ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

Protecting Access To Medicare Act (PAMA)

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 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 labs that over 59 million seniors rely on for their lab tests under Medicare.
- By drastically cutting rates, including for the top-25 most commonly performed lab tests, HHS 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 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.
- In an acknowledgement of the ongoing harm facing seniors, Congress has taken important initial steps to address the impact, 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 will threaten access to testing for seniors and our most vulnerable populations.

IMPACT TO TOP 25 LAB TESTS

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

SKEWED DATA

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

59 MILLION SENIORS AT RISK

Seniors will continue to face significant year-over-year cuts to their lab benefits and access 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 one percent of laboratories nationwide. The data was 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.**

Already, nursing home residents are bearing the brunt of these cuts. 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 PAMA cuts continue, these labs, which send personnel to nursing homes to collect specimens and turnaround results quickly, will have no choice but to limit the number and frequency of facilities they serve. Without their services, nursing home residents will have to be transported to hospitals by ambulance for specimen collection and testing – negatively impacting patient care and driving up Medicare costs.

The consequences of these ongoing cuts – a nearly 30 percent reduction for many tests in the first three years of implementation – have been severe. In a survey conducted before the pandemic by the Infection Disease Society of America (IDSA), over 79% of respondents reported they would be unable to provide the full range of testing needed to rapidly diagnose diseases following 2018-2019 PAMA cuts.

Key Dates Related to Upcoming PAMA Requirements

- Cuts to designated lab tests under the Clinical Lab 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 implementation.
- MedPAC's upcoming report, as mandated by the *LAB Act*, will be released **June 2021** and will recommend a less burdensome data process designed to capture private payor rates for laboratory services.
- ACLA's ongoing legal challenge (*ACLA v. Azar)* is still pending and currently under review by the U.S. District Court for the District of Columbia.

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Recent Legislative Actions Provide Temporary Relief Amid Public Health Crisis

In 2019, President Trump signed the *Laboratory Access for Beneficiaries (LAB*) Act into law, 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 and pathology 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 must vulnerable populations, when and where they are in greatest need of access. Furthermore, as the country looks to the industry to scale up and prepare for spikes in demand for COVID-19 testing, it is imperative that laboratories are not hamstrung by the threat of drastic and unreasonable reductions caused by PAMA.

Legal Challenges Point to Flaws in PAMA Implementation

In light of the serious regulatory and legal challenges to PAMA implementation, ACLA has continued to support and advance its legal challenge (*ACLA v. Azar*) in the courts. In July 2019, a favorable ruling from the U.S. Court of Appeals for the District of Columbia recognized that ACLA is entitled to challenge the harmful regulatory overreach by the HHS Secretary in his implementation of PAMA. While *ACLA v. Azar* continues to be under judicial review, it remains essential that policymakers take immediate action to mitigate the continued harm from PAMA cuts.

Robust Access To Laboratory Services Requires Reimbursement Model Reflective of the Total Market

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 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 cuts or other ill-advised payment schemes such as competitive bidding directly undermines clinical laboratories' ability to respond to these emerging health threats. Worse, such cuts undervalue the essential and complex inputs that laboratories rely on to achieve quality, accurate, efficient and reliable testing that is foundational for our public health response. In fact, patients have already experienced the harms of such an approach firsthand. The competitive bidding demonstration project under the *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003 serves as a case study on the unintended market failures from competitive bidding for laboratory services, one that required remedial action on the part of federal courts and ultimately Congress to stop the program entirely.

Moving forward, policymakers must prioritize reforms that ensure continued stability and broad access to innovative 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 clinical laboratory fee schedule that is truly representative of the full market and supports continued innovation and access to vital laboratory services.