ACLA AMERICAN CLINICAL LABORATORY ASSOCIATION | **STOP LAB CUTS**

ACLA Urges Congress to Enact SALSA

Set a Sustainable Path for Patient Access to Laboratory Services, and Keep Our Clinical Lab Infrastructure Healthy

Summary Points

- Prior to the COVID-19 pandemic, Medicare reimbursement for clinical laboratory services had been set on an unsustainable path of multi-year, double-digit cuts.
- The cuts are a result of flawed implementation of the *Protecting Access to Medicare Act of 2014 (PAMA*) which only used the lowest private market rates to set Medicare rates.
- The bipartisan *Saving Access to Laboratory Services Act* (SALSA) would reform PAMA by collecting accurate and representative data from all laboratory market segments that serve Medicare beneficiaries, setting a sustainable path forward.

ACLA urges Congress to enact SALSA to reform PAMA, protecting patient access to laboratory services.

Background

In 2014, Congress passed PAMA to reform the Medicare Clinical Laboratory Fee Schedule (CLFS) to a single national fee schedule based on 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 10 percent annual cuts for the majority of the fee schedule in 2018-2020, with more cuts scheduled. These cuts amounted to **nearly $4 billion in cuts from laboratories** providing the most commonly ordered test services for Medicare beneficiaries. Congress, on a bipartisan basis, has now intervened **three times** to "press the breaks" on PAMA, beginning with the enactment of the *Laboratory Access for Beneficiaries (LAB) Act* in 2019, followed by the *Coronavirus Aid, Relief, and Economic Security (CARES) Act* in 2020 and the *Protecting Medicare and American Farmers from Sequester Cuts Act* in 2021. However, cuts of up to 15 percent are only delayed and are scheduled to resume January 1, 2023.

The COVID-19 pandemic has demonstrated the clear need for patient access to timely, accurate and reliable clinical laboratory testing for the diagnosis, monitoring, and screening for all diseases. The impact of these cuts will include roadblocks to investments to meet unmet clinical needs and necessary research to improve care across diseases and health conditions, including cancer. Further, these cuts could make it far more challenging for the clinical laboratory community to invest in testing capacity and infrastructure to meet the health care needs of the country, especially in medically underserved communities and during a time when many patients are resuming routine care.

The PAMA cuts, and the resulting risks to patients, are a direct contradiction to the national goals of bolstering public health to bring the United States out of the pandemic, preparing for the future, and to expand and improve the quality of care available to patients.

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. If enacted, SALSA would achieve this goal and the original Congressional intent of PAMA with the following reforms:

Use Statistical Sampling of a Representative Pool of All Clinical Laboratory Market Segments
In the LAB Act-required report released in June 2021, MedPAC found that sampling of private payer rates from independent laboratories, hospital laboratories and physician office laboratories (POLs) is feasible, would produce accurate, representative data and would correct current, below-market Medicare rates. Further, sampling would reduce the reporting burden by requiring fewer laboratories to report. Therefore, for widely available tests, *the Saving Access for Laboratory Services Act* would require statistical sampling to obtain representative, private payor data from independent laboratories, hospital laboratories and POLs. A "widely-available test" is a test that is both performed by more than 100 National Provider Identifier (NPI) entities and whose Medicare reimbursement rate is under $1,000. For tests that are not widely available CDLTs, all labs performing that test, above the current minimum revenue threshold, would report their market data to ensure an appropriate data set (the same as current law for these tests).

Annual "guardrails" to increase rate stability and protect against shocks from increases or decreases in CLFS rates
The Saving Access for Laboratory Services Act would set annual limits on year-to-year payment rate reductions and increases effective January 1, 2023. Currently, PAMA limits how much a test's reimbursement can be reduced each year in 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 both laboratories and the Medicare program by protecting against rapid payment reductions and rapid spending increases.

Changes to Applicable Information Reported to CMS
The Saving Access for Laboratory Services Act 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 significant 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 lab's claims.

Changing the Frequency of Data Collection Periods
The Saving Access for Laboratory Services Act 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.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic diseases.