



September 9, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1807–P; Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure:

The Association for Diagnostic and Laboratory Medicine (ADLM) appreciates the opportunity to provide comments on the proposed rule, "*Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies*" [CMS–1807–P]. The rule, in addition to many suggested changes to physician fee schedule (PFS) reimbursement, outlines forthcoming payment cuts and reporting requirements for clinical laboratories.

In 2014, Congress included a provision in the Protecting Access to Medicare Act (PAMA) that overhauled the Centers for Medicare and Medicaid Services (CMS) process of adjusting lab fees based on historical rates, regional variations, and annual updates for inflation. This system was criticized for not reflecting technological advancements. In its place, lawmakers directed the agency to rebase the Clinical Laboratory Fee Schedule (CLFS) to more closely reflect private sector payment rates.

PAMA requires CMS to collect private sector data from applicable testing facilities and use that information to set new payment rates for each laboratory test under Medicare. Under the statute, CMS was permitted to cut payments for ‘overpaid’ tests by up to 10 percent a year for the first three years, up to 15 percent a year for the following three years, and then by an unlimited amount moving forward—until the market-based fee for each test is achieved. The agency has met the first threshold and is now planning to cut fees for some lab tests by 15 percent starting January 1, 2025.

While we understand the legislative mandate behind these reductions, the scale and pace of the cuts pose a significant threat to patient access to this essential component of the healthcare delivery system. The cumulative impact of additional cuts will likely to exacerbate financial

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pressures on laboratories, particularly those serving rural and economically disadvantaged communities. In addition, laboratories are not immune to general market conditions. As supplies and labor costs continue to grow, laboratories struggle to maintain and hire essential personnel. Further cuts will continue to damage the nation's laboratory infrastructure at a time when it is needed most.

ADLM urges CMS to work with the laboratory community to correct inadequacies in the current process. At the time of the initial payment data collections there were more than 250,000 laboratories in the United States. Of these, only 1,942 were required to submit payment information—less than one percent of all testing facilities. Most of the payment data came from large, national commercial laboratories, which offer volume discounts. ADLM is concerned that the payment rates under the existing rules are not representative of the size and scale of the broader community of laboratory test providers, thus unnecessarily increasing the size of the cuts and potentially decreasing patient access to laboratory services.

One solution to this problem is the passage of the Saving Access to Laboratory Services Act (SALSA), which would create a more equitable and representative data collection process. The bill would direct CMS to utilize statistical sampling to ensure it obtains more representative payment data for setting fees. In addition, the measure would provide greater price stability by placing limits on payment increases and decreases and reducing the administrative burden on laboratories. ADLM believes these changes will result in a more streamlined, accurate payment process.

ADLM urges CMS to engage with legislators and the healthcare community to advance this legislation and the reforms included within the measure. We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,



Anthony A. Killeen, MD, MSc, PhD
President, ADLM