The Protecting Access to Medicare Act (PAMA) was signed into law, in 2014, with the intention of basing clinical laboratory testing fees on market rates. Implementation of the law, however, has resulted in significant cuts in reimbursement for many clinical laboratory tests.

Since implementation, the American Society for Histocompatibility and Immunogenetics (ASHI) has been strong in its criticism of the law’s flawed data collection methodology. ASHI remains concerned with the Centers for Medicare and Medicaid Services’ (CMS) reliance on these skewed payment data samples when determining Clinical Laboratory Fee Schedule (CLFS) rates.

Community and regional laboratories have been significantly impacted by the over-representative sample of large commercial labs used in CLFS rate setting. In turn, ASHI has actively worked with lawmakers and agency officials to address the issue and reverse these harmful cuts.

Last year, ASHI strongly supported the introduction and passage of the Laboratory Access for Beneficiaries (LAB) Act. The legislation, introduced in June of 2019 and signed into law in December, delays the next round of PAMA reporting requirements by one year, requires the Medicare Payment Advisory Commission (MedPAC) to conduct a thorough study of CMS’ data collection methodology, and requires that they report their findings with recommendations to Congress.

While passage of the LAB Act represents a critical step forward, much work remains to ensure that laboratories are appropriately reimbursed for the important work we perform. ASHI continues to monitor developments closely and work with allies to shape and advocate for policies reversing these harmful payment cuts.

**ASHI encourages you to review the following for additional background and helpful information:**

The Clinical Diagnostic Test Payment System final rule—which implemented PAMA – requires laboratories, including physician offices laboratories and hospital outreach laboratories that bill using a 14X TOB, to report laboratory test HCPCS codes, associated private payor rates, and volume data if they:

- Have more than $12,500 in Medicare revenues from laboratory services on the CLFS, and
- Receive more than 50 percent of their Medicare revenues from CLFS and physician fee schedule services during a data collection period

Before passage of the LAB Act, the next data reporting period was scheduled to begin January 1, 2020 and end on March 31, 2020. During that time, applicable labs were to report the data collected during the first half of 2019. As a result of the LAB Act, this data will now be reported between January 1, 2021 and March 31, 2021.

We encourage laboratories to prepare for data reporting next year in order to ensure CMS’ data collection is as robust as possible. In the meantime, ASHI will continue working with Congress and the Administration to fight for appropriate reimbursement and closely monitor MedPAC’s findings and recommendations.