



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 labs, and physician office labs. CMS's implementation failed to capture sufficient data from all major laboratory segments. As a result, CLFS rates declined far more than projected when PAMA was enacted – ultimately threatening access to timely, accurate, and reliable lab services, the nation's laboratory infrastructure, and investment in the next generation of diagnostics.

The seriousness of ACLA's concerns with PAMA is underscored by its multi-year legal challenge to the law, resolved in 2017 in ACLA's favor with a ruling by the Court of Appeals for the D.C. Circuit. 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 Appeals ruled that CMS's 2016 final rule is arbitrary and capricious. It also ruled in ACLA's favor on procedural grounds, finding that laboratories have been harmed by PAMA's implementation.

The Court of Appeals decision addressed one of PAMA's most vexing problems of ensuring data reporting from all laboratory sectors, however further legislative action is needed to provide CMS direction on collecting representative data from labs, therefore putting Medicare payment for clinical laboratory services on a sustainable pathway forward. Congress has acted six times to delay the second round of data reporting under PAMA, now scheduled for 2026, when payment cuts are of up to 15% on ~800 tests will resume.

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.