**ASSOCIATION FOR MOLECULAR PATHOLOGY**
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October 21st, 2026

Dr. Mehmet Oz
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA CLFS_Annual_Public_Meeting@cms.hhs.gov

Re: Preliminary Determinations for Calendar year 2027 (CY2027) for the Private Payor rate-based CLFS Payment System.

Dear Administrator Oz:

On behalf of the Association of Molecular Pathology (AMP), thank you for the opportunity to submit comments on the new private payor rate-based Clinical Lab Fee Schedule (CLFS) preliminary determinations for calendar year 2027 (CY2027). AMP is an international medical and professional association representing approximately 3100 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the *in vitro* diagnostics industry.

Clinical laboratories play a vital role in healthcare, informing more than 70% of clinical decisions.[1] Over the past two decades, molecular pathology procedures for oncology, infectious diseases, and inherited conditions have become essential to patient diagnosis, treatment selection, and clinical management. Advances in molecular diagnostic technologies, including next-generation sequencing (NGS), have strengthened precision medicine and improved patient outcomes across the spectrum of health conditions. Despite this critical role, laboratories accounted for only approximately 1% of Medicare spending in 2024.[2]

AMP is deeply concerned that the preliminary rates released by the Centers for Medicare & Medicaid Services (CMS) do not appear to consistently reflect appropriate reimbursement rates for these important services. Of the more than 300 non-proprietary molecular pathology procedures on the CLFS, preliminary rates indicate that 78% will receive payment reductions relative to their 2026 national limitation amounts (NLAs). Of the molecular procedures, 116 will face reductions of 30% or more. Review of the supplementary data used to calculate the volume-weighted median raises questions about the accuracy and representativeness of the reported private payer rates. We characterize these flaws below.

**Concerns Regarding Data Accuracy**

[1] https://www.cdc.gov/lab-week/resources-archive/feature-story.html

[2] Based on internal calculations using data from NHE Fact Sheet | CMS and Total Medicare Part B Spending on Lab Tests Rose in 2024, Driven by Increased Spending on Genetic Tests | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services

*Limitations in Reporting and Measuring the Data Representativeness*
One challenge with the development of many of the new unique molecular pathology codes is the low test volumes for these codes when compared with other pathology services. As a result, there is very limited pricing data available for these codes. The limited number of reporting laboratories compound this concern. Following PAMA legislation enactment, the Office of Inspector General estimated that approximately 12,547 laboratories would be required to report data in compliance with the Protecting Access to Medicare Act of 2014 (PAMA; Public Law 113-93).[3] For this most recent 2026 PAMA reporting cycle, preliminary data indicates that only 6,304 laboratories submitted data, despite CMS making court-mandated revisions to the definition of an applicable laboratory designed to improve representation of payments across all laboratory types. The limited number of reporting entities disproportionately affects weighted median calculations for services with fewer submissions. This is particularly concerning for molecular pathology services for which 10 *or fewer* taxpayer identification numbers (TINs) reported data, affecting approximately 16% of all molecular pathology procedure codes.

Payment adjustments of the magnitude proposed by CMS must be supported by reliable and representative data. Given the concern that molecular pathology codes are more acutely impacted by any errors, CMS should not finalize rates for molecular pathology services with identifiable data integrity concerns or evidence that the weighted median may be distorted by statistical outliers or an uneven distribution of reported prices.

*Potentially Flawed Data and Outlier Methodology*
AMP understands that CMS applied the following quality control measures before calculating the preliminary weighted medians:

- Removed duplicate records matching on TIN, National Provider Identifier (NPI), HCPCS code, payment rate, and volume when volume exceeded one, retaining only one record for the calculation.
- Removed reported payment rates exceeding 100 times the 2025 CLFS rate.

AMP is concerned that this methodology inadequately addresses inaccurately low rates. In particular, 38% of the molecular pathology procedures have a reported payment of $0.01. Another 53% of procedures have reported payments below $1. The payment amounts are far from realistic and raise serious questions about data accuracy and whether the reported values reflect actual reimbursement for services performed. Conversely outlier values of 30% or more from the CY2026 CLFS rates are disruptive to the accurate calculation of a weighted median. Including what obviously appears to be flawed data to calculate payment determinations, without appropriate review, risks undermining the relative value of similar or like services across the Molecular Pathology Procedures family.

Because CMS has the authority to make quality control data adjustments, it should also establish a consistent, statistically justified methodology for identifying and addressing potentially erroneous low-value outliers in addition to those considered high-value. **AMP recommends that CMS engage statistical and laboratory medicine experts to evaluate the distribution of reported prices and establish appropriate criteria for excluding data points that are highly likely to be erroneous. This review should assess both ends of the distribution rather than presume that only unusually high values warrant scrutiny.**

**Challenges Associated With Retrospective Data Reporting**
The transition to retrospective reporting may have also contributed to inaccuracies in the data submitted to CMS. On January 30, 2026, Congress revised the PAMA data collection period to January 1 through June 30, 2025, replacing the previously planned reporting period associated with 2019 data. AMP supports using a more recent period because it better reflects the current costs of performing molecular diagnostic testing; however,

[3] Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040; 09/16)

laboratories may not have been preparing to report 2025 data as it was being collected, as they were not anticipating Congress's changes to PAMA. The new reporting period of May 1 through July 31, 2026, also forced laboratories to retrieve, prepare, and report historical payment data within a limited timeframe. These changes, combined with confusion surrounding the revised definition of an applicable laboratory, created substantial challenges for laboratories to assess reporting obligations and comply with them. The fact that CMS's Frequently Asked Questions document to advise stakeholders was 18 pages long further illustrates the confusion in understanding compliance requirements.[4] Although AMP recognizes that the reporting dates were established by Congress rather than CMS, the limited lead time provided laboratories with fewer opportunities to prepare their systems and records for reporting.

**In light of the short turnaround time for reporting, AMP urges CMS to consider how these challenges may have affected data completeness and reliability, particularly for molecular pathology codes with limited reporting volumes or unusually low payment rates.**

**Potential Impact of Private Payer Contracting on Hereditary Cancer Codes**

AMP has specific concerns about the preliminary reductions for CPT codes 81432, 81435, and 81437, which describe genomic sequencing panels for hereditary breast and related cancers, hereditary colon cancer-related disorders, and hereditary neuroendocrine tumor-related disorders, respectively. The preliminary weighted median rates reflect reductions of 31.4%, 55.1%, and 59.1%, respectively.
These reductions may be at least partly attributable to changes in the code descriptors effective January 1, 2025. The revisions incorporated deletion and duplication analysis into the existing codes, rather than creating entirely new CPT codes, consolidating the associated work and resources into a single code and subjecting the revised codes to the CY2025 CLFS pricing process.

Many private payer contracts follow an October-to-September fiscal year for negotiations and may have retained the previous code descriptors and payment terms when the revised codes took effect. Renegotiations reportedly often did not begin until after January 1, 2025, during the PAMA data collection period. Consequently, reported payment rates may reflect contractual arrangements established before the revised codes incorporated the additional work and resources.

**CMS should exclude these codes from the private-payer-based payment determination method this year because most, if not all, of the reported data do not reflect negotiated payments for the work included in the current code descriptions.**

**Limitations of the Applicable Laboratory Definition and Impact on Pediatric Testing**

AMP is concerned that the definition of an applicable laboratory excludes laboratories that primarily serve populations with limited Medicare utilization, including pediatric patients. As a result, the reported data may not adequately represent reimbursement for services disproportionately used in pediatric care. This is concerning because the limited data that was reported to CMS is resulting in drastic Medicare payment cuts, which in turn is expected to have a cascading impact on private payer rates.

Specifically, we note that there is substantial variation in the limited data reported for several genomic sequencing and exome sequencing procedures commonly used in pediatric populations, and as a result, will face significant preliminary payment reductions. For example, CPT code 81425, which describes genome sequencing analysis, is used to evaluate seriously ill pediatric patients with unexplained constitutional or heritable disorders but will be cut by 40% over the next few years.

[4] https://www.cms.gov/files/document/clinical-laboratory-fee-schedule-pama-reporting-frequently-asked-questions-faqs.pdf

When laboratories serving these populations are underrepresented in PAMA data, the resulting weighted medians may not reflect the true costs or market-based reimbursement associated with these services. These concerns extend beyond Medicare because private payers frequently use CLFS rates to establish or negotiate laboratory reimbursement. Thus, the Medicare cuts will place significant, inappropriate downward pressure on payment rates that will continue to affect laboratories for many years, given the interdependent relationship between Medicare and private-payer pricing. This is especially concerning pediatric testing, where reductions based on unrepresentative data could affect laboratory sustainability and restrict access to medically necessary genomic testing for pediatric patients. CMS should assess whether the current applicable laboratory definition and reporting requirements produce representative data for these services before finalizing substantial payment reductions.

**Flawed Premise of the PAMA Payment Methodology**

AMP is concerned that the fundamental premise of the PAMA payment methodology fails to account for the power imbalance in private payer negotiations and the realities of laboratory contracting. Although PAMA uses private payer reimbursement to establish Medicare payment rates, private payers frequently use the published CLFS rates as a starting point for their own negotiations with laboratories. Many laboratories, particularly independent and smaller laboratories, lack the negotiating power to challenge payer-determined rates and have limited ability to negotiate reimbursement that reflects the actual costs of providing testing. Some contracts explicitly establish payment as a percentage of the CLFS rate for specific CPT codes, creating a circular process in which Medicare rates influence private payer reimbursement, which is then used to establish future Medicare rates. This dynamic effectively creates a "race to the bottom" in many cases and undermines the premise that reported private payer rates independently reflect market-based reimbursement.

Furthermore, private payer contracts frequently involve negotiations across multiple CPT codes, with laboratories accepting lower reimbursement for certain services to secure more favorable rates for others or to maintain access to a payer's patient population. Consequently, the reimbursement reported for an individual CPT code may reflect broader contractual considerations rather than the cost of performing that specific test or its standalone market value. Using these rates to establish Medicare payment without accounting for these contractual dynamics risks perpetuating pricing disparities and penalizing the laboratory community for participating in a complex contracting environment. AMP is concerned that PAMA's methodology places disproportionate weight on these arrangements without adequately accounting for their impact on the resulting payment rates.

Finally, AMP is concerned about the reliability of reported payment amounts, particularly whether all required patient cost-sharing amounts were consistently included. Although PAMA reporting is intended to account for applicable coinsurance and patient payments in addition to amounts paid by private payers, laboratories may have inadvertently omitted these amounts because of confusion about reporting requirements or limitations in the data available to them. Without access to sufficiently detailed data, it is difficult to determine whether such omissions occurred or how they may have affected the calculated weighted medians. These potential inconsistencies further underscore the need for CMS to validate reported data before implementing substantial payment reductions. Collectively, these structural flaws raise serious questions about whether private payer rates provide a reliable and equitable basis for determining Medicare reimbursement for clinical laboratory services.

**Recommendations**

To protect patient access while maintaining the integrity of the PAMA process, AMP recommends that CMS:

1. **Maintain the 2026 NLA for codes with questionable data until rates can be validated.** CMS should not finalize substantial reductions when the underlying data show evidence of reporting errors, insufficient

representation, or statistical distortion. The existing 2026 NLA should remain in place for affected codes until reliable data support a revised rate.

2. **Conduct a targeted statistical review of potentially unreliable rates.** CMS should work with experts in statistics and laboratory medicine to evaluate codes for which the preliminary weighted median differs from the existing NLA by 30% or more in either direction. This review should assess the distribution of reported prices, the number of reporting TINs, potential outliers, and other indicators of data reliability. Where the data are not statistically reliable, CMS should recalculate rates using validated data or collect additional information before finalizing payment.
3. **Apply a balanced methodology for identifying outliers.** CMS should evaluate potentially erroneous high and low payment values using consistent, statistically justified criteria. The agency should not remove high-value outliers while allowing implausible low-value payments to distort the weighted median.

Thank you for the opportunity to comment on the CY2027 preliminary CLFS rates. AMP looks forward to working with CMS to ensure that payment determinations are based on accurate, representative data and that the implementation of PAMA does not unnecessarily compromise access to essential laboratory testing. Should you have any questions or require additional information from AMP members, please contact Samantha Pettersen at spettersen@amp.org.

Sincerely,

Aaron D. Bossler, MD PhD
President, Association for Molecular Pathology