

Enact H.R. 2377/S. 1000, the *Saving Access to Laboratory Services Act (SALSA)* to Improve Patient Access to Laboratory Services and Keep Our Clinical Lab Infrastructure Healthy

Summary Points

- Since the implementation of the *Protecting Access to Medicare Act (PAMA)*, Medicare payment for clinical laboratory services has been cut by up to 10 percent on three separate occasions, totaling \$3.8 billion.
- Congress has stepped in four times to delay further reductions.
- Cuts of up to 15 percent for approximately 800 tests under the Medicare Clinical Laboratory Fee Schedule (CLFS) are scheduled for January 2025.
- These cuts are a result of flawed implementation of the PAMA, which used the lowest private market rates to set Medicare rates.
- The bipartisan *Saving Access to Laboratory Services Act (SALSA/H.R. 2377/S. 1000)* is a responsible set of policies to reform PAMA by requiring collection of accurate and representative data from the entire laboratory market that serves Medicare beneficiaries, setting a sustainable path forward.
- SALSA would protect patient access to laboratory services, bolster clinical laboratory infrastructure, and foster innovation in the next generation of laboratory services.

ACLA urges Congress to reform PAMA by enacting SALSA and protecting patient access to laboratory services.

Background

Clinical laboratory services are foundational to quality clinical care. Seventy percent of medical decisions depend on laboratory test results, making it critical for patients to have access to timely, accurate and reliable clinical laboratory testing for the diagnosis, monitoring, and screening for diseases,¹ both as part of routine health care and in times of public health outbreaks.

In 2014, Congress passed PAMA to reform the Medicare CLFS to a single national fee schedule based on a survey of private payor rates for clinical laboratory services. Congress intended for the collection of private market data from all types of laboratories, including hospital outreach laboratories, independent laboratories, and physician office laboratories. Unfortunately, the first round of data collection failed to collect data from large, significant segments of the market.

The result was three years of up to 10 percent annual cuts for 75 percent of the fee schedule in 2018-2020, amounting to **\$3.8 billion in payment reductions for laboratories** providing the most commonly ordered test services for Medicare beneficiaries. Congress has intervened **four times** to prevent further PAMA cuts. However, cuts of up to 15 percent have only been delayed and will resume on January 1, 2025.

The seriousness of ACLA's concerns with PAMA is underscored by its multi-year legal challenge to the law, resolved in ACLA's favor with a ruling by the D.C. Circuit Court of Appeals. ACLA challenged CMS's definition of "applicable laboratory" (an entity that is required to report private payor rates to CMS) because the definition did not comport with the statutory language, and excluded almost all hospital laboratories from reporting their private payor rates to CMS, thereby decreasing Medicare CLFS rates below true market-based rates. The Court of Appeals ruled that CMS's 2016 final rule was arbitrary and capricious. It

¹ <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

also ruled in ACLA's favor on procedural grounds, finding that laboratories have been harmed by PAMA's implementation.

If imposed, these steep Medicare cuts for clinical laboratory services could reduce patient access to testing and impede research and innovation in the next generation of laboratory services that can improve and save lives. These cuts also undermine the nation's testing capacity and infrastructure that is critical in times of health emergency, day-to-day care, and essential to meeting the growing health care needs of the country, including in medically underserved communities.

Summary of SALSA Reforms

The solution to reforming PAMA and setting Medicare reimbursement back on a sustainable path is straightforward: CMS must collect accurate and representative data from all laboratory market segments that serve Medicare beneficiaries as Congress originally intended. If enacted, SALSA would achieve this goal with the following reforms:

Use Statistical Sampling of All Clinical Laboratory Market Segments

MedPAC found in June 2021 that sampling of private payor rates from independent laboratories, hospital laboratories, and physician office laboratories (POLs) is feasible and would produce accurate, representative data—correcting current, below-market Medicare rates. Further, sampling would reduce the reporting burden by requiring fewer laboratories to report. Therefore, for widely available tests, SALSA would require statistical sampling to obtain representative, private payor data from independent laboratories, hospital laboratories, and POLs.

Annual “Guardrails” to Increase Rate Stability and Protect Against Shocks from Increases and Decreases in CLFS Rates

SALSA would set annual limits on year-to-year payment rate reductions and increases effective January 1, 2025. Currently, PAMA limits how much a test's reimbursement can be reduced in each of the first six years of PAMA's implementation, but there are no limits on payment reductions in future years, nor limits on rate increases. Creating a limit for both rate reductions and increases would create stability for laboratories and the Medicare program by protecting against rapid payment reductions and spending increases.

Changes to Applicable Information Reported to CMS

SALSA would implement two changes to the definition of “applicable information” that would help ensure the CLFS rates are more reflective of the market and ease the reporting burden. First, Medicaid managed care rates would be excluded from the definition of “applicable information.” Medicaid managed care rates are not true “market rates” because, by law, these rates cannot exceed Medicare rates. Including these rates artificially skews rates downward. Second, to reduce the reporting burden, SALSA creates the option for a laboratory to exclude manual (physically mailed) remittances from reporting, if these remittances do not exceed more than 10 percent of the laboratory's claims.

Changing the Frequency of Data Collection Periods

SALSA would increase the length of time between data collection periods to four years (currently three years). This would provide more stability to CLFS rates and reduce the reporting burden across the entire laboratory industry by reducing the frequency of reporting.