's federal advocacy efforts this year and look forward to providing additional updates as we work towards achieving a long overdue solution to this flawed policy framework. In addition to providing reimbursement stability for labs, our work will center on reducing the burdens PAMA placed on labs in terms of submitting commercial payer data to the Centers for Medicare and Medicaid Services to set Medicare payment rates.

Importantly, ASHI continues to closely monitor developments surrounding the Food and Drug Administration's [Final Rule](#) regulating Laboratory Developed Tests (LDTs). In a significant development welcomed by ASHI, a federal judge struck down the LDT Final Rule on March 31<sup>st</sup>, ruling that the FDA does not have authority to regulate LDTs as medical devices. While the final rule contained a multi-year implementation period, the first compliance date was set to occur on May 6, 2025. It is not yet clear whether the Administration plans to appeal the ruling. ASHI is actively engaged in this effort and will continue to keep our members apprised of relevant developments as we continue our advocacy for optimal regulation of LDTs.