COLLEGE of AMERICAN PATHOLOGISTS

Preparing for PAMA Reporting Requirements

On February 3, 2026, President Trump signed into law the Consolidated Appropriations Act of 2026, which included important revisions to upcoming PAMA rate cuts and reporting deadlines. As a reminder, PAMA (the Protecting Access to Medicare Act) required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Unfortunately, the first round of data collection in 2017 failed to capture an adequate and representative sample of private market data, leaving out virtually all hospital outreach laboratories and significantly under-sampling physician office laboratories. The significant under-sampling led to nearly $4 billion in cuts to those laboratories providing the most commonly ordered test services for Medicare beneficiaries.

With the recent changes, the next PAMA reporting period will be May 1, 2026 through July 31, 2026. The Act also updates the data collection period, such that laboratories will report based on data collected between January 1, 2025 and June 30, 2025, rather than 2019 data. Importantly, the Act ensures there are no additional CLFS rate cuts scheduled for 2026.

Because these changes, while positive, do not relieve the administrative burden on laboratories, the CAP is continuing to advocate for the RESULTS Act. **In the meantime, laboratories should prepare to meet the updated PAMA requirements by determining whether they are an applicable laboratory and gathering the required 2025 private payor data.**

NOTE: Even if a laboratory did not previously meet the definition of an applicable laboratory, laboratories should carefully assess whether they meet revised requirements to report. Regulations finalized in 2018 made two revisions to the regulatory definition of applicable laboratory: 1) Medicare Advantage (MA) plan revenues are excluded from total Medicare revenues, the denominator of the majority of Medicare revenues threshold; and (2) Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

WHAT IS AN APPLICABLE LABORATORY?

Under the revised final policies for the new Medicare CLFS, an applicable laboratory is a laboratory (as defined under the CLIA regulatory definition of a laboratory in 42 C.F.R. § 493.2) that bills Medicare Part B under its own NPI or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under TOB 14x. In addition, the laboratory must meet a "majority of Medicare revenues" threshold, that is, in a data collection period it receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or PFS during the data collection period. It also must meet a low expenditure threshold, that is, it receives at least $12,500 of its Medicare revenues from the CLFS during the data collection period.

WHAT PRIVATE PAYOR DATA MUST BE REPORTED TO CMS?

The reporting entity must report applicable information for each clinical diagnostic laboratory tests (CDLT) furnished by its component applicable laboratories. Applicable information is the private payor rate for each test for which final payment has been made during the data collection period, the associated volume for each test, and the specific HCPCS code associated with the test. If an applicable laboratory has more than one payment rate for the same private payor for the same test, or more than one payment rate for different

payors for the same test, the reporting entity will report each such payment rate and the volume for the test at each such rate.

WHAT IS A PRIVATE PAYOR?

For purposes of the private payor rate-based CLFS, the term “private payor” is defined as: (1) A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act); Or (2) A group health plan as defined in Section 2791(a)(1) of the PHS Act); Or (3) A MA Plan under Part C as defined in section 1859(b)(1) of the Social Security Act (the Act); Or (4) A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).

WHAT ENTITY IS RESPONSIBLE FOR REPORTING APPLICABLE INFORMATION TO CMS?

The TIN-level entity must report applicable information individually for all its laboratory components that are applicable laboratories. As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI or the 14x TOB (in the case of a hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI), meets the majority of Medicare revenues threshold and low expenditure threshold.

RESOURCES

CMS: CLFS Reporting Webpage
CMS: Medicare Learning Network: Is My Lab an Applicable Lab? (Video)