POCTA
POINT OF CARE TESTING ASSOCIATION

Challenges with PAMA Implementation for Point of Care Testing

Background

POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the point of care, such as in a physician's office, offers benefits to patients, the health care system and public health. Point of care testing better enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients, which can stop transmission of infectious diseases.

When diagnostics are available at the point of care, such as in a physician's office, physicians and patients receive the results in real time, which minimizes delays in starting or changing treatment and providing timely information on the patient's clinical needs. Point of care testing is frequently used to diagnose illnesses like COVID-19, flu and HIV, and to monitor chronic conditions like diabetes, instances where immediate results can make for significant clinical difference.

CMS Implementation of PAMA

Section 216 of the Protecting to Access to Medicare Act of 2014 (PAMA) significantly revised the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). On January 1, 2018, Medicare began using private payor rate information reported by applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the CLFS.

POCTA's members supported the enactment of PAMA as providing an opportunity to modernize CLFS to reflect innovations in *in vitro* clinical diagnostic laboratory testing that were poorly reflected in the former CLFS that was based upon historical charge data from the early 1980s. At the same time, POCTA members recognized that implementation of PAMA could have negative impacts on clinical diagnostic laboratory tests furnished at the point-of-care—in particular, tests performed in the physician office lab (POL) setting.

CMS's implementation of section 216 of PAMA skewed data collection toward large reference labs, and thus the data published by CMS and the rates that resulted beginning in 2018 do not represent the overall lab marketplace, and they especially under-represent POLs, and therefore point of care testing. Specifically, under the data collection methodology established by CMS, only a laboratory that realized more than $12,500 in Medicare payments made under the CLFS during the applicable six-month data collection period (January 1 to June 30) was permitted to report private payor payment rate information to CMS. As a result, less than one percent of POLs reported payment rate data to CMS.

By taking this approach, CMS did not account for many factors, including the fact that the cost experience of a large independent lab is very different from the cost experience of a kit-based test furnished by a physician. Large labs furnish tests on huge multi-channel analyzers that can process thousands of tests 24-hours per day. The POL does not have the high-volume throughput and ability to pool specimens for many different types of testing compared with the large reference laboratories. Moreover, kit-based tests used at point of care are developed with on-board controls that can easily be run by non-laboratorians. Although these tests may be relatively simple to operate, they are not generally less expensive than the systems run by large reference laboratories. Not surprisingly, private payer rate information obtained from one data warehouse confirms that private payers generally pay POLs much more than the private payer rates reported by independent labs to Medicare, which means the PAMA rates for these tests are not reflective of the market.

Negative Impact Unique to POC Testing

CMS's chosen methodology and the resulting payment decreases have threatened to compromise patient access to point of care testing, particularly in physician office settings. If the cost for a physician or clinic to purchase and furnish point of care tests exceeds reimbursement, many physicians and clinics may discontinue offering these services to Medicare beneficiaries.

This is particularly problematic for health care provided in rural and underserved communities. People living in rural areas often have to travel further to reach a testing site. This issue is exacerbated for individuals who do not have health insurance. Managing patients in these communities could become more difficult if they have diminished access to testing. It is likewise disconcerting for urban areas where infectious disease, like COVID-19, can be more prevalent and the spread more threatening because of population density. Providers risk losing patients to follow up if they cannot provide immediate test results, and then large communities are at great risk of disease spread.

Temporary Relief from scheduled 2022 Rate Cuts

At the time PAMA was enacted, the Congressional Budget Office (CBO) projected $2.5 billion in cuts to reimbursement rates over 10 years if PAMA was implemented as Congress intended. However, PAMA has already led to nearly $4 billion in cuts to laboratories since 2018 (after only three years of cuts).

The bipartisan 2019 Laboratory Access for Beneficiaries (LAB) Act initially delayed the second round of data reporting. Congress acted twice more through the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Protecting Medicare and American Farmers from Sequester Cuts Act in 2021 to not only, again, delay the data reporting, but also delay additional cuts to laboratories by one year.

Absent congressional action, more than 800 tests will receive up to 15 percent cuts on January 1, 2023, threatening access to testing for seniors and our most vulnerable populations.

Solution: Enact SALSA legislation

POCTA has joined other stakeholders in supporting H.R.8188/S.4449, the Saving Access to Laboratory Services Act (SALSA). This legislation was introduced by Sen. Sherrod Brown (D-OH) and Richard Burr (R-NC) in the Senate and Reps. Bill Pascrell (D-NJ), Scott Peters (D-CA), Richard Hudson (R-NC), Gus Bilirakis (R-FL) and Kurt Schrader (D-OR) in the House.

The bill would make several favorable reforms to the CLFS data collection and rate-setting processes that we expect would be specifically beneficial for point of care testing, including the following:

- Suspends CDLT reporting requirement through 2025, and extend reporting frequency from every three years to every four years;
- Replaces much of the current data collection program with a statistical sampling approach that requires that the sampling methodology (1) be representative of the range of private payor payment rates of the different types of applicable laboratories (independent labs, hospital labs, and physician office labs) that furnish the test, and (2) accurately and proportionally represent the range of private payor payment rates received by each such types of lab based on utilization of the test by each type of lab;
- Revises eligible lab criteria in a way that enables more reporting from physician office labs; and
- Labs would not be required to submit payment data from Medicaid managed care organizations.

We encourage Members of Congress to co-sponsor H. R.8188/S.4449in order to preserve access to point of care tests for seniors and our most vulnerable population.