Protecting Access to Medicare Act (PAMA)

Flawed Implementation Threatening Care for Seniors

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. Unfortunately, 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 53 million seniors rely on for their Medicare lab benefits.
- By drastically cutting rates, including for the top-25 most performed lab tests, HHS is threatening access to lab services for beneficiaries living with diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency and countless other common health conditions. These reductions, far greater than originally intended by Congress, dramatically exceed savings estimates by both CBO and OMB.
- Reducing access to clinical lab services will ultimately drive up the cost of care for the Medicare program and beneficiaries, particularly those who reside in medically underserved communities and rural areas. Laboratories serving the most vulnerable – those facing a nearly 30 percent cut for many tests in the first three years of PAMA with the potential for further reductions – will be forced to shut down operations, reduce services, eliminate tests and/or lay off employees.
- Congress must delay the next PAMA data reporting period to allow time for a data collection process that is representative of all segments of the laboratory market and protects access to care for Medicare patients.

Threatening Seniors' Health

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 (i.e., hospital labs and physician office labs), were underrepresented. 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 will have an adverse impact on patient care.

HHS' misguided approach to PAMA impacts millions of beneficiaries managing multiple chronic conditions. By drastically cutting rates, including for the top-25 most performed lab tests, HHS is threatening access for beneficiaries managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency and countless other common diseases and conditions. These reductions, far greater than originally intended by Congress, dramatically exceed savings estimates by both CBO and OMB.

Reducing access to clinical lab services will ultimately drive up the cost of care for the Medicare program and beneficiaries, particularly those who reside in medically underserved communities, including rural areas. These communities and patients rely on a shrinking number of smaller, local laboratories. These labs will face the brunt of the PAMA cuts – a nearly 30 percent cut for many tests in the first three years of PAMA with the potential for further reductions. As a result, laboratories serving the most vulnerable and homebound seniors will be forced to shut down operations, reduce services, eliminate tests and/or lay off employees. Ultimately, patients will have fewer options to receive the clinical laboratory diagnostics that keep them healthy and out of the hospital.

Additionally, most labs servicing long-term care facilities, like nursing homes, provide rapid results on a daily basis. This is because many senior patients require close, routine monitoring. If the PAMA cuts continue, labs servicing nursing homes may no longer be able to provide this service. Long-term care facilities will likely be less equipped to closely monitor important patient indicators, putting these patients at risk for preventable complications or further harm.

Although labs serving rural communities and nursing homes are being hardest hit by the PAMA cuts, even labs serving more ambulatory beneficiaries in urban and suburban communities are facing workforce reductions and facility consolidations that could have negative impacts on beneficiary access.

Mitigating the Harm to Patient Care

ACLA brought a lawsuit against HHS *(ACLA v. Azar),* challenging its flawed data collection process. The goal of ACLA's legal challenge is simple: require the Secretary to comply with existing law and Congressional intent in collecting data that represents the true market for clinical laboratory services.

Several organizations have issued amicus briefs in support of ACLA's position, including the College of American Pathologists, along with AdvaMed and the National Association for the Support of Long-Term Care and the American Association of Bioanalysts / National Independent Laboratory Association.

While ACLA continues to pursue our legal options to protect seniors from the ongoing harm caused by PAMA, Congress must take immediate steps to stop PAMA's flawed implementation and allow the necessary time to move to the market-based reimbursement system that was intended.

Advancing a Common Sense Solution: Delay Data Reporting For One Year

The 2017 PAMA data reporting was fatally flawed. Despite the clear intent of PAMA to capture representative data from the broad laboratory market – independent labs, hospital labs and physician

office labs – the initial data collection resulted in information from less than one percent of all laboratories that was skewed toward the data of large, lower-priced independent labs.

Most hospital laboratories were prohibited from providing private payor data to CMS in the initial round of data collection, even though hospital labs make up approximately 26 percent of Clinical Laboratory Fee Schedule (CLFS) spending. Physician office laboratories made up 7.5 percent of the data submitted, despite representing approximately 20 percent of CLFS spending. All laboratories are reimbursed by the PAMA rates, even if they were not part of data submission.

While CMS amended the PAMA regulation at the end of last year to require more hospital laboratories to collect and report data, few hospital labs are aware of the requirement and will not have the time to build the necessary systems to report as currently required. Absent immediate action, CMS will repeat the same flawed data collection in 2020.

The same mistake cannot be made twice. A one-year delay of PAMA data reporting activities will accomplish two critical goals:

- Allow a more representative share of labs to report private market data; and
- Provide valuable time for stakeholders and policymakers to determine how to reform PAMA and ensure a truly market-based system that will protect Medicare beneficiary access.

In addition to a delay of the data reporting period, Congress should require a study on how to create a market-based fee schedule. Given the urgent need for a transition to a reimbursement system that is truly representative of the market, Congress should mandate a third-party assessment that identifies and provides concrete recommendations as to how to reform PAMA data collection and rate-setting. The study recommendations should be published as early as six months after enactment and no later than twelve months. Such a report would help build stakeholder and policymaker consensus on the necessary statutory and regulatory changes needed for PAMA.