

## Saving Access to Laboratory Services Act (SALSA, H.R. 2377/S. 1000)

- Clinical laboratory services have tremendous value. Although they account for less than 1% of total Medicare spending, or about \$8.4 billion annually, they inform 70% of all medical decisions.
- Due to the flawed implementation of the *Protecting Access to Medicare Act* (PAMA) in 2018, clinical laboratories experienced three years of up to 10% payment cuts under Medicare, totaling \$3.8 billion. If Congress does not act, deeper cuts of up to 15% will resume January 1, 2025. PAMA reform is needed.
- Laboratories must also begin to implement significant new regulatory compliance obligations under the U.S.
  Food and Drug Administration's (FDA) onerous new rule to regulate laboratory developed testing services as medical devices. The combination of PAMA cuts with costly new regulatory obligations could further compromise patient access and laboratory investments in novel diagnostics.
- ACLA is grateful that for the past four years Congress has delayed further Medicare payment cuts and data reporting; however, year over year delays have real downsides for patients and clinical laboratories.
  - Clinical lab payments, following three 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. This includes novel tests foundational to personalized medicine, that can further improve and save lives.
- Now is the time for permanent, sustainable PAMA reform by enacting the *Saving Access to Laboratory Services Act* (SALSA). Supported by 70 patient, consumer and provider organizations, SALSA will:
  - o Preserve patient access to life-saving diagnostic tests that inform clinical decision making;
  - Provide payment stability for the Medicare program and for clinical laboratories, facilitating long-term
    R&D to drive innovation in diagnostics for earlier detection and increasingly personalized medicine;
  - o Preserve clinical laboratory infrastructure for day-to-day care and in times of public health emergency.
- SALSA will achieve these goals by:
  - Using statistically valid <u>sampling</u> methods to accurately determine private payer rates—improving accuracy, reducing Centers for Medicare & Medicaid Services (CMS) and laboratory red tape;
  - Mitigating reductions facing laboratories over the next three years and thereafter,
  - Putting in place annual 5% guardrails on increases and decreases in Clinical Laboratory Fee Schedule (CLFS) payment, protecting both laboratories and the federal government.

Urge your Member of Congress to cosponsor SALSA today and press House and Senate Leadership to make passage of the bill a priority this year.

