Frequently Asked Questions (FAQs)
Lawsuit Filed by ACLA Against HHS Challenging PAMA Final Rule
December 11, 2017

Why has the lawsuit been filed?
The lawsuit was filed to challenge the Acting Secretary of the U.S. Department of Health and Human Services's (HHS) implementation of the data reporting requirements of Section 216 of the Protecting Access to Medicare Act (PAMA). Specifically, the lawsuit challenges 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 Clinical Laboratory Fee Schedule (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. As a result, the final reimbursement rates are based on insufficient and unrepresentative price information that does not accurately reflect the broad laboratory market. If finalized, these rates will create severe disruptions in access to laboratory services, particularly for the most vulnerable Medicare beneficiaries.

Who are the plaintiff and defendant in the lawsuit?
The plaintiff is the American Clinical Laboratory Association (ACLA). 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 defendant in the lawsuit is the Acting Secretary of the U.S. Department of Health and Human Services, Eric Hargan, who is sued in his official capacity.

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. Having over 40 separate interactions with federal officials between 2014 and today related to the implementation of PAMA Section 216 and specifically the proper definition of "applicable laboratory," ACLA and its membership have exhausted all potential avenues for dialogue on these matters.

What are the key arguments in the lawsuit?
The suit challenges 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.

Because the information reported to the Secretary does not reflect the market as a whole and does not comply with Congress's directives, any Medicare rates that are later set using the reported information will not meet the standard that Congress intended. By excluding virtually all hospital laboratories, for example, from the statutory reporting requirements and by relying instead on non-representative data, the Secretary has ensured that the Medicare rates are not consistent with market-based rates and will be much lower than Congress intended.

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

What is the timeframe for action now that the suit has been filed? What happens next?
Now that the suit has been filed, we are working with the government to reach agreement on a schedule for further proceedings.

What does this do to the PAMA rates scheduled to go into effect January 1, 2018?
ACLA has asked the court to enjoin the Secretary from continuing to violate the statute. If ACLA is successful, the Secretary will need to collect the data that Congress required and then use the properly collected data to calculate applicable rates.

Is there still a need for Congress to act?
Yes. Our lawsuit seeks to require the Secretary to comply with existing law. Nonetheless, regardless of what happens in the lawsuit, 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 published by CMS represent drastic pricing reductions far beyond those intended by Congress. If finalized, these rates 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 this year for the unacceptable Medicare laboratory reimbursement cuts scheduled for January 2018.

How will ACLA members and Medicare beneficiaries be impacted if the PAMA rates are implemented?
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, the Secretary's final rule will disrupt the market and prevent beneficiaries from having access to the essential laboratory services they need.

What will happen if the lawsuit is successful?
If successful, the lawsuit will require HHS to return to the drawing board and publish a rule that is consistent with congressional requirements.

American Clinical Laboratory Association

Protecting Access to Medicare Act (PAMA) Timeline

Date	***PAMA Development***
April 1, 2014	Enactment of PAMA. Section 216 establishes Medicare policies for clinical diagnostic laboratory tests including reporting of private sector payment rates and establishment of market-based payment.
June 30, 2015	Date specified in statute for establishment of parameters for data collection through notice and comment rulemaking
October 1, 2015	Proposed Rule for Medicare Clinical Diagnostic Laboratory Tests Payment System published
June 23, 2016	Publication of Final Rule for Medicare Clinical Diagnostic Laboratory Tests Payment System published
August 5, 2016	CMS Listing of HCPCS codes for collection and reporting for initial reporting period (January 1 – March 30, 2017) posted
August 8, 2016	CMS Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System posted
September 13, 2016	Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template released
October 2016	CMS Frequently Asked Questions on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule released
November 2, 2016	CMS Conference Call on Data Reporting Required by PAMA
January 4, 2017	Additional Guidance for Clinical Laboratories as Data Reporting Begins released
January 9, 2017	CLFS User Manual released
March 9, 2017	Updated Frequently Asked Questions Regarding Applicable Laboratory Status released
March 30, 2017	Announcement of 60-day period of "enforcement discretion" through May 30, 2017 allowing applicable laboratories an additional 60 days report private payor data required under PAMA to CMS without fear of penalty
September 22, 2017	CY 2018 Preliminary Private-Payor Rate-Based CLFS released
November 22, 2017	CY 2018 Final Private Payor Rate-Based CLFS released