

Protect Patient Access to Critical Testing Services: Enact the RESULTS Act

Reforming and Enhancing Sustainable Updates to Laboratory Testing Services

ACLA endorses the RESULTS Act, bipartisan legislation that would improve rate setting under the Medicare Clinical Laboratory Fee Schedule (CLFS), the only market-based Medicare payment system. The RESULTS Act would:

- Reform the Protecting Access to Medicare Act (PAMA) by dramatically improving the data used to set rates on the CLFS.
- Support and enhance beneficiary access to innovative clinical laboratory services.
- Reduce the administrative burden of data collection and reporting for laboratories and the Centers for Medicare and Medicaid Services (CMS).
- Provide stability to the CLFS through improved rate setting and mitigation of steep year-toyear rate reductions.

The time is now for urgently-needed foundational reform of CLFS rate setting.

Clinical laboratory tests are the backbone of our health care system, informing 70 percent of medical decisions and providing patients and their doctors with information needed to prevent disease, enable early diagnosis, and manage health conditions in an increasingly personalized manner. Following years of artificially suppressed Medicare rates, destabilizing payment cuts, and uncertainty, the time is now for Congress to reform the Medicare laboratory payment system.

PAMA, which passed in 2014, was meant to establish market-based rates for clinical laboratory services paid under the CLFS through collection of private payor rate data and volumes from independent, hospital outreach, and physician office laboratories. However, when PAMA was implemented, this goal was not achieved, as CLFS rates were set based on data collected from less than one percent of all laboratories, resulting in artificially low payment rates and cutting nearly \$4 billion from the CLFS between 2018 and 2020. Without congressional action, about 820 laboratory tests' CLFS rates will be cut by up to 15 percent beginning January 1, 2026, with further deep reductions planned for 2027 and 2028, threatening patient access to routine and life-saving diagnostics.

Recognizing the drastic, unintended consequences of PAMA's failed implementation, Congress has stepped in for the last five years to delay additional payment cuts and for the last six years to delay further data reporting under the current flawed system.

The RESULTS Act would:

• Give CMS access to comprehensive private payor data that is representative of payments received by hospital outreach, independent, and physician office laboratories.

Under the RESULTS Act, CMS would secure paid claims data from an independent not-for-profit

comprehensive commercial payor database (one that includes at least 50 billion fully-paid claims from over 50 commercial payors and claims administrators) to set CLFS rates based on the volume-weighted median of private payor rates for widely available tests. Widely available tests, which comprise 99 percent of total CLFS volume, are those for which 100 or more clinical laboratories were paid under the CLFS in a specific time period. For non-widely available tests, such as proprietary tests for rare diseases, laboratories would continue to report private payor data to CMS directly. Data collection and reporting for Advanced Diagnostic Laboratory Tests (ADLTs), of which there are 19, would continue to occur annually.

Dramatically reduce administrative burden on clinical laboratories and CMS.

Clinical laboratories no longer would bear the burden of collecting and reporting private payor rate data about widely-available tests. Rather, the RESULTS Act would require CMS to secure private payor data for these tests from an independent, not-for-profit commercial claims database. CMS would be required to collect data from clinical laboratories only for non-widely available tests.

• Set annual "guardrails" to protect against destabilizing decreases in CLFS rates.

The RESULTS Act would freeze CLFS rates at current 2025 levels for 2026-2028, cancelling the pending cuts of up to 15% in 2026 and cancelling further cuts of up to 15% in 2027 and 2028. Once fully implemented in 2029, RESULTS would limit payment reductions to 5 percent per year to protect laboratories from sudden destabilizing rate changes that could reduce patient access to innovative testing services. Currently, test payment can be reduced up to 15 percent in 2026, 2027, and 2028, with no cap on decreases thereafter.

Exclude non-market based rates from CLFS rate calculations.

The RESULTS Act would exclude Medicaid managed care rates from CLFS rate calculations, as they are not truly market-based rates.

Extend the time between data collection periods.

The RESULTS Act would extend the time between data collection periods from three years to four years to provide more stability for CLFS rates and decrease the reporting and administrative burden.