

Protecting Access to Medicare Act (PAMA)

Background & Overview

Key Highlights

- In 2014, Congress passed the *Protecting Access to Medicare Act (PAMA)* to ensure millions of seniors could maintain access to critical health services, including comprehensive reforms to how Medicare pays for laboratory tests. Yet, the U.S. Department of Health and Human Services (HHS) has taken a flawed and misguided approach to PAMA implementation, leading to severe cuts to laboratories that over 56 million seniors rely on for lab tests and diagnostics.
- Drastically cutting reimbursement, including for the most commonly performed lab tests, could threaten access to critical lab services. The most significant cuts impact tests used for diagnosing and treating beneficiaries with diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency and countless other common health conditions.
- The industry's response to COVID-19 reinforces the need to strengthen our laboratory infrastructure and stop unsustainable cuts to the services that are vital to our public health. During the pandemic, clinical laboratories quickly responded to the unprecedented demand for COVID-19 testing by rapidly developing new tests, validating different swabs and specimen types and advancing innovative techniques that expanded capacity and reduced the time needed to return results. This level of market innovation is only possible through significant investment in high precision instruments, supplies, a highly trained workforce and biosafe facilities.
- In an acknowledgement of the harm facing seniors, Congress took important steps to address the impact of flawed PAMA implementation, including the passage of the bipartisan *Laboratory Access for Beneficiaries (LAB) Act*, and more recently, a delay of cuts as part of the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*. However, laboratory cuts are scheduled to return in 2022 and could threaten access to testing for seniors and our most vulnerable populations.



IMPACTS MOST USED TESTS

PAMA cuts target the most performed tests for diabetes, heart disease, kidney disease and certain cancers.



SKewed DATA

Ongoing issues with the data reporting process fail to capture the true representation of the laboratory market with hospital and physician offices underrepresented.



56 MILLION SENIORS AT RISK

Laboratory services that seniors rely on will continue to face year-over-year cuts, causing potential barriers to testing.

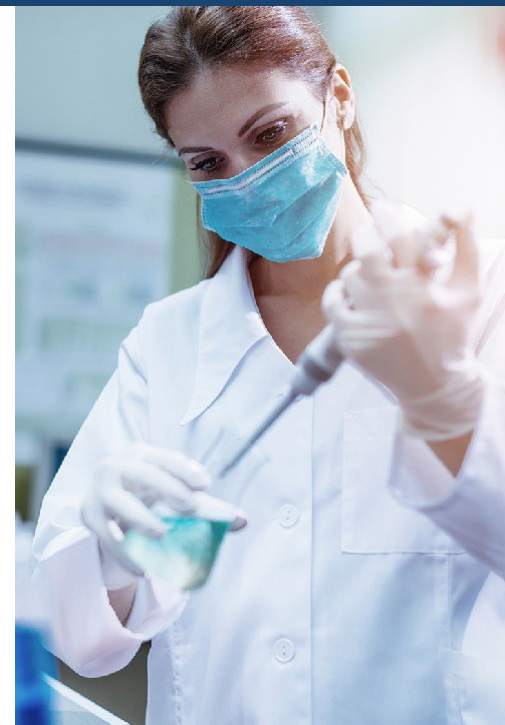
PAMA Cuts: An Ongoing Threat to Seniors' Access to Vital Tests

As part of PAMA implementation, Congress directed the HHS Secretary to establish market-based rates for clinical laboratories with one national fee schedule; however, the Secretary disregarded Congress' instruction and gathered private market rate information from an unrepresentative sample of less than 1 percent of laboratories nationwide. The data were dominated by the private market prices of the largest independent labs with the greatest economies of scale and the lowest prices, while data from market segments with higher private market pricing were underrepresented.

For example, hospital labs contributed just 1 percent of data in the first reporting period but account for approximately 26 percent of Medicare spending. Physician office labs represented just 7.5 percent of data submitted, despite making up 20 percent of Medicare spending. This incomplete and skewed data collection ignores the fundamentals of a market-based system. **By ignoring the payment data from more than 99 percent of the nation's laboratories, HHS' actions have already had an adverse impact on patient care and market stability.**

Our most vulnerable seniors bear the brunt of these cuts. Some specialized labs that serve nursing homes, skilled nursing facilities and long-term care facilities have already been forced to shut down operations, reduce services and lay off employees. Infectious disease testing may further be limited. Rural beneficiaries in need of routine testing to monitor chronic diseases may face delays – all of these examples will negatively impact patient care and increase Medicare costs.

The consequences of these ongoing cuts – between 20 and 30 percent for routine low-cost tests, according to CMS – have been severe. In a 2018 survey of health care providers by the Infectious Disease Society of America (IDSA), over 79 percent of respondents reported they would be unable to provide the full range of testing needed to rapidly diagnose diseases following the 2018-2019 cuts.



Key Dates for Upcoming PAMA Requirements

June 2021

- MedPAC's upcoming report, as mandated by the *LAB Act*, will be released in June and will explore options to capture private payor rates for laboratory services through a less burdensome data process.

January 2022

- Cuts to designated tests under the Clinical Laboratory Fee Schedule (CLFS) will resume January 1, 2022. These cuts will amount to up to 15 percent reductions in reimbursement for tests to diagnose a range of chronic conditions.
- Unless otherwise addressed, PAMA's data reporting requirements will be reinstated on January 1, 2022, exacerbating the flaws in PAMA's implementation.
- Laboratories are set to face additional cuts on top of PAMA in January 2022, including automatic payment reductions from the Medicare sequester, PAYGO provisions and Physician Fee Schedule conversion factor.

Recent Legislative Actions Provide Temporary Relief Amid the Public Health Crisis

In 2019, the *Laboratory Access for Beneficiaries (LAB) Act* was enacted, which paved the way for initial, necessary reforms to PAMA. This important bipartisan legislation delayed PAMA's data reporting by one year and commissioned a study from the Medicare Payment Advisory Commission (MedPAC) on improvements that can be made to address PAMA's data collection and payment deficiencies.

Congress again recognized the serious consequences of PAMA cuts as clinical laboratories were called upon to develop new tests and expand laboratory capacity in response to the COVID-19 pandemic. As part of the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, Congress passed a bipartisan one-year delay of cuts to clinical laboratory services and an additional one-year delay of the next PAMA reporting period in order to protect seniors and the most vulnerable beneficiaries from a loss or reduction of laboratory services.

Unfortunately, even after clinical labs have made unprecedented investments to expand COVID-19 testing capacity, this relief is only temporary. The impending PAMA cuts in 2022 could threaten the ability of labs to continue providing access to our most vulnerable populations, when and where they are in greatest need of access. Furthermore, as the country looks to the industry to maintain robust COVID-19 testing, it is imperative that laboratories are not hamstrung by the threat of drastic and unreasonable reductions caused by PAMA.

Robust Access to Laboratory Services Requires Reimbursement Model Reflective of the Entire Market

Clinical laboratories' response to COVID-19 provides the clearest example of the need to strengthen our laboratory infrastructure and stop unsustainable cuts to the services that are vital to our public health. During the COVID-19 pandemic, clinical laboratories quickly responded to the unprecedented demand for COVID-19 testing by rapidly developing new tests tailored to a range of testing platforms using different types of specimens. This level of market innovation is only possible through significant investment in high precision instruments, testing supplies, a highly trained workforce, biosafe facilities and biosafe and cold transport chains. It also reinforces the importance of adequate reimbursement for laboratories to cover the ongoing costs associated with expanding capacity to meet the widespread testing needs for the country, including testing for essential workers, schools and universities and vulnerable populations in nursing homes and other care facilities.

Subjecting clinical laboratory services to year-over-year inappropriate payment cuts or other ill-advised payment schemes directly undermines clinical laboratories' ability to respond to these emerging health threats. Moving forward, policymakers must prioritize reforms to PAMA that promote greater stability and broad access to vital laboratory tests.

The COVID-19 pandemic exposed how critical the laboratory industry is to our country's health, both medically and economically. It should not take a pandemic to ensure that access to life-saving and cost-effective laboratory services remain strong into the future. With unsustainable cuts to lab services set to begin again in 2022, it's critical that Congress remedy PAMA by establishing a Medicare Clinical Laboratory Fee Schedule that is truly representative of the entire market and supports continued innovation and access to vital laboratory services.