

SAVING ACCESS TO LABORATORY SERVICES ACT (SALSA)

H.R. 2377 / S. 1000 FREQUENTLY ASKED QUESTIONS

What is the Saving Access to Laboratory Services Act (SALSA)?

SALSA is bipartisan legislation that would reform reimbursement under the Medicare Clinical Laboratory Fee Schedule (CLFS) to prevent a fourth round of harmful cuts from taking place, while also setting a sustainable reimbursement path to ensure long-term patient access to these services.

Why is SALSA needed?

Since implementation of the laboratory provisions within the *Protecting Access to Medicare Act of 2014* (PAMA), Medicare reimbursement for clinical laboratory tests has been on an unsustainable path of multi-year, double-digit cuts with a new round of cuts of up to 15 percent for more than 800 tests currently scheduled to take place January 1, 2025. PAMA implementation relied on a narrow and unrepresentative sample of the nation's clinical laboratory test prices to set Medicare rates. This has led to drastic cuts to clinical laboratories for hundreds of tests on the CLFS that, if left unchecked, could jeopardize access to many clinical laboratory tests that are used to diagnose, monitor, prevent, and manage common diseases for Medicare beneficiaries.

What was the outcome of the ACLA lawsuit brought against the Centers for Medicare & Medicaid Services (CMS) implementation of PAMA, and what are the implications of the decision?

In 2017, ACLA filed a lawsuit challenging the implementation of the data reporting requirements of Section 216 under PAMA. As part of the lawsuit, this most recent decision resolved in ACLA's favor with a ruling by the U.S. Court of Appeals for the D.C. Circuit. ACLA had 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 it had the effect of excluding almost all hospital laboratories from reporting their private payor rates to CMS. This decision artificially decreased Medicare CLFS rates below true market-based rates. In the ruling, the Court of Appeals determined that CMS's 2016 final rule was arbitrary and capricious. It also ruled in ACLA's favor on procedural grounds, finding that laboratories have been harmed by PAMA's implementation.

How would SALSA reform PAMA?

SALSA would improve the way Medicare reimbursement rates for clinical laboratory services are determined by:

- **Utilizing sampling on certain Medicare tests** – To ensure that representative data is used in CLFS rate-setting and to alleviate the overall reporting burden on laboratories, SALSA would require statistical sampling of private payor data from independent laboratories, hospital laboratories, and physician office laboratories for "widely available" tests – those that are performed by more than 100 laboratories and whose Medicare reimbursement rate is under \$1,000. Use of statistically valid sampling would eliminate bias in favor or against private payor rates paid to a particular type of lab or from a single market segment. Just 21 of the 1,942 laboratories that reported data in the 2017 reporting period were hospital laboratories. Independent laboratories accounted for 90 percent of data reported to CMS in 2017, yet they accounted for only 50 percent of Medicare CLFS volume at that time.

- **Establishing guardrails for rate changes** – SALSA would set a limit of five percent on how much any individual CLFS rate for a widely available test could be increased or decreased from year to year. This would create stability for both laboratories and the Medicare program by mitigating the shock of rapid rate fluctuations up or down. Under current law, a CLFS rate can be decreased by up to 15 percent annually in 2025, 2026 and 2027, after which there are no limits on annual decreases to CLFS rates.
- **Improving the types of private payor data used to set CLFS rates** – First, it would exclude Medicaid managed care rates from reportable data, because by law, the Medicaid rates may not exceed Medicare CLFS rates. Inclusion of Medicaid managed care rates skews CLFS rates downward artificially. Second, it would greatly reduce the overall reporting burden by permitting laboratories to exclude manual (paper) remittances from their reporting, provided they do not comprise more than 10 percent of the data the laboratory is required to report.
- **Changing the frequency of data collection periods** – Data reporting would occur every four years under SALSA. Under current law, data reporting is to occur every three years. Increasing the length of time between reporting periods would bring stability to CLFS rates and reduce reporting burdens across the laboratory industry.

How would SALSA affect current PAMA data reporting now scheduled for the first quarter of 2024?

SALSA would delay the timeline to allow for the collection of the representative samples. The new timeline would be as follows:

TIMELINE

- 2024-2025*: Notice and comment rulemaking for statistical sampling – no new data collection until after new rules are finalized
- 2026: Applicable data collection period
- 2027: Data reporting to CMS followed by CMS publishing new weighted medians
- 2028: First year of new rates from 2027 data reporting period

Data cycle repeats at four-year intervals from the 2026-2027 cycle

How would SALSA affect scheduled rate cuts and rate increases for 2024 and beyond for widely available tests?

Here is the timeline for payment **cuts** under SALSA:

For widely available tests –

- 2024*: 0 percent
- 2025: No more than 2.5 percent rate change
- 2026 and thereafter: No more than 5 percent rate change

Here is the timeline for payment **increases** under SALSA:

For widely available tests –

- 2024-2025*: No more than 2.5 percent
- 2026-2027: No more than 3.75 percent
- 2028 and thereafter: No more than 5 percent

**Timelines are based on the legislation as introduced in 2023 and would be amended upon passage to reflect an updated timeline.*

Who has introduced SALSA? Who is co-sponsoring the legislation?

Bipartisan, bicameral authors of SALSA are Senators Sherrod Brown (D-OH) and Thom Tillis (R-NC), and Representatives Richard Hudson (R-NC), Bill Pascrell, Jr. (D-NJ), Gus Bilirakis (R-FL), Scott Peters (D-CA), Brian Fitzpatrick (R-PA), Larry Bucshon (R-IN), Ann Kuster (D-NH), and Dan Crenshaw (R-TX).

Visit StopLabCuts.org to see who has co-sponsored the legislation.

Does SALSA have Congressional support?

Yes. Congress has historically recognized the potentially harmful effects of PAMA – acting four times with bipartisan and bicameral legislation – to delay both data reporting and cuts. There is widespread recognition of the need to permanently reform PAMA, and SALSA has bipartisan champions in both the House and the Senate.

What will happen if SALSA is not enacted in 2024?

Without congressional action this year, laboratories across the country will face yet another round of cuts to reimbursement for tests used to diagnose and manage common conditions like heart disease, cancer, and diabetes. As a result, laboratories will face tough decisions that could lead to a reduction in services offered to patients. In short, these scheduled Medicare cuts will undermine the laboratory infrastructure essential for day-to-day care and needed to respond to emergencies like the pandemic. Ongoing cuts to payment will also stifle innovation and investment in new screening and diagnostic tests.