



## **Proposed Rule Implementing Clinical Lab Provisions of PAMA Creates Unworkable Timeline, Lacks Critical Guidance Needed by Labs, Inconsistent with Statute and Congressional Intent**

### **Background**

Section 216 of the Protecting Access to Medicare Act (PAMA) makes extensive changes to how reimbursement is determined under the Clinical Laboratory Fee Schedule (CLFS). First, PAMA repeals “technological changes” authority by the Centers for Medicare & Medicaid Services (CMS) to make unlimited reductions to individual test codes without providing clear justification or rationale. Second, Section 216 creates a new reimbursement framework, basing Medicare payment rates for laboratory services paid under the CLFS on private payor rates that are reported to CMS by “applicable laboratories.” The PAMA statute requires final rulemaking to be completed by CMS by June 30, 2015. Based on the guidance in the final rule, applicable laboratories would begin reporting private payor rates, CMS would create a weighted median for each laboratory test code on the CLFS, and new payment rates would go into effect on January 1, 2017.

The American Clinical Laboratory Association (ACLA) supported Section 216 of PAMA, as it repealed the ability of CMS to make indiscriminate reductions, and it established a reimbursement framework that would base reimbursement on the full scope of the laboratory market. ACLA, as well as other stakeholders, have met regularly with CMS since enactment of PAMA and provided commonsense recommendations on how to implement this sweeping reform.

Creating an entirely new reimbursement system for the CLFS is a complex and challenging task. Despite the ongoing engagement of ACLA and other stakeholders, CMS was unable to meet the statutory deadline of June 30, 2015 for publication of a final rule. In fact, CMS only recently issued the proposed rule, with comments due on November 24, 2015.

ACLA is deeply concerned with many aspects of the proposed rule. Several components of the proposed rule are inconsistent with the PAMA statute and with Congressional intent, the proposed rule fails to give sufficient guidance to laboratories on data collection and reporting, and the timeline for laboratories to submit data to CMS is simply not possible.

## Issues

Areas of significant concern for ACLA and its member laboratories include:

### *Definitions*

#### Applicable Laboratory

When Congress enacted Section 216 of PAMA, its intent was very clear – to establish a market based reimbursement system for clinical laboratory services. A basic principle of this effort is that Medicare reimbursement is to reflect the scope of prices paid in the laboratory market. The statute defines an applicable laboratory as “a laboratory that, with respect to its revenues under [title XVIII of the Social Security Act], a majority of such revenues are from [the Physician Fee Schedule or the Clinical Laboratory Fee Schedule]. Simply put, laboratories that receive the majority of their Medicare revenue from the PFS or CLFS are applicable laboratories.

In order to remain consistent with Congressional intent, regulations must ensure that the data collected reflect the full laboratory market – independent laboratories, physician office laboratories, and hospital laboratories. Only then can accurate reimbursement rates be established. According to a September 2015 report from the HHS Office of Inspector General (OIG), *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data*, 57% of CLFS payments are made to independent labs, 24% of payments are made to hospital labs, and 19% are made to physician office labs.

Despite clear guidance provided by Congress, the proposed rule excludes the majority of the laboratory market from data reporting. The proposed rule estimates that 52% of independent labs, 94% of physician office labs, and the “majority” of hospital labs will be prohibited from supplying data to CMS.

A primary reason why such large swaths of the market will be excluded is due to the way the proposed rule defines applicable laboratories – by Taxpayer Identification Number (TIN). By using this flawed criterion, the vast majority of hospital laboratories, for example, will not be applicable laboratories, since laboratory revenue will never be the majority of a hospital’s Medicare revenue. Only hospital laboratories with a separate TIN from the rest of the hospital will be considered applicable laboratories. Use of the TIN to define applicable laboratories will result in reimbursement rates that do not reflect the laboratory market, and is also in direct conflict with the statute, which defines an applicable laboratory as a laboratory – not an “entity.”

**Recommendation: Define applicable laboratory by CLIA number, not TIN, but permit applicable laboratories under common ownership to submit their data through a combined report from their parent entity.**

#### Advanced Diagnostic Laboratory Test

PAMA creates a new category of tests, Advanced Diagnostic Laboratory Tests (ADLTs). Tests must meet one of three criteria to be considered an ADLT. Criterion A states, “the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.”

Despite this clear language, when discussing the ADLT definition the proposed rule states, “we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA,” and further proposes that an ADLT is “a molecular pathology analysis of DNA or RNA.” The proposed rule fails to include tests that are solely comprised of protein biomarkers in the ADLT definition, despite the fact that proteins are explicitly included in the PAMA statute.

**Recommendation: Define ADLT to include tests that are solely comprised of proteins. This revised definition would reflect the statute and Congressional intent.**

#### *Data Collection and Reporting*

PAMA’s January 1, 2017 effective date for the new CLFS reimbursement system was based on the assumption that the final rule would be published by June 30, 2015. If CMS had been able to meet that deadline, laboratories would have had sufficient time to begin the burdensome task of collecting data on their private payor rates and volumes, assembling this data in the format required by the final rule, verifying the data, and submitting the data to CMS. CMS would have had the necessary time to review the millions of data points submitted by laboratories and calculate a weighted median. However, the delay in rulemaking makes these tasks impossible to complete by January 1, 2017.

As outlined in the proposed rule, the initial data reporting period would be January 1, 2016 through March 31, 2016. This reporting period has been proposed even though the final rule implementing PAMA will not be published. Critical information needed by laboratories will not be available. Laboratories will not know if they are required to report information, key questions about how information should be collected and submitted will remain unanswered, and no information about the method of submitting information will have been supplied by CMS. Laboratories should not have to meet unrealistic deadlines and be exposed to civil monetary penalties for not reporting correctly, because CMS has failed to meet statutory deadlines for rulemaking.

**Recommendation: Laboratories need sufficient time to prepare for PAMA reporting. After the final rule and all necessary guidance are published, laboratories will need six months to build the necessary information systems to collect and report data. The data collection period should be six months, with a six month gap between the close of the data collection period and the beginning of the three month reporting period.**

#### **Conclusion**

Section 216 of PAMA makes sweeping changes to how laboratory reimbursement is determined under the CLFS. Creating a new reimbursement system is a complex and challenging task, for CMS and for laboratories. Several components of the proposed rule are inconsistent with the PAMA statute and Congressional intent, and the proposed rule fails to provide sufficient time for laboratories to collect and report data. We urge Congress to express their concerns to CMS and urge the Agency to make important changes in the final rule.