



## **Long-term PAMA Reform Is Needed to Protect Patient Access to Clinical Laboratory Services, Foster Innovation and Support Laboratory Infrastructure**

Clinical laboratory services have tremendous value for patients and are foundational to the nation's health care system. Clinical laboratory tests inform 70% of all medical decision, while accounting for less than 1% of total Medicare spending.

Since implementation of the *Protecting Access to Medicare Act* (PAMA) in 2016, clinical laboratories have experienced three consecutive years of up to 10% payment cuts under Medicare, totaling \$3.8 billion. Beginning in 2020, Congress stepped in to delay further cuts and data reporting, providing short term relief for labs. **However, if Congress does not act, deeper cuts of up to 15% will resume January 1, 2026.**

### **Flawed Implementation of PAMA Has Led to Artificially Suppressed Payment Rates**

Congress enacted PAMA to reform the Clinical Laboratory Fee Schedule (CLFS) by establishing market-based CLFS rates derived from private payor rates reported to the Centers for Medicare & Medicaid Services (CMS) by independent labs, hospital outreach labs, and physician office labs. **However, CMS only collected data from less than 1% of labs, resulting in Medicare rates that were artificially and dramatically suppressed.**


CMS' poor data collection was a result of burdensome reporting requirements, technical challenges with the reporting mechanism, and not appropriately including hospital laboratories in the definition of labs required to report data. Subsequently, in 2017, ACLA challenged CMS' "applicable laboratory" definition in the DC District Court of Appeals and prevailed, with the Court ruling that CMS' implementation of PAMA was "arbitrary and capricious" and that labs had been harmed.

PAMA reform is urgently needed to ensure accurate, representative data is collected and used to set Medicare CLFS rates, which will bring stability and predictability to clinical laboratory payment, ensuring laboratory infrastructure remains strong.


### **Laboratory Payment Has Not Kept Up with the Cost of Providing Patient Care**

While Congress has repeatedly recognized that flawed PAMA implementation cannot continue, delays have resulted in a stagnant Medicare fee schedule that does not account for the resources needed to continue providing high-quality laboratory services. Medicare payments to clinical laboratories have failed to keep pace with rising costs for years and have remained unchanged at 2020 levels. During this time inflation has soared, putting financial strain on labs and forcing them to absorb escalating expenses for labor, supplies and transportation. Increased costs threaten labs' ability to provide critical testing services and could limit patient access nationwide, intensifying the urgency for a sustainable solution. Although short-term reprieves from Congress have prevented additional, deeper payment reductions, when cuts constantly loom and the long-term reimbursement policy is uncertain, laboratories cannot plan or invest in the future, stifling innovation to develop the next generation of diagnostics.

Clinical laboratories have been subject to Medicare cuts or 0% updates for **18 of the last 25 years.**



**Now is the time to STOP LAB CUTS**

 **ACLA**  
AMERICAN CLINICAL LABORATORY ASSOCIATION

[stoplabcuts.org](http://stoplabcuts.org)

### **Long-Term PAMA Relief is Needed to Protect Clinical Laboratory Services**

Labs need certainty, stability, and support to continue providing life-saving services and developing innovations that drive the next generation of diagnostics.

**Now is the time for permanent, sustainable PAMA reform. Congress should enact a long-term solution to:**

- **Preserve patient access to life-saving diagnostic tests that are foundational to informed clinical decision-making;**
- **Provide payment stability and predictability for clinical laboratories, facilitating long-term R&D to drive innovation in diagnostics for earlier detection laboratory services and provide stability and predictability to clinical lab reimbursement.**
- **Protect clinical laboratory infrastructure for day-to-day care and in times of public health emergency.**