

The *Saving Access to Laboratory Services Act (SALSA)* Supports Innovation

Investment in the Laboratory Diagnostics of Tomorrow Requires Predictable Payment for the Tests of Today

Innovation in laboratory diagnostics is revolutionizing the delivery of health care. The work of America's clinical laboratories is:

- **Identifying cancers in their earliest and most treatable stages through more accessible screening tests.** Blood-based cancer screening can help improve screening rates and will be particularly important for difficult-to-diagnose cancers that often don't present symptoms until the late - and more deadly – stages of the disease.
- **Creating companion diagnostics that use biomarkers to precisely match a patient with the right treatment option,** delivering on the promise of personalized medicine and improving patient outcomes by reducing the use of unnecessary, ineffective, harmful, and costly therapies.
- **Providing answers to families of infants and children with rare diseases** by using rapid whole genome sequencing that can look for thousands of genetic mutations with a single blood or saliva sample.
- **Protecting public health by developing novel diagnostic approaches to emerging pathogens,** putting laboratories at the forefront of preparedness and saving lives.
- **Reducing patient risk and lowering costs** by replacing invasive and costly diagnostic procedures with less invasive and more accurate blood tests.

Payment Uncertainty Slows Diagnostic Innovation

Enacting SALSA will provide clarity and predictability so clinical laboratories can plan multi-year investments in research and development (R&D), further enabling patient access to cutting-edge diagnostic tests.

- Less innovation means cuts to Medicare payments don't just hurt seniors, they harm **all** patients who could benefit from advancements in laboratory diagnostics.

- When cuts constantly loom and the long-term reimbursement policy is uncertain, laboratories cannot plan or invest in the future. R&D projects are often de-prioritized or put on hold – leaving new tests that could pave the way for treatments and cures out of reach.
- In addition to looming cuts, laboratories must now begin to implement significant new regulatory compliance obligations under the U.S. Food and Drug Administration’s (FDA) recently finalized 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.
- The uncertainty associated with the *Protecting Access to Medicare Act’s* (PAMA) payment cliff being “fixed” year-by-year limits annual planning and makes multi-year budgeting impossible.
- Allowing the resumption of Medicare cuts under PAMA would reduce the capital available for clinical laboratories to invest in innovative R&D of the next generation of tests.

Background

- After \$4 billion in cuts over three years starting in 2018 and wide recognition of flaws in PAMA, Congress has stepped in on a bipartisan basis repeatedly to delay additional cuts to clinical laboratories under the Medicare Clinical Laboratory Fee Schedule (CLFS).
- Delaying further cuts under PAMA has been helpful, but temporary fixes year over year have frozen reimbursement at the same time lab expenses have increased, creating uncertainty for clinical laboratories. This slows innovation by hindering long-term planning and preventing companies from proceeding fully with R&D that drives tomorrow’s diagnostics, including companion diagnostics, whole genome sequencing, and other advanced tests on the cutting edge of medicine.
- SALSA provides a sustainable, balanced, long-term solution to PAMA, allowing for greater predictability in Medicare reimbursement and for the R&D necessary for our country to remain at the forefront of medical innovation.
- Congress must act now before cuts of up to 15 percent for approximately 800 tests under the CLFS resume Jan.1, 2025.

**The solution is for Congress to pass SALSA.
Eliminate the uncertainty and increase innovation—pass SALSA this year.**