



COURT OF APPEALS RULES THAT PAMA RULE IS ARBITRARY AND CAPRICIOUS

In 2014, Congress passed the *Protecting Access to Medicare Act* (PAMA). Section 216 of the law reformed the Clinical Laboratory Fee Schedule (CLFS) to establish 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.

Failed Implementation of PAMA Led to Artificially Suppressed Payment Rates and Cuts

CMS's implementation of PAMA failed to capture sufficient data from all major laboratory segments. For example, just 21 of the 1,942 laboratories that participated in the 2017 reporting period were hospital laboratories. Independent laboratories accounted for 90 percent of data reported to CMS in 2017, yet they accounted for only 50 percent of Medicare CLFS volume at that time. The data on which the rates were based was not representative of the laboratory market, and as a result, from 2018-2020 clinical laboratories experienced three consecutive years of up to 10% payment cuts under Medicare, totaling \$3.8 billion. These reductions far exceeded the Congressional Budget Office (CBO) projection at the time PAMA was enacted of \$2.5 billion over ten years. Future reductions are scheduled to resume January 1, 2026, which threaten patient access to timely, accurate, and reliable lab services, harm the nation's laboratory infrastructure, and reduce investment in the next generation of diagnostics.

ACLA Legal Challenge

The seriousness of ACLA's concerns with PAMA was underscored by its multi-year legal challenge to the law, which was resolved in 2022 in ACLA's favor with a ruling by the Court of Appeals for the D.C. Circuit that CMS's 2016 final rule is arbitrary and capricious.

ACLA challenged CMS's definition of "applicable laboratory" (an entity that is required to report private payor rates to CMS) because the definition did not comport with the statutory language and it had the effect of excluding almost all hospital laboratories from reporting their private payor rates to CMS, thereby decreasing Medicare CLFS rates below true market-based rates.

The Court of Appeal's decision addressed one of PAMA's most vexing problems- ensuring data reporting from all laboratory sectors. However, the court could not require CMS to recalculate rates because PAMA prohibits judicial review of "the establishment of payment amounts," **giving rise to the urgent need for legislation to ensure accurate, representative data is collected and used to set Medicare CLFS rates.**

Congressional Action

Recognizing PAMA's harms and challenges, since 2019, Congress has acted five times to delay additional payment cuts and six times to delay the second round of data reporting under PAMA. If Congress does not act this year, the next round of PAMA reductions of up to 15% will resume in 2026.

ACLA urges Congress to enact long-term PAMA reform to establish sustainable reimbursement rates, ensure patient access to vital laboratory testing, and support the nation's laboratory infrastructure and investment to advance laboratory testing to improve and save lives.