POINT OF CARE TESTING ASSOCIATION

Challenges and Solutions 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, 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 RSV, flu, HIV and other sexually transmitted diseases, 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). Pursuant to PAMA, 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 PAMA undermined that confidence and our support. CMS implementation decisions skewed data collection toward large reference labs, and thus the data used by CMS to set rates in 2018 did not represent the overall lab marketplace. The fee schedule especially under-represents POLs, and therefore point of care testing.

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 generally not 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 testing generally and point of care testing in particular, especially testing 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. 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 diseases, like HIV, can be more prevalent. 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

Recognizing these shortcomings and risks, Congress acted six times since 2018 to delay the second round of data reporting and attendant payment reductions. In early 2026 Congress decided (Consolidated Appropriations Act, 2026) to allow the next round of data reporting to proceed, but with updated data collection periods to enable CMS to collect more current laboratory test pricing information.

In September 2026, CMS posted proposed (preliminary) payment rates for laboratory services to be effective in January 2027. The proposed payment rates confirm concerns from testing stakeholders, particularly those that

provide point of care testing. The proposed rates rely on data from only two percent of all laboratories and just one percent of physician office labs and less than 20 percent of all hospital outreach labs. More than 4,000 independent labs billing Medicare did not report any data to CMS. For more than 20 percent of codes, no laboratories reported commercial data. The proposed rates would again impose steep payment cuts that threaten patient access to laboratory services.

Solution: Enact the RESULTS Act

POCTA has joined other stakeholders in supporting S. 2761 and H.R. 5269, the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act. This legislation was introduced by Sens. Thom Tillis (R-NC) and Raphael Warnock (D-GA) in the Senate and Reps. Richard Hudson (R-NC), Scott Peters (D-CA), Gus Bilirakis (R-FL), and Brian Fitzpatrick (R-PA) in the House.

The RESULTS Act would make favorable reforms to the CLFS data collection and rate setting processes that we expect would reduce threats for point of care testing. Highlights include:

- *Gives CMS access to comprehensive private payor data that is representative of payments received by hospital outreach, independent, and physician office laboratories.* CMS would secure paid claims data from an independent not-for-profit comprehensive commercial payor database (one that includes at least 50 billion fully-paid claims from over 50 commercial payors and claims administrators) to set CLFS rates based on the volume-weighted median of private payor rates for widely available tests. Widely available tests, which comprise 99 percent of total CLFS volume, are those for which 100 or more clinical laboratories were paid under the CLFS in a specific time period. For non-widely available tests, such as proprietary tests for rare diseases, and Advanced Diagnostic Laboratory Tests (ADLTs), of which there are 18, laboratories would continue to report private payor data to CMS directly.
- *Reduces administrative burden on clinical laboratories and CMS.* Clinical laboratories no longer would bear the burden of collecting and reporting private payor rate data for widely-available tests. CMS would be required to collect data from clinical laboratories only for non-widely available tests.
- *Sets annual "guardrails" to protect against destabilizing decreases in CLFS rates.* CLFS rates would be frozen at current 2025 levels for 2026-2028, avoiding the pending cuts of up to 15% in 2027 and eliminating further cuts of up to 15% in 2028. Once fully implemented in 2029,

RESULTS would limit payment reductions to 5% per year to protect laboratories from sudden destabilizing rate changes that could reduce patient access to innovative testing services.

- *Excludes non-market-based rates from CLFS rate calculations.* The RESULTS Act would exclude Medicaid managed care rates from CLFS rate calculations, as they are not truly market-based rates.
- *Extends the time between data collection periods.* The RESULTS Act would extend the time between data collection periods from three years to four years to provide more stability for CLFS rates and decrease the reporting and administrative burden for labs and CMS alike.

We encourage Members of Congress to co-sponsor S. 2761/H.R. 5269 to preserve access to point-of-care tests for seniors and our most vulnerable population.