ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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August 28, 2025

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

Re: Protecting Access to Medicare Act Implementation and the Clinical Laboratory Fee Schedule

Dear Administrator Oz:

On behalf of the Association for Molecular Pathology (AMP), I am writing to express our deep concern about the continued negative impact of the Protecting Access to Medicare Act of 2014 (PAMA) on the Medicare Clinical Laboratory Fee Schedule (CLFS) and patient access to essential molecular diagnostic services. AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, microbiology, genetics, and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Our members are deeply committed to delivering high-quality testing that guides patient care, yet the sustainability of their work is threatened by looming cuts to CLFS payment rates in 2026.

We urge the Centers for Medicare & Medicaid Services (CMS) to take immediate action to preserve patient access to vital molecular diagnostic tests by delaying these cuts and updating reporting requirements while Congress and stakeholders work together to modernize the CLFS payment determination process. Clinical laboratory testing is foundational to modern medicine, informing approximately 70% of all clinical decisions[1] while representing less than 1% of total Medicare spending[2]. Yet, molecular diagnostic test payment rates have been cut far more than Congress intended as a result of significant problems with the implementation of PAMA. Specifically, the flawed data collection process resulted in inaccurate information. The

[1] https://www.cdc.gov/lab-week/about-archive.html
[2] Calculated using data from the follow sources: https://oig.hhs.gov/documents/evaluation/10140/OEI-09-24-00350.pdf; https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet

consequences of this process are significant – AMP's 2023 *PAMA Impact Survey*[3] found that **approximately 95% of laboratory respondents indicated that reimbursement cuts would force them to reduce or entirely eliminate certain molecular tests for Medicare beneficiaries.** Further, survey results indicate that inadequate reimbursement could disrupt coordination of medical care, and increase the length of time it takes for patients and providers to receive critically important laboratory results. The payment cuts will also continue to have a cascading effect as new tests and their corresponding codes are created and then crosswalked to codes with declining payments, threatening the future of laboratory test innovation, development and adoption. Overall, it is clear that PAMA payment reductions threaten patient access to timely, accurate, and innovative diagnostic services – particularly in oncology, infectious disease, and inherited conditions – and compromise the long-term viability of molecular medicine.

Without intervention, laboratories face payment reductions of up to 15% for more than 800 CLFS codes in 2026, followed by rate-setting in 2027 which will be based on commercial payor data from the first half of 2019 – data that will be more than six years out of date. Such outdated rates will fail to reflect current private-payer cost structures, especially for high-complexity molecular diagnostic tests.

AMP respectfully urges CMS to take the following actions using its existing rulemaking authority:

1. **Maintain Current CLFS Rates in 2026**
   AMP strongly supports the congressional request that CMS maintain the current CLFS payment rates given the authority Congress granted CMS to reduce payment rates by no more than 15% for 2026.

2. **Update and Modernize Data Collection and Reporting**
   AMP strongly urges that CMS adjust regulatory requirements to move the next data collection period to January 1 – June 30, 2025 instead of using the outdated 2019 data to ensure the data reflects current commercial payer rates and volumes. Further, it is essential that CMS also delay reporting by one year to January 1 – March 31, 2027, as requested by numerous members of Congress, to allow laboratories time to prepare and validate data. This change aligns with CMS' prior precedent in adjusting timelines for PAMA implementation.

AMP members have witnessed firsthand the consequences of inadequate reimbursement, including test menu reductions, service consolidations, and reduced capacity to care for patients. Without prompt CMS action, Medicare beneficiaries risk losing access to critical diagnostic services that guide cancer treatment, detect rare genetic diseases, and identify infectious pathogens.

We welcome the opportunity to meet with you and your team to discuss these recommendations and share more findings from AMP's *PAMA Impact Survey*. Our members stand ready to work

[3] https://www.amp.org/AMP/assets/File/advocacy/AMP_PAMA_Impact_Survey_Output%202_28_23%20AMP%20Final_.pdf?pass=21

with CMS to ensure the CLFS reflects a fair and sustainable payment system that protects patient access while supporting innovation in molecular diagnostics.

Thank you for your consideration.

Sincerely,

Jane S. Gibson, PhD
President, Association for Molecular Pathology