**Frequently Asked Questions (FAQs)**
**PAMA Appeal Filed by ACLA**
**October 19, 2018**

**Why has the appeal been filed?**
On September 21, 2018, the district court for the District of Columbia issued its decision in *ACLA v. Azar*, the lawsuit filed by ACLA on December 11, 2017 challenging implementation of the data reporting requirements of Section 216 of the Protecting Access to Medicare Act (PAMA). While the district court indicated ACLA's "arguments on the merits raise important questions," the court refused to address those questions, concluding the statutory bar on judicial review "of the establishment of payment amounts" precluded it from doing so, even though the vast majority of laboratories were exempted from the requirement to report private payor data to CMS to determine Medicare reimbursement for lab tests under the Clinical Laboratory Fee Schedule (CLFS).

**Who are the parties to the appeal?**
ACLA as the party filing is the petitioner in the appeal. Key to the mission of ACLA is to advocate for laws and regulations recognizing the essential role that laboratory services play in delivering cost-effective health care, and to protect and advance its members' interests relating to federal health programs, such as the Medicare program. ACLA members, the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital and nursing home laboratories, provide millions of lab tests each year to Medicare beneficiaries. Services provided under PAMA are therefore of high priority and great importance to ACLA and the patients its members serve.

The respondent, the party against whom the appeal is filed, is the Secretary of the U.S. Department of Health and Human Services, Alex Azar, who is sued in his official capacity.

**Why did ACLA pursue PAMA in the courts?**
ACLA filed suit in December 2017 to challenge the Acting Secretary of the U.S. Department of Health and Human Services' (HHS) implementation of the data reporting requirements of Section 216 of the Protecting Access to Medicare Act (PAMA). Specifically, the lawsuit challenged the unlawful exemption of the vast majority of laboratories from the requirement to report private payor data to CMS to determine Medicare reimbursement for lab tests under the CLFS.

According to the HHS Office of Inspector General (OIG), there are approximately 246,000 laboratories in the U.S. In 2015, over 61,000 laboratories billed the Medicare program. Based on a September 2016 report, the OIG estimated 12,547 laboratories would meet the applicable laboratory definition in the PAMA statute and would be required to report private payor information to CMS. Instead, only 1,942 laboratories provided information to CMS, excluding 99.3% of the laboratory market as identified by OIG. Hospital labs contributed only 1% of the data compared to their 24% share of Medicare CLFS spending, and physician office labs contributed only 7.5% of the data, compared to their 20% share of Medicare CLFS spending.

The clear instructions of Congress to HHS to gather commercial price information from all sectors of the clinical laboratory market and base Medicare payment rates on that data, were ignored.

**What were the key arguments in the lawsuit?**
The suit challenged the Secretary's final PAMA regulations, which disregard and violate the statute's specific, unambiguous directives requiring that all applicable laboratories report relevant data to the Secretary. Congress took care to specify which laboratories would be obligated to report market data to ensure that information would be reported and collected from a broad, diverse group of market participants. In promulgating PAMA regulations, however, the Secretary disregarded Congress's express instructions and unreasonably and arbitrarily exempted significant categories and large numbers of laboratories from the reporting requirements that Congress imposed. The Secretary's final rule carves out large categories of laboratories — excluding 99.3 percent of the laboratory market — from the statutory reporting requirements.

The Secretary's final rule contravenes the plain language of PAMA, is an unreasonable application of statute, is arbitrary and capricious, and should be vacated.

**What was the intended objective of PAMA as it relates to laboratories and ACLA's view of that objective?**
PAMA sought to modernize the CLFS by establishing a market-based Medicare payment system for clinical laboratory services based on the collection of private payor rates across all sectors of the clinical laboratory community. ACLA supported PAMA and continues to support the intent of Congress to establish a fair and predictable market-based system. However, the Secretary's flawed implementation of PAMA is based on a flawed data collection process that threatens the viability of many laboratories to continue operations, and jeopardizes patient access to key laboratory tests. ACLA interacted extensively with HHS, CMS, and other federal executive branch agencies and staff to provide laboratory stakeholder insight into the proper implementation of PAMA Section 216.

**Is there still a need for Congress to act?**
Yes. Regardless of what happens in the appeal, a legislative solution remains necessary to eliminate the severe damage to laboratories and their patients caused by the flawed implementation of PAMA. The PAMA rates that went into effect in January 2018 represent drastic pricing reductions far beyond those intended by Congress. These rates, and the additional reductions scheduled for January 2019, will create severe disruptions in access to laboratory services, particularly for the most vulnerable Medicare beneficiaries.

We will continue to work with Congress to secure a legislative solution for the unacceptable Medicare laboratory reimbursement cuts that have resulted from HHS' flawed implementation of PAMA.

**What is the impact of PAMA's flawed implementation on ACLA members and Medicare beneficiaries?**
ACLA represents the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital and nursing home laboratories. If the

Secretary's failure to comply with Congress's directives is not corrected, laboratories may be forced to stop providing essential services, especially in remote rural areas, and many laboratories will be forced out of business. Beneficiaries may be unable to obtain essential laboratory testing services, especially very sick and elderly patients in nursing home facilities who depend on laboratory testing services. The result will be to dramatically decrease the quality of care and force beneficiaries into hospital emergency rooms. In short, contrary to Congress's intent, instead of reforming Medicare reimbursement rates to more closely reflect the market, cuts to Medicare lab services resulting from the current flawed implementation of PAMA, will prevent beneficiaries from having access to the essential laboratory services they need.