

The *Saving Access to Laboratory Services Act (SALSA)*: The Right Choice for Patients, the Medicare Program, and Laboratories

Background

The *Protecting Access to Medicare Act (PAMA)*, enacted in 2014, was intended to peg Medicare rates for clinical laboratory testing to those paid by private insurers. To do so accurately, the Centers for Medicare & Medicaid Services (CMS) was required by the law to gather robust data from 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. However, CMS only collected data from fewer than one percent of labs, resulting in Medicare rates that were artificially and dramatically suppressed.

As a result, Medicare payment tests on the Clinical Laboratory Fee Schedule (CLFS) experienced three years of up to 10 percent cuts on the most commonly ordered tests, totaling nearly \$4 billion, far more than the estimated 10-year Congressional Budget Office (CBO) projection of \$2.5 billion. If Congress does not act, cuts of up to 15 percent for approximately 800 tests are scheduled to resume in January 2025 and continue in 2026, 2027. Further reductions would negatively impact patient access, harm the nation's clinical laboratory infrastructure, and diminish research and development in the next generation of innovative diagnostic tests.

ACLA is grateful that for the past four years Congress has delayed further Medicare payment cuts and data reporting. Now is the time for permanent PAMA relief, as year over year delays have real downsides for patients and clinical laboratories.

- Clinical lab payments, established under PAMA using 2016 data and subject to three subsequent years of reductions, have not changed since 2020. Meanwhile, labor rates, transportation and supply costs have gone up. Patient access is compromised when labs are squeezed to continue providing services with fewer resources.
- Uncertainty in payment rates from year to year stifles innovation, delaying the realization of advances in clinical laboratory diagnostics including those foundational to personalized medicine, that can further improve and save patient lives.

Now is the time to enact permanent, sustainable PAMA reform through the
***Saving Access to Laboratory Services Act (SALSA)*.**

Patient Access to Laboratory Services Is Essential to Quality Care. Patient access to clinical and pathology testing is essential. While laboratory testing services account for less than one percent of total Medicare spending, these services drive 70 percent of all clinical decision making, allowing clinicians and patients to determine the best course of care, which may include identification of targeted therapies. Laboratory services are foundational to informed and increasingly personalized, quality health care.

Reductions in Medicare reimbursement for laboratory services could result in access challenges for patients

through shrinking test menus, increased time to deliver test results, and the elimination of community-based service centers. For example, there has already been a significant consolidation in the number of laboratories serving vulnerable patient populations in skilled nursing facilities.

Laboratory Services Innovation Improves Patient Health and Reduces Costs. Early detection of disease can allow for less invasive and more effective treatments potentially reducing health care spending overall. Clinical laboratories are driven to invest in increasingly advanced diagnostics to screen for disease earlier and deliver on the promise of personalized medicine. Labs are also innovating in ways to make testing more accessible.

Clinical Laboratories Are a Key Part of the Nation's Critical Health Care Infrastructure. Clinical laboratories are part of the backbone of day-to-day clinical decision making, while also serving in an essential role in response to public health emergencies, like COVID. Laboratories protect patients and public health through the rapid development of new tests and can provide massive scale during public health emergencies. PAMA's reimbursement path could damage our laboratory infrastructure.

SALSA is Bipartisan, Bicameral Legislation that Sets Medicare Payments for Laboratory Services on a Sustainable Path. H.R. 2377 / S. 1000 does this by making four key changes:

- Requiring CMS to utilize statistically valid sampling of private payor rates paid to hospitals, physician offices and commercial laboratories to determine Medicare payment rates.
- Providing payment stability for both laboratories and CMS, SALSA would limit both increases and decreases in payment.
- Improving data accuracy, SALSA would exclude Medicaid managed care rates due to their non-market-based payment rates.
- Reducing the administrative burden on both CMS and laboratories, SALSA would move data collection and reporting from every three years to every four years.

Cost Estimate. Because PAMA utilizes private sector payment rates to determine Medicare payment, an accurate understanding of changes in the commercial market over time is critical to projecting future commercial rates and therefore the likely impact on Medicare payments for laboratory services. To that end, ACLA analyzed FAIR Health¹ private sector data to better understand private sector payment change for laboratory services from 2016-2022. The data indicated an annual volume-weighted private sector payment change over the last six years of 1.4 percent, lower than the CBO assumption of CPI-U, or 2.3 percent over the same period. ACLA employed the FAIR Health data analysis in a comprehensive microsimulation model of all policies in SALSA to project a cost estimate for the bill of \$2.9 billion over 10-years. This is half of the preliminary estimate CBO shared with the authorizing committees in 2022.

We respectfully request your co-sponsorship of SALSA and support for Congress to enact SALSA this year before the next round of cuts.

¹ FAIR Health data comes from more than 60 health plans, insurance carriers and third-party administrators and includes more than 30 billion claim records from plans that cover an estimated 75 percent of the privately insured population. It meets CMS requirements regarding research sample size and reliability in all 50 states and DC.