Summary Testimony of Susan Van Meter, President, American Clinical Laboratory Association before the Health Subcommittee of the House Energy & Commerce Committee, United States House of Representatives, January 8, 2026

The Medicare payment system for clinical laboratories is critically flawed and urgently needs to be fixed. Continued instability and unsustainable cuts to the Clinical Laboratory Fee Schedule (CLFS) threaten patient access to essential testing, our nation's clinical laboratory infrastructure, and the skilled workforce at laboratories in all 50 states, particularly those serving rural communities, nursing homes, and medically underserved populations. Without a fair, accurate, and stable payment system, America's laboratories will struggle to sustain the workforce, innovation, and capacity needed to deliver the diagnostic services patients rely on every day.

Laboratory test results are the "GPS" of health care, informing roughly 70 percent of medical decisions at a modest overall cost. The CLFS accounts for less than 1 percent of total Medicare spending. [1,2]

The CLFS, the only Medicare payment system Congress determined should approximate commercial market rates, suffers from significant, foundational flaws that have resulted in inaccurate, artificially low Medicare rates that to this day are based on incomplete and skewed data from 2016, collected from fewer than 1 percent of clinical laboratories.

ACLA strongly endorses the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services Act (RESULTS Act) (H.R. 5269 / S. 2761), a commonsense approach to setting the CLFS on a sustainable pathway and ensuring patient access to innovative clinical laboratory services. As clinical laboratories continue to innovate and tailor health care solutions though personalized medicine, the RESULTS Act is a critical step to safeguard access to these life-saving tools for patients across the nation, reinforce our health care infrastructure, and support continued innovation in laboratory medicine.

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[1] MedPAC Payment Basics, Clinical Laboratory Services Payment System (Nov. 2025).

[2] Center for Disease Control and Prevention: https://www.cdc.gov/lab-week/about-archive.html.

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Chairman Griffith, Ranking Member DeGette, and Members of the Committee, thank you for the opportunity to testify today. I am Susan Van Meter, President of the American Clinical Laboratory Association. ACLA is the trade association representing leading laboratories that develop and offer essential diagnostic test services to patients and providers. ACLA advocates for expanded access to the highest quality testing services, improved patient outcomes, and advancing the next generation of personalized care.

Ensuring innovation in diagnostics and broad patient access to necessary testing requires a fair, accurate, and stable Medicare payment system. Regrettably, the Clinical Laboratory Fee Schedule (CLFS) , the only Medicare payment system Congress determined should approximate commercial market rates, suffers from significant, foundational flaws that have resulted in inaccurate, artificially low Medicare rates that to this day are based on incomplete and skewed data from 2016. Furthermore, it is an administratively burdensome system ripe for reform. ACLA strongly endorses the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services Act (RESULTS Act) (H.R. 5269 / S. 2761), authored by members of this Committee, as a

commonsense approach to provide the changes necessary to set the CLFS on a sustainable pathway, ensuring patient access to innovative clinical laboratory services.

America's clinical laboratories are an indispensable part of our health care system. Laboratory tests screen for disease, provide patients and clinicians with objective diagnostic information to inform clinical care, power increasingly personalized precision medicine, contribute to the discovery of novel therapeutics, and identify emerging pathogens. Laboratory test results inform roughly 70 percent of medical decisions, yet payments under the CLFS account for less than just 1 percent of total Medicare spending, or around $8 billion annually. [3,4]

Clinical laboratories' investments in cutting-edge diagnostics are leading to extraordinary advancements and changing health care as we know it for patients across the country. For example, with biomarker testing, clinical laboratories check for abnormal changes in certain genes, proteins, or other molecules that could indicate the presence of a wide range of diseases and conditions. This type of personalized medicine allows clinicians to tailor treatments for cancer patients based on their unique genetic makeup, molecular profiles, and disease characteristics. Studies demonstrate that cancer patients who receive biomarker-driven, personalized targeted therapy avoid ineffective and costly treatments and have better outcomes.[5] Also, clinical laboratories are helping deliver answers to families and physicians of sick infants and children by leveraging rapid whole genome sequencing (rWGS). This cost-effective genetic testing method can diagnose any one of thousands of genetic disorders in seven days or less. It is uniquely suited for diagnosing rare diseases,

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[3] MedPAC Payment Basics, Clinical Laboratory Services Payment System (Nov. 2025).

[4] Center for Disease Control and Prevention: https://www.cdc.gov/lab-week/about-archive.html.

[5] Ah Chi, BS, et al. "Trends in Survival Rates of Non–Small Cell Lung Cancer With Use of Molecular Testing and Targeted Therapy in Korea, 2010-2020."; JAMA Network Open. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802526

especially in critically ill infants and children, helping end what is often a long diagnostic odyssey and providing essential information that can clarify a condition and determine the right path of clinical care for these children. A key study shows that a genetic diagnosis has the potential to impact clinical management for more than 60 percent of critically ill infants and generate more than $15,000 in healthcare savings per child who receives genome sequencing.[6] Finally, clinical laboratories deliver great value through common tests, such as a complete blood count (CBC). A CBC test measures the amounts and sizes of red blood cells, hemoglobin, white blood cells and platelets. This simple, low cost blood test can be used to help monitor and diagnose a wide range of medical conditions and assess the health of a patient's immune system.[7] A CBC is often the first sign a patient may have a blood-based cancer, like leukemia. Clinical laboratories were reimbursed for over 36 million CBCs for Medicare patients in 2024 alone.

Clinical laboratories deliver tremendous value to patients and families, providing outsized benefits, relative to the overall cost associated with laboratory services. Regrettably, the CLFS lacks stability and predictability, which is essential to ensuring that clinical laboratories can continue to invest to develop and offer innovative testing services relied on by millions of patients and their clinicians. The challenge has been the implementation of the Protecting Access to Medicare Act (PAMA), which requires CLFS rates to be based upon rates paid by private payors. The CLFS is the only Medicare fee schedule designed to reflect commercial market rates, and so far, the experiment has not been successful.

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[7] A CBC is currently reimbursed under the CLFS at $7.77. This rate is scheduled to be cut by 11 percent on January 31, absent a change in the law.

PAMA Background

Under PAMA, which became law in 2014, Congress intended for CLFS rates to be equal to the weighted median of private payor rates as reported to the Centers for Medicare and Medicaid Services (CMS) every three years by laboratories from all sectors of the market so that Medicare rates closely approximate rates currently paid across the commercial market. However, when PAMA was implemented, this goal was not achieved. The first data collection period was the first half of 2016, with private payor rates and associated volumes reported to CMS in 2017; the new fee schedule took effect in 2018. CMS collected 2016 commercial market data from less than 1 percent of all laboratories. Those reporting data were chiefly large reference laboratories that have among the lowest commercial market rates. Hospital laboratories, which have among the highest commercial market rates, were underrepresented: only 21 hospital laboratories reported data to CMS in 2017. The lackluster and skewed data reporting resulted in artificially low Medicare payment rates for 2018 and thereafter. Rates reductions were to be phased in in 2018, 2019, and 2020 were limited to cuts of up to 10 percent. The consequence of utilizing insufficient data was that Medicare payments to laboratories were cut by nearly $4 billion between 2018 and 2020, almost four times the Congressional Budget Office (CBO) estimate of $1 billion in cuts for that three-year time period and double what CBO projected the total amount of cuts would be over ten years. These significant cuts were not only deep, but were widespread, affecting 72 percent of the tests on the CLFS.

The second data collection period was scheduled for the first half of 2019. However, Congress delayed data reporting in each year from 2020 to 2025 and delayed further rate reductions five times without changing the data collection period. ACLA and our member laboratories are grateful for rate reductions having been delayed. Without further congressional intervention,

starting on February 1, 2026, laboratories will be required to report private payor rates and volumes from 2019, and this data will be used to develop CLFS rates for 2027-2029 – which is far different from Congress's intent for CLFS rates to be based on current commercial rates. And without Congressional action, about 800 laboratory tests' CLFS rates, still based on the flawed 2016 data, will be reduced further, by up to 15 percent beginning January 31, 2026.

Sustained cuts of such a large magnitude threaten patient access to life-saving diagnostics and reduce investment in the next generation of clinical diagnostics.

Core Challenges of PAMA

Three foundational flaws prevent the CLFS under PAMA from being a market-based fee schedule with rates that are predictable and sustainable and that are sufficient to ensure clinical laboratories can provide broad and timely access to both routine and innovative testing services for all Medicare beneficiaries.

1. CMS Lacks Access to Timely and Comprehensive Commercial Market Data

PAMA's first major flaw is the failure to use current and comprehensive commercial market data representatives of all three segments of the laboratory market, hospital outreach laboratories, independent laboratories, and physician office laboratories. Without all three segments' private payor data, CLFS rates cannot accurately and fairly reflect rates paid in the commercial market. The success and integrity of a Medicare fee schedule based on commercial market rates rests on the currentness and completeness of the private payor data inputs used to develop it. Fewer than 1 percent (1,972) of the 261,524 clinical laboratories in the U.S. in 2015 reported 2016 commercial

market data to CMS in 2017.[8] CMS initially excluded most hospital laboratories from reporting.[9] In fact, more than 90 percent of the 2016 data were from independent laboratories (90.1 percent), even though they accounted for only 50 percent of CLFS volume in 2016. Physician office laboratories, 23 percent of CLFS volume, contributed only 7.5 percent of the data, while hospital outreach laboratories provided only 1 percent of the data, although they comprised about 27 percent of 2016 CLFS volume.[10] The overrepresentation of independent laboratories and underrepresentation of hospital outreach laboratories drove down CLFS rates. Although CMS subsequently amended its regulatory definition of "applicable laboratory" at 42 C.F.R. § 414.502 to include hospital outreach laboratories that bill Medicare Part B on the CMS 1450 under bill type 14x, prior experience, including CMS's lack of enforcement of reporting requirements, indicates that 2019 private payor data reported by laboratories again will be incomplete and heavily skewed toward independent labs. CMS has provided little education to laboratories in the last several years on the mechanics and requirements for reporting.

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[8] Summary of the Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf. See also and Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), HHS OIG Data Brief (September 2016), *available at* https://oig hhs.gov/reports/all/2016/medicare-payments-for-clinical-diagnostic-laboratory-tests-in-2015-year-2-of-baseline-data/

[9] ACLA filed suit in the federal District Court for the District of Columbia in December 2017, challenging the regulation's definition of "applicable laboratory" arguing the rule was arbitrary and capricious. On July 15, the U.S. Court of Appeals for the D.C. Circuit issued a decision in *ACLA v. Becerra* supporting ACLA's legal challenge to the 2016 CMS regulations implementing Sec. 216 of PAMA. The court ruled in ACLA's favor on both substantive grounds and on process—importantly finding that CMS's definition of "applicable laboratories" was arbitrary and capricious. CMS has issued regulations that specify that hospital outreach laboratories are indeed applicable laboratories and must report data under PAMA. The court did not vacate the CMS regulation because the law prohibits judicial review of "the establishment of payment amounts" – though the law does not prohibit judicial review of the agency's actions to implement the law. USCA Case #21-5122, July 15, 2022.

[10] Centers for Medicare & Medicaid Services, *Summary of Data Reporting in the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System* (Sept. 22, 2017, at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

Current law requires 2019 data to be reported between February 1 and April 30, 2026. But laboratories' information systems housing the data will have changed significantly since 2019, and staff turnover will make retrieval of the private payor rates and volumes challenging—or impossible—for many labs. Furthermore, the private payor rates and volumes collected a year before the start of the COVID pandemic, do not reflect today's commercial market: by the time CLFS rates using that data are set, the data will be 8 years old. When CMS proposed regulations to implement PAMA, it said: "We believe the data collection period should immediately precede the data reporting period…[I]t will result in more accurate reporting by laboratories and, thus, more accurate rate setting by CMS, because laboratories will have more recent experience and be more familiar with the information they are reporting."[11] Clearly, this will not be the case with 2019 data reported in 2026.

Additionally, about one-third of the Healthcare Common Procedure Coding System (HCPCS) codes on the CLFS are new since 2019, so no laboratory could report any commercial market data to CMS about those codes. As a result, CMS, with stakeholder input, bears the burden of repricing each one of the codes that are new since 2019 individually (through crosswalking or gapfilling) at the CLFS Annual Meeting during the summer of 2026. Coupled with other new codes that must be priced at the same meeting, and also other codes whose pricing methodology is being reconsidered, CMS likely will have to price several hundred codes at one meeting.

2. Medicare Reductions Under PAMA are Far Deeper Than Intended

PAMA's second major flaw is an outgrowth of the first: incomplete commercial market data led to artificially low CLFS rates. Current law allows for continued reductions of up to 15 percent

[11] 80 Fed. Reg. 59386, 59399 (Oct. 1, 2015).

annually in each of 2026, 2027, and 2028, despite the depth of cuts already taken from 2018 to 2020. Many of the tests whose rates could decrease by as much as 15 percent in 2026 (on top of 10 percent cuts in each of 2018, 2019, and 2020) are routine tests that are used to monitor chronic conditions like diabetes and diagnose acute illnesses. These tests are performed by independent, hospital, and physician office laboratories, many of which cannot sustain a business model with large decreases in reimbursement. For example, sharp cuts in Medicare reimbursement and high labor costs present challenges for laboratories that serve beneficiaries in nursing homes, who are unable to travel to a physician office or patient service center for specimen collection. This segment of the laboratory market is labor-intense, has razor-thin margins, and is comprised primarily of small independent laboratories that cannot recover losses easily. This problem is more acute for laboratories serving these patients in rural areas.

Further, these deep Medicare reductions have depressed many commercial market rates, as private payors oftentimes base their contracted rates on Medicare rates. Analysis of commercial market payment data demonstrates that inclusion of comprehensive and representative data would have resulted in generally higher CLFS rates in 2018 and thereafter.[12] PAMA also requires laboratories to report payment data from Medicaid Managed Care Organizations. Medicaid Managed Care rates are not commercial market rates; they are typically under capitated arrangements with states and tied to Medicaid fee for service rates, which cannot exceed Medicare

[12] ACLA has examined a limited, publicly available commercial market claims dataset from the Health Care Cost Institute that demonstrates hospital outreach and physician office laboratories' commercial market rates are generally higher than those for independent laboratories (https://healthcostinstitute.org/wp-content/uploads/images/pdfs/HCCI%20Lab%20Brief_103124.pdf). ACLA's analysis of the significantly more comprehensive FAIR Health commercial claims data set from 2016 – 2024, yields a similar conclusion.

rates and are therefore artificially depressed. These non-commercial market rates should be excluded from data required to be reported.

3. Administrative Burden

PAMA's third major flaw is the high administrative burden on both CMS and clinical laboratories. Consider the scale and intensity of the undertaking for clinical laboratories to report each and every payment rate from each private payor and the associated volumes for all 1,600 codes on the CLFS. A large commercial reference laboratory may have contracts with 2,000 private payors across the country and offer the vast majority of tests on the CLFS. A regional, rural, or small independent, hospital, or physician office laboratory may have few administrative staff who can accomplish the task of collecting private payor data and volumes from 2019 and lack the resources to hire additional staff or vendors to assist with claims tracking and validation. Reporting data from 2019 may prove impractical for laboratories that have changed or updated billing systems over the last seven years. Institutional knowledge of the initial reporting responsibilities may be lost. Given these realities, the inevitable outcome will again be low rates of participation in data reporting.

The challenges of reporting the data were evident in the low quality of data reported to CMS in 2017. ACLA does not believe that laboratories reported inaccurate and incomplete data intentionally. But a review of the complete 2016 data file and statements that CMS included in its summary of the data underscore that many of the labs that did report applicable information did not understand what was to be included or excluded from the data or found that it was impossible to access the information in their systems retroactively. In addition to providing administrative relief, reducing the reporting burden on clinical laboratories and burden on CMS of reviewing and analyzing the data would result in higher quality, more representative data on which to base future rates.

The RESULTS Act: Common Sense Policy to Ensure Patient Access to Clinical Laboratory Services

ACLA strongly endorses the bipartisan and bicameral **Reforming and Enhancing Sustainable Updates to Laboratory Testing Services Act (RESULTS Act) (H.R. 5269 / S. 2761),** whose authors include members of this Committee. The RESULTS Act is a commonsense approach to reforming the way CLFS rates are set, addressing PAMA's most vexing problems by:

- **Ensuring the CLFS rate-setting process is based on current and comprehensive commercial market data that is representative of independent, hospital outreach, and physician office labs.**
    - Under the RESULTS Act, CMS would obtain 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 that are not Advanced Diagnostic Laboratory Tests (ADLTs). Non-ADLT widely available tests, which comprise 99 percent of total CLFS volume, are those for which more than 100 clinical laboratories were paid under the CLFS in a specific time period. The qualifying claims data entity would provide to CMS only information about widely available tests that meets the definition of "applicable information": final payments made by private payors during the year in which the data collection period occurs and the associated volumes at each rate for tests furnished during the data collection period. More specifically, a qualifying independent database of private payor claims data would have to be able

to "provide version control of claims to enable the collection and submission of only claims representative of final payment amounts."

- For non-widely available tests that are not ADLTs, such as proprietary tests for rare diseases that do not meet ADLT criteria, 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 currently, would continue to occur annually.

- To ensure that Medicare rates for non-ADLT tests (both widely available and non-widely available) are based on current commercial data going forward, while providing time to establish the new RESULTS framework, data from 2027 would be reported in 2028 to reset Medicare rates in 2029, and future cycles would continue to ensure that Medicare rates are based on current commercial data.

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

- **Establishing "guardrails" to protect against destabilizing decreases in CLFS rates.**

  - The RESULTS Act would freeze CLFS rates at current levels for 2026-2028, cancelling the pending cuts of up to 15 percent in 2026 and cancelling further cuts of up to 15 percent in 2027 and 2028. Once fully implemented in 2029, the RESULTS Act would limit payment reductions to 5 percent per year, providing stability to the Medicare program, as steep payment shifts could reduce patient access to innovative testing services. Currently, CLFS rates can be reduced by up to 15 percent in 2026, 2027, and 2028, with no limit on decreases thereafter.

- **Dramatically reducing 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 obtain verified final payment data for these tests from an independent, not-for-profit commercial claims database.[13] CMS would be required to collect data from clinical laboratories only for non-widely available tests, a dramatically smaller dataset.
    - The RESULTS Act would reduce burden further by extending the time between data collection and reporting periods from three years to four years.

In short, the RESULTS Act offers a commonsense approach to addressing PAMA's flaws and would provide appropriate stability and predictability in Medicare rates for clinical laboratories and the patients they serve. Shoring up the CLFS also would promote greater diagnostic innovation. Clinical laboratory testing services are the "GPS" for guiding patient care. As clinical laboratories continue to innovate and tailor health care solutions though personalized medicine, the RESULTS Act is a critical step to safeguard access to these life-saving tools, reinforce our health care infrastructure, and support continued innovation in laboratory medicine.

The RESULTS Act has been endorsed by over 30 patient and consumer organizations, representing patients and families living with cancer, rare diseases, neurological disorders, diabetes,

[13] One such database that would meet the legislation's criteria is the FAIR Health database. FAIR Health includes over 54 billion privately billed medical and dental claims data from over 75 payors. Information on current federal government uses of FAIR Health is available here: https://www fairhealth.org/federal-data-source Information on use of FAIR Health by state governments is available here: https://www fairhealth.org/state-data-source

and more, and as many provider groups from laboratory organizations to physician and hospital associations.[14]

I am grateful for the opportunity to discuss these critical issues with you, and ACLA commits to continue working with this Committee to advance common sense legislation to reform the CLFS that ensures that patients continue to have access to lifesaving tests developed and furnished by our nation's clinical laboratories. I look forward to your questions.

[14] See patient and consumer letter of support at: https://stoplabcuts.org/wp-content/uploads/2025/11/2025-SLC-RESULTS-Act_Patient-Consumer-Stakeholder-Letter_Dec-19-2025.pdf. See provider letter of support at: https://stoplabcuts.org/wp-content/uploads/2025/10/2025-RESULTS-Act_Provider-Letter-10.30.25.pdf