

October 21, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically: CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Administrator Oz:

On behalf of our nearly 5,000 member hospitals, health systems and other healthcare organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 healthcare leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Preliminary Calendar Year (CY) 2027 Medicare Clinical Laboratory Fee Schedule (CLFS) Rates and accompanying documents released on Sept. 21, 2026, ("preliminary rates").

America's hospitals and health systems, including their clinical laboratories, are the backbone of the U.S. healthcare system, providing 24/7 care to patients and communities. Hospital care today is more advanced, more effective and more resource-intensive than ever, reflecting major gains in medical innovation and the highly skilled workforce, technology and infrastructure required to deliver it. Patients are living longer, recovering faster and receiving treatments that would have been unimaginable just a generation ago. Innovation in laboratory diagnostic testing plays an important role in these trends. As such, as communities across the country face ever-increasing demand for healthcare services, it is essential that Medicare clinical laboratory payments support the sustainability and availability of these services.

Many AHA members operate hospital outreach laboratories that provide clinical laboratory tests to individuals other than admitted inpatients or registered outpatients (such as community-based or referred patients). These outreach laboratories deliver essential health information used to diagnose and treat patients in physician offices, nursing homes and other clinical settings. Such testing is of particular benefit to patients



in rural communities because it brings essential diagnostic testing closer to home, eliminating long-distance travel and accelerating medical treatment.

Under Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), certain “applicable” laboratories, including hospital outreach laboratories, were required to report their private payer data to CMS between May 1 and July 31, 2026.¹ By law, beginning in 2027, CMS will use these data to update and calculate Medicare Part B CLFS rates for clinical diagnostic laboratory tests. As such, hospital and health system outreach laboratories have a direct stake in ensuring CLFS rates are based on private payer information from all sectors of the laboratory market.

Unfortunately, the preliminary rates CMS released on Sept. 21 highlight the need for substantial reforms to its methodology. Specifically, these preliminary rates are based on incomplete data. Indeed, only 2% of laboratories paid under Medicare Part B reported any information at all to CMS. Despite the AHA’s and other national laboratory stakeholders’ best efforts to encourage reporting, many laboratories obligated to report their data simply failed to do so. Moreover, there was widespread confusion among laboratories that did report, both about whether they truly qualified as “applicable laboratories” and what data to report, which contributed to the poor-quality data. Further, CMS did not receive any data at all for 25% of the laboratory codes for which it sought private payer data. In addition, CMS did not release information that would allow stakeholders to examine the extent to which reporting laboratories were representative of all applicable laboratories.

The AHA is concerned that this underreporting means that CMS’ calculated preliminary rates do not reflect the “market-based payments” that Congress mandated in PAMA. They have resulted in substantial proposed cuts to Medicare CLFS reimbursement for hundreds of codes. These cuts would reduce access to clinical laboratory services for Medicare beneficiaries and hinder laboratories’ ability to plan, invest in research and development, and maintain the infrastructure needed to bring new tests to patients. Without long-term payment reform, continued uncertainty could slow scientific discovery and delay patient access to innovations that improve care.

We are also concerned that CMS’ approach to collecting applicable private payer information directly from clinical laboratories is inadequate for setting fully “market-based” rates. This is evidenced by the small number of laboratories that reported their applicable data and the lack of awareness among those obligated to report.

To help address these concerns, the AHA urges CMS to provide support and technical assistance to Congress as it seeks to pass the Reforming and Enhancing Sustainable Updates for Laboratory Testing Services (RESULTS) Act of 2025, which would establish a better way for CMS to collect private payer data to set Medicare Part B CLFS rates.² The bipartisan legislation would give CMS access

¹ Pub. L. 113-93

² H.R. 5269, S. 2761.

to comprehensive private payer data that are representative of payments received by hospital outreach laboratories, independent laboratories and physician office laboratories, allowing it to use these data to set CLFS rates. The bill would also reduce the administrative burden on clinical laboratories and CMS and establish “guardrails” to protect against the types of destabilizing CLFS rate cuts like the recently released preliminary rates. Its passage would help ensure the CLFS is truly market-based as PAMA originally intended.

However, until Congress passes the RESULTS Act, we strongly urge CMS to use the flexibility it has under current law to lessen the substantial CLFS payment cuts for the preliminary rates. Specifically, for test codes whose weighted medians are lower than current rates, we request CMS use its authority to reduce rates by less than the maximum allowable reduction. Also, we ask that the agency maintain rates for new tests that were recently cross-walked or gap-filled, rather than repeating the flawed PAMA process. Finally, we ask that CMS address errors in the data that have resulted in inaccurate preliminary CLFS rates for certain codes.

DATA USED TO SET PRELIMINARY CLFS RATES IS NOT REPRESENTATIVE OF PRIVATE PAYER RATES

The preliminary rates that CMS calculated do not include inputs from the full laboratory market serving Medicare beneficiaries. Of all the laboratories paid under Medicare Part B, only 2% reported any applicable private payer information to CMS. This includes only 1% of physician office laboratories, 16% of independent laboratories and less than 20% of hospital outreach laboratories. Using such an incomplete data set to calculate preliminary rates has resulted in a distorted and incomplete picture of the private payer market.

In addition, CMS did not release the information that is needed to examine the extent to which the sample represented the universe of laboratories. This information is key to understanding the extent to which the preliminary rates are truly “market-based” and representative of the entire laboratory market. We understand that CMS released this type of information after the 2017 data reporting period, and we urge it to do so again.

CMS has the information needed to identify each laboratory that qualified as an “applicable laboratory” during the data collection period and notify laboratories of their reporting obligations. Laboratory stakeholders asked CMS to provide a list of applicable laboratories to help clarify these obligations. CMS did not release the information, which may have contributed to uncertainty among laboratories about whether they qualified as “applicable laboratories” and what information they were required to report. Greater clarity may have supported a stronger and more complete response rate.

CMS’ PRELIMINARY WEIGHTED MEDIANS ARE UNDERPRICED DUE TO DATA QUALITY

CMS' preliminary rates are well below the amounts private payers pay to laboratories. Specifically, the agency reported receiving information for 1,528 codes. The preliminary rates published for 75% of those codes are lower than current Medicare Part B rates. Half of those codes would see the maximum allowable reduction of 15% in 2027, followed by further reductions in 2028 and 2029. The cumulative cut in Medicare Part B payments for laboratory tests over the coming three years would be approximately \$3.3 billion in a system that totals approximately \$8.5 billion in payments per year.

This payment reduction over three years is significant and concerning. Specifically, while CMS states that it applied quality-control measures to address potentially unreliable data, it calculated weighted medians so far below current CLFS rates that they should have raised concerns. For example, the preliminary rate for code 86386 (Nuclear matrix protein 22) is an astounding \$0.02, over 99% lower than the current CLFS rate of \$21.78. Since fewer than 10 laboratories reported data for this and many other codes, there is no way for commenters to see the underlying data. However, it is reasonable to conclude that rates such as these, based on such a small sample of data, do not reflect the actual rate private payers pay for these tests. By contrast, if CMS calculated weighted medians using comprehensive, representative data on fully adjudicated paid claims from a private payer database, as the RESULTS Act would authorize, the results would differ in that they would reflect the market rather than claims reported by only a small fraction of laboratories.

Large cuts would also extend to other high-volume codes. CMS' fact sheet on the preliminary rates lists cumulative cuts in Medicare rates at 16% for chemistry tests, 22% for molecular pathology tests, 23% for genomic sequencing tests and 19% for immunology tests. Many of the highest volume individual test codes would see even greater cumulative cuts of up to 36%. This includes common and high-volume tests such as complete blood count, complete metabolic panel, HbA1c, thyroid-stimulating hormone and vitamin D. These routine tests manage common conditions in Medicare beneficiaries such as diabetes and heart disease. Such deep cuts to these high-volume, low-cost tests would put at risk the financial viability of hospital outreach and other laboratories, potentially leading to closure of small and rural hospital outreach laboratories. This, in turn, would put access to testing for Medicare beneficiaries at risk.

For now, we urge CMS to limit the harm by using its existing authority to reduce rates by less than the maximum allowed. Specifically, under current law, if a test's weighted median private payer rate is below its current Medicare rate, the agency may lower the rate until it reaches that median, but by no more than the annual "applicable percent." That limit is 15% in 2027, 2028 and 2029. However, the law does not require CMS to make the full 15% cut; it only prohibits cuts that exceed that amount. Smaller reductions would help preserve Medicare beneficiaries' access to diagnostic tests that guide most clinical decisions.

CMS NEEDS ADEQUATE PRIVATE PAYER DATA TO PRICE LABORATORY TEST CODES

The AHA is concerned that preliminary rates for many laboratory test codes do not reflect market rates, as CMS received no applicable information for 472 laboratory test codes — 25% of the codes for which it sought information.

Because the statute does not specify how to price codes without applicable information, CMS used its typical process to price new codes. Specifically, it either crosswalks a code to a comparable existing rate or gap-fills it using charges and other payment data. The process includes public notice, stakeholder recommendations, advisory panel review, preliminary and final decisions, and a 60-day reconsideration period. However, this process does not fit the task at hand. For example, CMS normally takes about seven months to review and crosswalk or gap-fill roughly 100 new codes. However, the agency took only about three months to review the 472 codes with missing information. Stakeholders had only days to prepare responses, and CMS grouped the codes rather than reviewing them individually. More than 85% were placed on two consent agendas that were not shared publicly in advance, limiting meaningful public input.

CMS finally released its preliminary payment determinations for these codes on Oct. 19, announcing that it would accept public comment through Nov. 19. CMS removed 62 codes that became effective on or after July 1, 2025, because those codes were not active during the applicable data collection period and, therefore, lacked relevant private payer rate information. AHA appreciates CMS' decision to maintain the existing crosswalk or gap-fill determination for these 62 codes until data is available from the next private data collection cycle. However, for the remaining 410 codes, we are concerned that CMS' rushed process to determine crosswalks and gap-fills did not meet the agency's standard of due diligence to appropriately price these codes without private payor data and will lead to further rate inaccuracy.

The challenges CMS faced in pricing these codes underscore the need for a more reliable and representative source of private payor data. The RESULTS Act would help address this problem by improving data available to CMS to set CLFS rates. However, until such reforms are enacted, AHA recommends that CMS use notice-and-comment rulemaking to create a more reliable method for pricing codes without applicable information and avoid unnecessary repricing of recently reviewed codes.

We appreciate your consideration of these issues. Please contact me if you have questions, or feel free to have a member of your team contact Roslyne Schulman, AHA director for outpatient payment policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy