

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 the laboratories that over 56 million seniors rely on for their lab tests under Medicare.
- Drastically cutting rates, including for the top-25 most performed lab tests, is threatening access to critical lab services 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 provides the clearest example of the need to strengthen our laboratory infrastructure and eliminate future 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, validating different swabs and specimen types and advancing innovative techniques that reduced the time needed to return results and expanded testing capacity. 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.
- In an acknowledgement of the ongoing harm facing seniors, Congress has taken important steps to address the impact of flawed PAMA implementation, including the bipartisan passage of the 2019 *Laboratory Access for Beneficiaries (LAB) Act*, and more recently, a delay of ongoing laboratory cuts as part of the 2020 *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.



IMPACT TO TOP-25 LAB TESTS

PAMA cuts target the top-25 most performed lab tests for diabetes, heart disease, kidney disease and certain cancers.



SKEWED DATA

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



56 MILLION SENIORS AT RISK

Seniors will continue to face significant, year-over-year cuts to their lab benefits and potential barriers to testing.

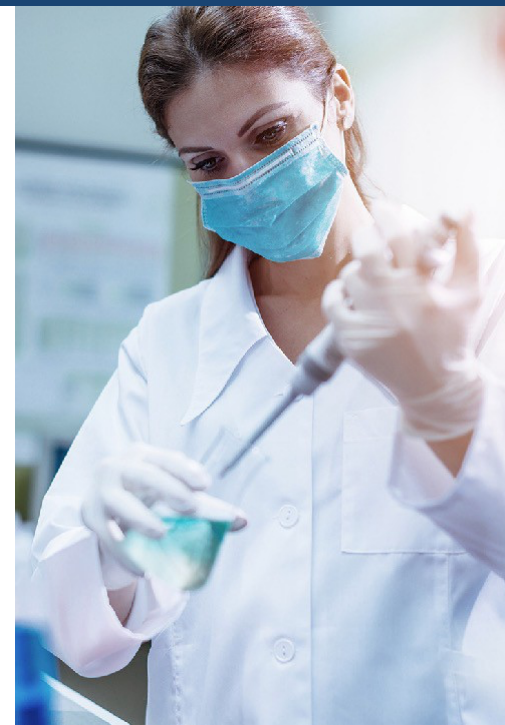
PAMA Cuts: An Ongoing Threat To Seniors' Access to Vital Tests

As part of PAMA implementation, Congress directed the HHS Secretary to establish market-based rates for clinical laboratories; 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. If the cuts continue, nursing home residents without access to testing at their facility will have to be transported to hospitals by ambulance for specimen collection and testing. Infectious disease testing may 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 – over 25 percent reductions for many tests – have been severe. In a 2019 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 upwards of 15 percent reductions in reimbursement for tests to diagnose a range of chronic conditions, including heart disease and diabetes.
- Unless otherwise addressed, PAMA's flawed data reporting requirements will be reinstated on January 1, 2022, exacerbating the flaws in PAMA's implementation.

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 as clinical labs continue to make unprecedented investments to expand COVID-19 testing capacity, this relief is only temporary. The impending PAMA cuts in 2022 will 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 eliminate future 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.