Gregory N. Sossaman, MD, MASCP
ASCP President

September 12, 2025

The Honorable Mehmet C. Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–1832–P. Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on the Centers for Medicare & Medicaid Services (CMS) Physician Fee Schedule (PFS) Notice of Proposed Rulemaking (Proposed Rule) for calendar year (CY) 2026, published in the Federal Register on July 16, 2025.

Our comments address the following issues:

- Clinical Laboratory Fee Schedule rate-setting implementation under Sec. 216 of the Protecting Access to Medicare Act
- Efficiency Adjustment
- Development of Strategies for Updates to Practice Expense Data Collection and Methodology
- Update to Practice Expense Methodology – Site of Service Payment Differential
- Software as a Service
- Potentially Misvalued Services: Fine Needle Aspiration
- Quality Payment Program

A. Clinical Laboratory Fee Schedule: Rate-setting Implementation Under Sec. 216 of the Protecting Access to Medicare Act

Clinical laboratory testing is responsible for approximately 70 percent of medical decisions and is indispensable to the ability of physicians and other providers to care for their patients. CMS's current methodology for setting payment rates for the Medicare Clinical Laboratory

Fee Schedule (CLFS) was established in 2014 by Section 216 of the Protecting Access to Medicare Act (PAMA), which tasked the agency with identifying the commercial market rate for each laboratory test. CMS's regulations implementing the new rate setting methodology went into effect on January 1, 2018.

PAMA requires eligible clinical laboratories to report both the commercial payment rates and the associated volume for each service they perform that is reimbursed under the CLFS. The agency then uses the data to calculate a volume-weighted median payment for each laboratory service on the CLFS. PAMA required the Agency to "phase-in" these new payment rates, such that during the first 3-year cycle, rates are cut by no more than 10 percent per year. During the second 3-year cycle, rates may be cut by no more than 15 percent per year.

Unfortunately, CMS finalized a methodology that failed to approximate actual market rates. CMS's data collection approach—which captured data from less than one percent of all laboratories—was not representative of the laboratory market. Rather than surveying the entire laboratory market—hospital laboratories, independent laboratories, physician office laboratories, etc.—it relied heavily on data from large independent laboratories, which accounted for approximately 90 percent of all data received. The result was that the Agency's new rates were skewed by data from large laboratories with significant economies of scale. The resulting payment rates fell far short of market rates.

Not surprisingly, this had a profoundly negative impact on clinical laboratories. Private payers immediately adopted CMS's weighted median rates (without a phase in), and the result was that many smaller and rural laboratories were forced out of business. The Congressional Budget Office (CBO) estimated that the first three years of rate cuts would reduce total Medicare spending on services covered by the CLFS by about $1.0 billion. Ultimately, these submarket rates resulted in cuts in CLFS spending of about $3.8 billion—almost four times CBO's projection.

As a result of the flaws in PAMA, Congress delayed future data reporting by laboratories for each year from 2020 through 2025. It has also blocked additional rate cuts since 2021. ASCP, along with the American Clinical Laboratory Association and others in the laboratory community, have been working with Congress to fix PAMA. Whether Congress will fix PAMA or further delay the cuts is unclear. As a result, we urge CMS to help mitigate PAMA's flaws by doing the following:

1. **Maintaining Current CLFS rates**

The statute states that, "Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2028 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of *greater than the applicable*

percent (emphasis added) (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year."[1] To be clear, the statute does not mandate that CMS reduce the payment for a test code by the full applicable percentage reduction. It simply prohibits a rate reduction from exceeding the applicable phase-in percentage.

We urge that for those laboratory services with a weighted median that has not been fully achieved, CMS should use its existing authority to reduce rates in 2026 by less than the applicable percent allowed in the law. CMS has already cut the CLFS by far more than the amount CBO estimated.

2. Update the Date Range for Collecting and Reporting Data

ASCP urges the agency to update the data collection period from January 1-June 30, 2019, to January 1–June 30, 2026. This would allow applicable laboratories to collect and access *more current* data from reporting. According to the Bureau of Labor Statistics CPI Inflation Calculator, adjusting $1.00 for inflation from January 1, 2019 (the current data collection starting point), through July 2025 (the most recent date for which data is available from BLS) would equal $1.28. It would be inappropriate and unfair to impose what could amount to more than a 28 percent cut by using data that is 6 years old. Updating the data collection date should also enable CMS to receive more robust and complete data from as many applicable laboratories as possible. Since 2019, approximately 700 new CPT codes have been introduced.

CMS also should delay the data reporting period to January 1 – June 30, 2027 to facilitate reporting and to minimize the burden on applicable laboratories, as some laboratories may encounter significant challenges accessing archived payment data. Congress intended for Medicare rates for laboratory services to reflect *current* commercial payor market rates and this recommendation is more consistent with this expectation.

We note that when CMS first proposed regulations to implement PAMA, CMS demonstrated that it believed it had discretion to determine the timing and length of the data collection period and that policy considerations influenced its selection of a data collection period.

3. Conduct an Aggressive Education Campaign to Improve Reporting Compliance

ASCP believes that CMS can play a critical role in encouraging compliance with PAMA's reporting requirements so that the collected data provides an accurate reflection of market prices. During the first reporting cycle, the number of laboratories providing data was far below expectations. Ultimately, this led to payment rates that were not reflective of market rates and in substantial financial losses for many laboratories. We believe low compliance was largely a reflection of a lack of awareness of the reporting requirement, though some

[1] 42 U.S.C. § 1395m-1(b)(3)(A) (emphasis added).

laboratories may have lacked the resources to collect and submit requested data as well. To ensure that CMS can obtain more robust data for future reporting cycles and to encourage financial stability within the laboratory sector, we urge the Agency to initiate an aggressive education campaign, including all segments of the laboratory testing market.

B. Efficiency Adjustment

CMS is proposing a 2.5 percent "efficiency adjustment" in work relative value units (RVUs) and physician intra-service time for most services, affecting more than 7,000 physician services, with recuring reductions every three years. The agency is proposing this adjustment to address concerns it has about the accuracy of American Medical Association (AMA) Relative Value Scale Update Committee (RUC) survey data and to account for perceived efficiencies gained through practitioner experience, technological advances, and other operational improvements. The ASCP agrees with CMS about the need to ensure that the time data used in work RVUs is accurate, that high-volume services are frequently reviewed to account for efficiencies, and that payment rates are appropriate; however, we disagree with the notion that there are large-scale efficiencies that have been unaccounted for by the RUC. The RUC has already accounted for efficiencies in high-volume codes, particularly through the potentially misvalued code project, and it would be unfair to further reduce these services.

Recently published data does not support the concept that there has been an efficiency gain in procedure times. For example, a study published in the Journal of the American College of Surgeons analyzed intra-service times for 1.7 million surgeries across 249 CPT codes and 11 specialties, finding that overall operative times increased by 3.1 percent between 2019 to 2023, with 90 percent of CPT codes having longer or similar operative times in 2023 compared to 2019. Similarly, the Society of Thoracic Surgeons (STS) reviewed the intra-service time data related to arterial and venous coronary artery bypass graft procedures (HCPCS codes 33510-33523, 33533-33536) from the STS National Database from 2012 through 2022. This data, based on 1,448,393 procedures, shows that the intra-service times for arterial or venous CABG codes increased by 12 percent since the codes were last valued by the AMA/Specialty Society Relative Value Scale Update Committee (RUC) and CMS.

ASCP and others in the medical community are concerned with a number of aspects of this proposal, including:

- The -2.5 percent efficiency adjustment assumes a uniform level of efficiency gains across the vast majority of medical services, raising issues of fairness.
- Adjusting physician work RVUs and intra-service time for all codes, while exempting commonly performed services that are often used as key reference services, will

create challenges in the processes to update the RBRVS and ensure appropriate relativity of new and revised codes.
- Applying an efficiency adjustment to all work RVUs could have unintended consequences for budgeting, projecting, resource determination and staffing within physician practices and health systems that rely on stable physician work RVUs to use in their productivity and compensation plans.

Rather than finalize a -2.5 percent efficiency adjustment applied to nearly all CPT codes, ASCP urges CMS to work with the AMA RUC to ensure frequent review of codes with empirical data. If, however, CMS does adopt the proposed efficiency adjustment, we recommend that CPT codes 80503, 80504, 80505, and 80506 be classified within the proposal as time-based services and excluded from the adjustment. These pathology clinical consultation codes are billed on the basis of medical decision-making or total time. As a result, these codes align with the time-based framework already applied to excluded E/M services, such as CPT code 99213.

C. Development of Strategies for Updates to Practice Expense Data Collection and Methodology

CMS notes in the proposed rule that its PE methodology currently relies on AMA Physician Practice Information (PPI) Survey data. In fact, data from the AMA's 2008 survey are still integrated into PFS calculations today. In 2024, the AMA launched a new PPI survey and submitted it to CMS for consideration in implementing the PE/HR data and cost shares in PFS ratesetting for CY 2026.

In the proposed rule, CMS discusses significant concerns it has with the data's accuracy, utility, and suitability as an immediate replacement for the current PE/HR data and cost shares for use in setting payment rates for the PFS. These concerns include:

- Low Response Rates and Representativeness
- Small Sample Sizes and Sampling Variation
- Lack of Comparability to Previous Survey Data
- Potential Measurement Error
- Missing and Incomplete Data Submission

In the proposed rule, CMS notes that "in its current system, accurate measurement of the indirect to direct PE ratio and the PE/HR for each specialty is critical to ensure that allocated indirect PE RVUs (and therefore total PE RVUs) accurately estimate service-level PE as defined by PFS ratesetting steps. Because the PE methodology is budget neutral, inaccuracies in the PE/HR data for some specialties can significantly impact the overall

pool of PE available to distribute across all services, and therefore overall valuation and payment. Due to its concerns with the PPI survey data and the potential impact on specialty specific payment rates, CMS is not proposing to implement the PE/HR data or cost shares from the AMA's survey data at this time, and is proposing instead to maintain the current PE/HR data and cost shares for CY 2026 PFS ratesetting. CMS also further states that it plans to work with interested parties, including the AMA, to understand whether and how such data should be used in PFS ratesetting in future rulemaking.

ASCP shares the Agency's concerns, particularly the concern that "low sample sizes contribute to substantial statistical uncertainty regarding the true specialty-level PE/HR measures." Accordingly, we support CMS's proposal to maintain the current PE/HR data and cost shares for CY 2026 PFS ratesetting. ASCP maintains that the PPI cost share weights more accurately capture the proportion of total PFS payments that should be attributed to physician work. Thus, we appreciate the Agency's plans to work with the AMA and others to determine whether and how the cost share weight data should be applied in future PFS rate setting.

D. Update to Practice Expense (PE) Methodology – Site of Service Payment Differential

As noted above, due to concerns about the PPS survey data, the Agency plans to retain the current PE/HR data and not adopt the updated specialty-level values from the PPI survey at this time. In addition, CMS is proposing significant refinement to its PE methodology to reflect changes in physician practice settings. Specifically, the Agency is proposing to recognize greater indirect costs for practitioners in office-based settings compared to facility settings. CMS notes in the proposed rule that its original allocation methodologies assumed physicians maintained separate practice locations even if they furnished some care in hospitals. CMS states: "Since the methodologies were established decades ago, there has been a steady decline in the number of physicians working in private practice, with a corresponding rise in physician employment by hospitals and health systems. Therefore, we believe that the allocation of indirect costs for PE RVUs in the facility setting at the same rate as the non-facility setting may no longer reflect contemporary clinical practice." As a result, the Agency proposes reducing the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs.

ASCP shares CMS's concerns regarding the pay differential between hospital outpatient departments and physician offices. We maintain, however, that the proposed cuts to PE: (1) do not address the root cause of this differential, (2) do not reflect resource costs incurred by practices in the facility setting, (3) create significant impacts to many individual physicians and other health care professionals, and (4) could further drive practice

consolidation. A significant factor in this differential is that hospitals receive annual, inflation-based updates while physicians do not. This needs to be addressed, and we urge the Agency to work with Congress to establish a permanent annual increase in the PFS tied to the Medical Economic Index.

ASCP recommends against adopting the Agency's proposal to reduce the portion of facility PE RVUs that are allocated based on work relative value units (RVUs) to half the amount allocated to non-facility PE RVUs. We note that the current indirect PE RVU methodology already accounts for site-of-service differences and the proposed changes risk disproportionately impacting certain specialties.

E. Payment for Software as a Medical Device and Advanced Digital Health Technologies

In the proposed rule, CMS discusses recent developments in the use of software-based technologies to support clinical decision-making in outpatient and physician office settings. CMS describes these software-based technologies as "software as a service (SaaS)." The agency notes that the rapid adoption of these services has created a problem for CMS's practice expense (PE) methodology, as these "innovative applications are not well accounted for in [the Agency's] PE methodology."

ASCP greatly appreciates CMS's interest and initiative to develop a way to provide reimbursement for the use of emerging software-based technologies. Such technologies, from digital pathology to AI-enabled diagnostics, are evolving at a rapid pace and promise great improvements in patient care. Whether developed internally or provided by a third party, reimbursement is essential for the continued development and adoption of these technologies. The pathology and laboratory community are acutely aware that the lack of an appropriate reimbursement mechanism to pay for these technologies can have a dampening effect on the market for developing and adopting these technologies, such as has been the case for multiple analyte algorithmic assays.

SaaS technologies used in connection with services reimbursed under the CLFS should be reimbursed under the existing processes for valuing new services on the CLFS, such as the gap-fill and cross-walking processes. For those services specific to services reimbursed under the PFS, ASCP urges CMS to work with the AMA RUC in identifying appropriate costs and payment for these developing technologies. That said, given budget neutrality concerns for the physician fee schedule, we concur with the AMA that these services should not be reimbursed under the PFS but under a separate benefit category. We are concerned that these new technologies could adversely impact payment for physician

services. Such an approach could be analogous to how CMS handles physician-administered drugs paid under Part B and for payment of durable medical equipment.

Lastly, ASCP also wishes to address the nomenclature used for this issue: Software as a Service. As the Agency is likely aware, the U.S. Food and Drug Administration (FDA) uses a similar term, Software as a Medical Device, over which FDA maintains it has broad oversight authority. The Agency's authority over software has its limits, however. For example, Section 3060(a) of the 21st Century Cures Act (Cures Act) removed certain software functions, such as "off-the-shelf software used in medical devices," from FDA's definition of a medical device. We are concerned that adopting FDA's terminology could lead to confusion, possibly resulting in unintended consequences that could result in certain medical services being unable to secure reimbursement if not specifically approved by FDA. ASCP believes using a different nomenclature than FDA's to describe these services would better support the adoption of these technologies within medicine.

F. Potentially Misvalued Services: Fine Needle Aspiration

The Agency received several public nominations for potentially misvalued services for CY 2026, one of which was fine needle aspiration (FNA) (CPT 10021, 10004-10006). The nominator requested that CMS reevaluate the FDA code family, questioning the fundamental basis of CMS' 2019 work RVU reductions for FNA procedures. While the RUC had recommended work RVUs of 1.20 for CPT code 10021 and 1.63 for CPT code 10005, CMS instead implemented lower values of 1.03 and 1.46, respectively.

CMS is not proposing any changes to these codes, which were last re-evaluated in 2019. In considering the request, CMS notes that these codes have undergone multiple recent reviews. In addition to its 2019 review of these codes, they were nominated as potentially misvalued in both the CY 2020 and 2025 PFS proposed rules. ASCP agrees with CMS's view that these codes are not misvalued.

G. Merit-based Incentive Payment System (MIPS)

On January 31, 2025, President Trump issued an Executive Order, titled, "Unleashing Prosperity through Deregulation," to promote prudent financial management and alleviate unnecessary regulatory burden. ASCP believes that this directive should encourage the Agency to simplify the complicated rules and requirements that define an ineffective MIPS program. Despite being implemented in 2017, MIPS has yet to demonstrate improved health outcomes for Americans or lower avoidable spending. The program involves

excessive compliance costs for physicians. It also disproportionately hurts small and rural practices, by cutting their Medicare reimbursement up to 9 percent.

ASCP appreciates that CMS has been responsive to requests from the medical community for the following improvements to MIPS:

- Maintaining the performance threshold at 75 points for the next three performance periods (until the CY 2028 performance period/2030 payment year) to provide continuity and stability to physicians.
- Updating the benchmarking methodology used for calculating administrative claims-based quality measures to align with the benchmarking methodology used for cost measures. We recommend that CMS apply this approach to ALL quality measures, not just administrative claims measures.
- Adding electronic clinical quality measure (eCQM), *Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes*, which aligns with the Administration's focus on disease prevention and empowering individuals to engage in lifestyle change behaviors as part of their overall wellness.
- Refining the Total Per Capita Cost (TPCC) measure attribution methodology.
- Creating a two-year informational-only period for new cost measures, which helps ensure physicians have an opportunity to review and, if necessary, improve their performance on new measures before they are held accountable for them.
- Aligning with recommendations for an alternative framework for structuring MIPS Value Pathways (MVP) by proposing "Clinical Groupings" within MVPs.

MIPS Value Pathways: CMS has developed six new MIPS Value Pathways (MVPs), including one for Pathology. ASCP appreciates CMS's leadership here. Given past concerns with the ability of pathologists to meaningfully participate in MIPS, we hope that the new MVP will ease the burden on pathologists of demonstrating the value they bring to patient care. In line with that concern, however, ASCP urges the Agency to incentivize the reporting of this and other MVPs, rather than mandate them. Moreover, we recommend that CMS not sunset the traditional MIPS program. We look forward to continuing to work with the Agency to enable meaningful participation by pathologists.

Lastly, we note that Congress recognized the value of providing continuous feedback and the use of digital tools by physicians and practices by encouraging the use of private sector funded and physician-led qualified clinical data registries (QCDRs) to satisfy MIPS requirements. Utilizing specialty-led QCDRs provides an opportunity to evaluate care across an entire specialty, as well as at the individual physician level. The lack of a viable QCDR option due to numerous obstacles erected by CMS is unfortunate because capturing data through a registry allows for its collection and tracking across various settings and disease states. As a result, physicians are forced to use less clinically

meaningful measures and do not receive appropriate recognition for their registry activities, thus reducing the opportunity for quality improvement. ASCP urges CMS to eliminate these barriers and fully recognize the role of specialty-led QCDRs as a cornerstone of meaningful, clinically relevant quality improvement.

ASCP appreciates this opportunity to provide these comments. If we can be of any assistance on this matter, please do not hesitate to contact me or Matthew Schulze, Senior Director of the ASCP Center for Public Policy, at matthew.schulze@ascp.org.

Sincerely,

Gregory N. Sossaman, MD, MASCP
President, ASCP