

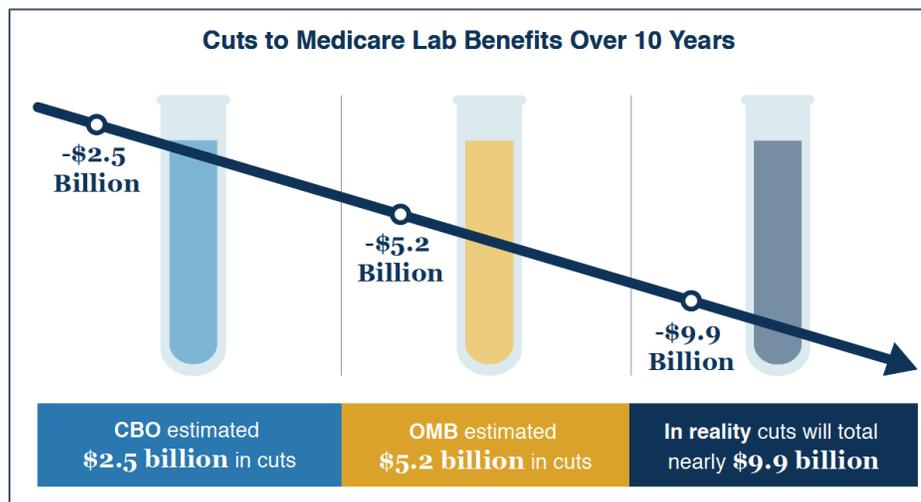
The Laboratory Access for Beneficiaries Act (LAB Act): A Critical Step in Protecting Seniors' Access to Vital Health Services

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. As part of PAMA implementation, the U.S. Department of Health and Human Services (HHS) was directed by Congress to establish market-based rates for clinical laboratory services. However, HHS disregarded Congress' instruction and gathered private market rate information from an unrepresentative sample of the market – less than one percent of laboratories nationwide. This incomplete and skewed data collection process resulted in drastic cuts to the Medicare laboratory services that 53 million seniors rely on for their health.

Recent data estimate that the year-over-year cuts under PAMA will reduce reimbursement for many essential tests by 30 percent or more. By drastically cutting rates for laboratory tests that are the foundation for early disease detection and diagnosis, HHS' overreach directly undermines care 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.

Cuts to Medicare Lab Services Under PAMA are Far Greater than Congress Intended and Dramatically Exceed Initial Public Projections

HHS' flawed PAMA implementation process poses far greater risk to beneficiaries than originally estimated. Original budget scores on laboratory cuts from the Office of Management and Budget (OMB) and the Congressional Budget Office (CBO) were based on underlying assumptions that PAMA would be carried out as Congress intended. However, because of HHS' ongoing reliance on a misguided data collection process, the consequences to seniors' care are far greater than first estimated.



The LAB Act: Advancing a Common Sense Solution by Delaying Data Reporting for One Year

In the first round of private-market rates collected in 2017, CMS prohibited essentially all hospital laboratories from reporting data to CMS, even though hospital labs make up approximately 26 percent of Clinical Laboratory Fee Schedule (CLFS) spending. While CMS amended the PAMA regulation in 2018 to require more hospital laboratories to collect and report data, few hospital labs are aware of the requirement. As a result, many hospitals that are now required to report have very little time to build the necessary data systems to meet these new requirements. Labs that fail to comply with data reporting requirements may be subject to civil monetary penalties of up to \$10,000 per day for each misrepresentation or omission..

The Laboratory Access for Beneficiaries Act (LAB Act) introduced in the U.S. House of Representatives by Reps. Peters (D-CA), Bilirakis (R-FL), Pascrell (D-NJ), Holding (R-NC), Schraeder (D-OR) and Hudson (R-NC) would take an important step by providing a one-year delay of PAMA data reporting activities. Suspending data reporting in 2020 accomplishes two critical goals:

- Allowing a more representative share of labs to report private market data; and
- Providing 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, the LAB Act would commission a study conducted by a neutral third party, the National Academy of Medicine, to assess how to improve PAMA implementation to better reflect Congress' original intent of a market-based fee schedule. Given the urgent need for a transition to a reimbursement system that is truly representative of the market, this independent analysis would provide concrete recommendations to Congress in areas including:

- How best to implement the least burdensome data collection process that would result in a representative and statistically valid data sample of private market rates from all laboratory market segments, including hospital outreach laboratories, physician office laboratories, and independent laboratories, and that would consider the variability of market segments by laboratory procedure code; and
- An appropriate rate-setting methodology that is representative of the market and ensures sustainable patient access.

NAM is also required to consult with stakeholders for comment and input throughout the study, as well as report the results of the study to the relevant Congressional committees within a time period set by Congress. Such a report would help build stakeholder and policymaker consensus on the necessary statutory and regulatory changes needed for PAMA.