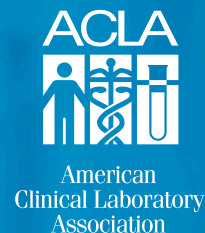


Key Issues & Facts on PAMA Reforms & Laboratory Services



Timely, accurate and reliable lab testing and diagnostic services are vital to care delivery and improved patient health.

- Laboratories are at the forefront of diagnosing our most complex diseases, supporting early intervention and preventive care while helping to manage chronic conditions for millions of Americans.
- Roughly 250,000 laboratories across the country perform lifesaving diagnostic services each day, ranging from routine blood tests to groundbreaking genetic tests. Whether independent labs, hospital outreach labs, physician offices, ambulatory surgery centers, ESRD, specialty or nursing homes labs, laboratories make it possible for providers to identify and treat the most complex conditions facing patients.

For nearly three decades, Medicare relied on a static, inflexible payment approach for laboratory services, which failed to keep up with increasingly advanced laboratory diagnostics and an increasingly diverse patient population.

- Under the Clinical Laboratory Fee Schedule established in 1984, Medicare paid for clinical laboratory services through a static rate system that became increasingly problematic because the fee schedule was largely restricted to infrequent inflation updates, leaving the Centers for Medicare and Medicaid Services (CMS) to resort to unpredictable gimmicks to adjust existing rates or establish new rates for breakthrough laboratory tests.
- To ensure Medicare beneficiaries had continued access to lifesaving tests, Congress specifically sought to establish a fair and predictable market-based payment system for clinical laboratories.
- 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. This was an important step in protecting seniors.

Yet the Department of Health and Human Services' (HHS) flawed, misguided implementation of PAMA threatens seniors' access to these lifesaving clinical tests, undermining Congress' intent to protect Medicare beneficiaries and support value-based care delivery.

- As part of PAMA implementation, Congress directed the HHS Secretary to establish market-based rates for clinical laboratories; however, the Secretary deliberately disregarded Congress' instruction by gathering rate information from less than 1% of laboratories nationwide.
- This blatant omission ignores the fundamentals of a market-based system. By ignoring the data from more than 99% of the nation's laboratories, HHS' actions will have a chilling effect on patient care and delivery system reforms moving forward.
- If this haphazard approach to data collection is maintained, it could establish a harmful precedent for the Department's review and approval of payment rates across all health services covered by Medicare and Medicaid.

HHS' failure to follow Congressional intent will result in an estimated \$670 million cut to vital lab services in 2018 alone – jeopardizing care to the most vulnerable Medicare beneficiaries and adding to overall costs for taxpayers.

- HHS' misguided approach to PAMA implementation will directly harm millions of beneficiaries managing multiple chronic conditions. By drastically cutting rates, particularly for the top-25 most performed lab tests, HHS is targeting beneficiaries managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency and countless other common diseases and conditions.
- Reducing access to clinical lab services will ultimately drive up the cost of care for beneficiaries and taxpayers. Most labs servicing long-term care facilities are providing rapid results daily, as many senior patients require close, routine monitoring. This same day turnaround helps identify any critical results at an early stage, keeping patients healthier and preventing more costly interventions. However, if the PAMA cuts continue, nursing home labs will no longer be able to provide this service, and these already fragile patients will be forced to travel by ambulance to the hospital for testing. Long-term care facilities will likely be less equipped to closely monitor important patient indicators, potentially putting these patients at risk for preventable complications or further harm.

- The harm from these cuts only increases for beneficiaries who are more frail or reside in medically underserved communities, such as rural areas. These communities and patients rely on a shrinking number of smaller, local laboratories: laboratories that will face the brunt of these cuts – a nearly 30 percent reduction overall in Medicare reimbursement. These cuts will force laboratories serving the most vulnerable and homebound to either shut down operations, reduce services, eliminate tests, and/or lay off employees. Ultimately, patients will have fewer options to receive the lab test services that will keep them healthy and out of the hospital, particularly patients who are less mobile or would have to travel further to receive laboratory services.
 - These cuts are already taking effect in some cases. For example, in a recent declaration, Dr. Mark Birenbaum, head of the American Association of Bioanalysts, reported that a laboratory serving skilled nursing facilities in New Jersey had to close while laboratories in Oregon and Washington had to consolidate in anticipation of cuts to critical services.
 - Peter Gudaitis, President of Aculabs, called the cuts “Armageddon” for laboratories serving elderly beneficiaries served by skilled nursing facilities, nursing homes, and assisted living facilities. Since these patients often can’t drive or travel by other means to a hospital or physician office for care, they rely almost exclusively on laboratories which specialize in sending phlebotomists to the patient’s bedside and returning same-day lab results. The cuts will result in a painful hit to beneficiaries’ access to care without any substantial way to replace critical lab services.
 - For Brookside Clinical Laboratory, a Pennsylvania-based lab that predominantly serves nursing homes and homebound seniors, the cuts under PAMA could severely limit clinicians’ ability to process rapid influenza tests within the immediate hours needed to adequately intervene, treat seniors’ symptoms and help avoid a broader infection outbreak. Annette Iacono, Vice President of Brookside, raised that, “this delay in reporting laboratory results will have a direct impact on treatment decisions and outcomes.” Further, for a growing number of beneficiaries who depend on house calls and in-home testing, payment cuts have already required Brookside to stop these visits, putting patients at greater risk for undetected blood clots and strokes.

Urgent action from policymakers is needed to mitigate the impact of potential cuts to beneficiaries’ care.

- ACLA recently filed a lawsuit against HHS, challenging its flawed data collection process. The goal is simple: require the Secretary to comply with existing law and Congressional intent in collecting data that represents the true market for clinical laboratories.
- However, given the urgent need to prevent beneficiary harm, Congress can take immediate steps to reverse the potential cuts to beneficiaries by:
 - **Establishing a bridge to allow for new data collection.** Congress can make a statutory adjustment to the fee schedule payments that would provide immediate relief while allowing time for HHS and CMS to revise the data collection and rate calculation process under PAMA.
 - **Ensuring a valid sample of data for HHS/CMS collection.** Congress can establish a valid stratified random data sample collected by CMS that represents all segments of the laboratory market. The sample strata are: hospital laboratories, physician office laboratories, large independent laboratories, and small independent labs, further stratified to assure representation across geographic areas, e.g. MSA, and including urban and rural regions.
 - **Streamlining data reporting:** Congress can take steps to streamline data collection requirements to improve reporting rates and reduce the burden on participating laboratories. This will allow policymakers to focus on data that is specific to the private market and will increase the accuracy of data calculations.
 - **Revising PAMA requirements to maintain fair and accurate rate-setting.** Congress can revise the statutory requirements under PAMA to calculate final payment rates that accurately reflect the laboratory market and provide adequate access for patient beneficiaries. The data methodology must be transparent – as is the case for other facets of the health system, including Medicare Advantage and Medicaid Managed Care – to ensure greater predictability for laboratory services and patient care.