

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 decisions while accounting for less than 1% of total Medicare spending^{1,2}.

Payment certainty and stability are needed to support a strong infrastructure that enables laboratories to continue providing life-saving services to patients and developing innovations that drive the next generation of diagnostics.

Clinical laboratory services account for **less than 1% of Medicare spending** but inform **70% of health care decisions.**

Tell Congress to **STOP LAB CUTS**

stoplabcuts.org



Unfortunately, since implementation of the *Protecting Access to Medicare Act* (PAMA) in 2016, cuts to the Medicare Clinical Laboratory Fee Schedule (CLFS) have put patient access to many of the clinical laboratory tests that are used to screen, diagnose, monitor, and manage common diseases for all patients in jeopardy. Medicare payments to clinical laboratories have been flat or reduced for 19 of the last 26 years, failing to keep pace with rising costs. In recent years 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.

PAMA Background: A Flawed Implementation Led to Billions in Reductions to Laboratories

In 2014 Congress enacted PAMA to reform the CLFS by establishing market-based 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 failed to appropriately implement PAMA in 2016 when it collected data from less than 1% of labs, resulting in new Medicare rates that were artificially and dramatically suppressed.** From 2018-2020 clinical laboratories experienced three consecutive years of up to 10% payment cuts under Medicare, totaling \$3.8 billion. These cuts far exceeded the projected \$2.5 billion in reductions over ten years estimated by the Congressional Budget Office (CBO). ACLA challenged CMS's implementation and prevailed in a court case that ruled CMS' implementation of PAMA was "arbitrary and capricious."

Congressional Action

Recognizing the harms and challenges associated with PAMA, Congress has stepped in five times to delay further cuts and six times to delay data reporting, providing short-term relief for labs. **However, if Congress does not act this year, deeper cuts of up to 15% will resume January 1, 2026. Legislation is needed to ensure accurate, representative data is collected and used to set future Medicare CLFS rates.**

¹ <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

² <https://oig.hhs.gov/documents/evaluation/10140/OEI-09-24-00350.pdf>

Without congressional action, clinical laboratory testing will face a fourth round of Medicare payment cuts of up to 15 percent.

It's time to STOP LAB CUTS

stoplabcuts.org



ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

Meaningful, long-term PAMA reform enacted by Congress this year will eliminate payment uncertainty for clinical laboratories, provide sustainable support for lab infrastructure, and ensure continued patient access to innovative 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 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.**