COLLEGE of AMERICAN PATHOLOGISTS

Issue Brief

Issue: Reform the Protecting Access to Medicare Act

CAP Position: The CAP's goal is to improve how data is collected and validated under the Protecting Access to Medicare Act of 2014 (PAMA) to ensure an accurate, market-based payment system for laboratories paid through the clinical laboratory fee schedule (CLFS). PAMA implemented a new methodology for the calculation of rates under the CLFS that requires applicable laboratories to collect and report private payer rates to the Centers for Medicare and Medicaid Services (CMS). CLFS rates are then set at the weighted median of these reported rates. However, the data collected by CMS does not accurately reflect all sectors of the clinical laboratory market, and therefore the resulting PAMA rates are skewed. Improvements to PAMA are needed to ensure more accurate PAMA rates and continued access to laboratory tests for Medicare patients.

Issue Position: Support efforts to:

1. Ensure private payer data accurately represents all segments of the market. The first data period failed to ensure that the data collected adequately reflected both urban and rural areas, and all segments of the laboratory market, including hospital, physician office, and large and small independent laboratories – in fact, fewer than two dozen hospital outreach labs out of more than 9,000 reported payment data. Recent changes by CMS, including adjustments to the definition of applicable laboratory[1], are moves in the right direction. However, Congress and CMS must ensure all laboratories required to report do so, and that the data the CMS collects adequately reflects all segments of the laboratory market.

2. Remove Medicaid managed care from the definition of private payor. Under PAMA, applicable laboratories report to CMS private payor rates, which currently includes rates from Medicaid managed care organizations. While Medicaid managed care utilizes private health plans, rates from Medicaid managed care can be no higher than Medicare rates and can be lower depending on the state. These rates are do not reflect private payor rates and therefore should be excluded from collection.

3. Require the validation of data collected by the CMS. Improvements to the data collection process and the CMS ability to validate the data are needed. While laboratories did their best to submit accurate data, it became clear in the data submitted to the CMS that many laboratories did not understand what was to be included or excluded from reporting, or where unable to access accurate information from their systems. A 2018 HHS OIG report found that "CMS performed limited quality assurance checks and relied on labs' self-certification of their reported data."[2] Therefore, Congress should require the CMS to publicize the data they collect and should support any efforts to audit/validate the data.

4. Reduce PAMA's burdensome reporting requirements. The current process developed by the CMS proved administratively burdensome and operationally cumbersome. The information laboratories were required to report was not always available in records' systems. Some vendors had to build custom reports that required validation and updates to improve the accuracy of the data submitted. Other laboratories had to custom build reports entirely. The hours required to report information to the CMS was significant. In total, some laboratories reported spending at least 240 hours assembling, validating, and reporting applicable information to the CMS.

Background: Included as part of the last Medicare sustainable growth rate (SGR) formula patch, Section 216 of PAMA required the CMS to establish a market-based payment system for laboratories paid on the CLFS. In November 2017, the CMS released final 2018 rates for tests included in the CLFS. These rates, delayed a year by the CMS, were calculated using a new methodology described in the PAMA legislation, which sets the rate at the weighted median of private payer rates collected from certain "applicable laboratories." In November 2018, the CMS made modest changes to the definition of applicable laboratory. The next CLFS data collection period is from January 1, 2019 through June 30, 2019, which will determine rates set for 2021-2023.

[1] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11076.pdf
[2] https://oig.hhs.gov/oei/reports/oei-09-17-00050.asp