COLLEGE of AMERICAN PATHOLOGISTS

August 28, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1850-P
P.O. Box 8010
Baltimore, MD 21244–8010

Submitted electronically to: http://www.regulations.gov

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots (CMS–1850–P) Docket RIN 0938-AV83

Dear Administrator Oz:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the hospital outpatient prospective payment and ambulatory surgical center payment systems (OPPS) proposed rule CMS-1850-P for calendar year 2027. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians whose diagnoses drive care decisions made by patients, primary care and specialist physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value are recognized throughout the care continuum and affect many patient encounters.

Summary of Recommendations

1. OPPS Payments for SaMS Diagnostic Services – The CAP opposes removal of SaMS technologies from the Clinical Laboratory Fee Schedule. Algorithm-only analyses performed on laboratory data should remain classified as clinical laboratory services and continue to be paid under the Clinical Laboratory Fee Schedule (CLFS) until an appropriate long-term payment solution is reached that remains budgetarily separate from the OPPS but also reflects the value, rather than the pricing, that these technologies contribute to diagnosis, treatment planning, and patient outcomes. The CMS should engage with stakeholders including the CAP regarding the nuances and complexities of algorithmic technologies within the pathology and laboratory health care space.

2. Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data – CMS should retain a meaningful definition of "shoppable" that focuses on services patients can reasonably select and schedule in advance; preserve flexibility for price estimator tools; and recognize that the final combination of many pathology services and their associated costs may not be reasonably predictable in advance. Doing this will better ensure that transparency requirements empower patients without creating confusion, imposing unnecessary administrative burden, or inadvertently hindering timely access to medically necessary care.

3. Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines – the CAP is supportive of strengthening the supply chain of domestically made products since pathologists were on the frontlines of the supply shortages during the COVID pandemic and believe that laboratory supplies should be added to this initiative. Adding critical laboratory supplies not only helps build the domestic supply chain more but will benefit the country during the next public health emergency since pathologists will be the first physicians to test for these pathogens. Extending the initiative to all clinical laboratories – not only those that operate as hospital departments – will help strengthen our public health preparedness and add potential value to domestic PPE production.

OPPS Payments for SaMS Diagnostic Services

1. Payment for Software as a Medical Service (SaMS)

In the proposed rule, CMS recognizes the rapid development and increasing use of software-based technologies that perform analyses of data, including diagnostic images, through complex algorithms and statistical predictive modeling to support diagnosis and treatment planning. CMS proposes to replace the term Software as a Service (SaaS) with Software as a Medical Service (SaMS) to avoid ambiguity and to better reflect the clinical context in which these technologies are used. **The CAP supports CMS's proposed terminology change from Software as a Service (SaaS) to Software as a Medical Service (SaMS) and urges CMS to finalize this proposal. This terminology more accurately reflects the medical nature of these services and appropriately distinguishes SaMS from commercial software products that are not furnished as part of patient care.**

As CMS works toward developing a comprehensive and consistent approach to payment for SaMS, the agency seeks a payment strategy that aligns with its mission to increase quality, improve health, reduce costs, and strengthen the health care system. The CAP appreciates CMS's acknowledgement that current Medicare Part B payment systems, including those proposed for SaMS, were designed primarily to pay for services that rely on material resources rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. Appropriate valuation methodologies for SaMS are challenging because the pricing and costs of these technologies are tied to the value and clinical outcomes they provide to patients and clinicians. These considerations raise questions about whether SaMS technologies are appropriately paid under existing Part B payment systems and suggest that CMS should explore a distinct payment framework based on patient and clinician value as a longer-term solution. The CAP believes the use of SaMS technologies in the

United States health care system will continue to grow and may increase substantially, placing additional strain on Medicare Part B payment systems. Medicare Part B payment systems were not designed to value technologies whose clinical utility is driven by proprietary algorithms, data interpretation, and scalable non-material costs, rather than by such traditional inputs as supplies, equipment, or facility resources. The CAP is concerned that attempting to force SaMS into legacy payment structures risks undervaluing these services as well as diluting the valuation of more traditional services, all of which provide meaningful clinical value to patients and treating physicians. **CMS should not adopt policy changes until it has fully evaluated the clinical, operational, and regulatory implications of implementing these new technologies, with direct input from relevant stakeholders including the CAP. Algorithm-only analyses performed on laboratory data should remain classified as clinical laboratory services and continue to be paid under the CLFS until an appropriate long-term payment solution is reached, which does not require budget neutrality or beneficiary cost-sharing. The CAP urges CMS to move expeditiously toward a durable, transparent, and clinically appropriate payment framework for SaMS that remains budgetarily separate from the OPPS, but also reflects the value, rather than the pricing, that these technologies contribute to diagnosis, treatment planning, and patient outcomes.**

For CY 2027, CMS proposes an interim payment policy that would assign SaMS technologies to new technology APCs, and designate 36 HCPCS codes as SaMS services. CMS further proposes to reassign designated SaMS services that are currently paid separately under clinical APCs with status indicator “S”, to new technology APCs that closely align with their current CY 2026 payment rates. **The CAP supports this interim approach for CY 2027, but only because the existing clinical APC structure does not adequately accommodate SaMS technologies. This interim policy can not substitute for development of a comprehensive long-term payment framework that does not implicate budget neutrality or beneficiary cost-sharing. CMS should make clear that reassignment to new technology APCs is a temporary measure while the agency develops a payment approach that is budgetarily separate from the OPPS, but also recognizes the clinical value, technical complexity, and evolving use of SaMS.**

CMS also proposes to create status indicator “O1” for SaMS technologies and to assign all services CMS proposes to designate as SaMS to that status indicator, with the same payment specification as status indicator “S,” to allow separate payment. **The CAP supports creation of status indicator “O1” for CY 2027, with the proviso that this preserves separate payment and does not constitute a pathway for future reductions, packaging, or discounting that would undermine patient access to these services. CMS should finalize this policy as an explicitly interim step, and should pair it with a clear process for development of an appropriate long-term payment mechanism.**

CMS requests comment on whether a new status indicator with the same specification as status indicator “T,” which would subject SaMS services to multiple procedure discounting, would provide more appropriate payment while addressing potential program integrity concerns. **The CAP opposes any policy that would arbitrarily subject SaMS technologies to multiple procedure**

discounting. Such an approach would be inappropriate for algorithmic medical services and would reduce payment for services that may be clinically distinct, independently necessary, and integral to patient diagnosis or treatment planning. CMS should not address speculative program integrity concerns through prospective across-the-board payment alterations that would constrain access to emerging medical technologies. The CAP also opposes unconditional packaging of SaMS services because such packaging, by failing to distinguish the value of the individual services, would obscure payment and create avoidable disruptions in patient access.

CMS indicates that its interim policies are intended to minimize disruption to patient care while the agency considers more comprehensive payment policies for SaMS technologies. CMS therefore proposes to maintain the current clinical APC and status indicator assignments for certain codes. **The CAP urges CMS to finalize its proposal to maintain the current OPPS status indicators for these services. Maintaining these assignments is necessary to avoid gratuitous disruption while CMS evaluates appropriate approaches for SaMS payment.**

2. SaMS Analyses Performed on Laboratory Tests

Within this proposed ruling CMS acknowledges the growth of distinct algorithmic analyses performed alone, apart from laboratory analyses. The CMS refers to these analyses as subsequent stand-alone algorithmic analyses that are separate from a CLIA certified laboratory's examination of human material, or "SaMS laboratory analyses performed on laboratory tests." These analyses are treated as clinical diagnostic laboratory tests (CDLTs) and are paid under the Clinical Laboratory Fee Schedule (CLFS).

Medicare only pays for CDLTs under the CLFS when they are furnished by laboratories that meet applicable CLIA certification requirements. CMS believes that because SaMS laboratory analyses performed on data generated by a prior laboratory test can be performed by any non-regulated entity with computer software, an entity that performs only algorithmic analyses of previously sequenced data may not qualify as a CLFS laboratory or require a CLIA certification. CMS therefore believes SaMS do not meet the statutory framework for required payment as CDLTs under the CLFS.

Based on this definition, CMS identified 10 HCPCS codes (Table 62) currently paid under the CLFS that it determined qualify as SaMS laboratory analyses performed on laboratory tests and proposes to not pay for them under the CLFS, but to use the latest available CLFS data to crosswalk them to new technology APCs under the OPPS. **The CAP opposes removal of SaMS technologies from the Clinical Laboratory Fee Schedule. Algorithm-only analyses performed on laboratory data should remain classified as clinical laboratory services and continue to be paid under the CLFS until an appropriate long-term payment solution is reached through the engagement with stakeholders including the CAP, regarding the nuances and complexities of classifying algorithmic technologies within the pathology and laboratory health care space.**

Within this proposal the CMS states that payment rates would closely approximate the current CY 2026 CLFS payment rates for these codes. CMS identified these services by reviewing the applicable

code descriptors to determine whether they describe laboratory methods and only an algorithmic analysis was described. The CMS, for CY2027, also proposes to assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPPS. **The CAP has a particular concern with CMS's inclusion of CPT code 81416 on Table 62 as a SaMS laboratory analyses performed on laboratory tests. CPT code 81416 requires the laboratory to perform next-generation sequencing (NGS) on the patient specimen in addition to the subsequent analysis. Accordingly, CPT code 81416 does not meet CMS's definition of a SaMS laboratory analysis performed on a laboratory test, and the CAP recommends that CMS remove the service from the proposed list. Additionally, CMS should recognize that CPT code 0208U was deleted from CPT in January 2022. The remaining 8 codes should continue to be paid through the CLFS rather than being crosswalked to new technology APCs under the OPPS.**

The CMS should recognize that these SaMS laboratory analyses performed on laboratory tests are typically ordered by but not performed by physicians and therefore should not be part of the Part B payment for OPPS services. **The CMS should recognize that pricing algorithm-only analyses performed on laboratory data on the OPPS under the APC system is not an appropriate mechanism to reimburse services that are not performed by physicians. Algorithm-only analyses performed on laboratory data should remain classified as clinical laboratory services and continue to be paid under the CLFS until an appropriate long-term payment solution is reached.**

CMS also suggests that, unlike the OPPS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, and that this may limit pricing transparency or create challenges in ensuring appropriate valuation. **The CAP requests that CMS provide an explanation of how shifting these services from the CLFS to the OPPS would enhance pricing transparency or valuation. The presence of beneficiary cost-sharing or budget neutrality adjustments does not demonstrate that the OPPS is a more appropriate payment system for SaMS laboratory analyses performed on laboratory tests. Indeed, the opposite is sufficiently plausible that shifting this type of service to a budget-neutral, cost-sharing program could create the appearance of seeking to shift costs from the government to beneficiaries and providers, contrary to Congressional intent. Section 1833(a)(1)(D) provides that payment for clinical laboratory tests paid under the CLFS may be made at 100 percent on an assignment-related basis, eliminating beneficiary liability. CMS should not use features of the OPPS as a rationale for removing services from the CLFS without demonstrating that the change would improve payment accuracy, protect patient access, and preserve appropriate clinical oversight. Congress deliberately established the CLFS as a payment system in which laboratory testing does not generally involve beneficiary cost-sharing, while the OPPS generally subjects services to beneficiary copayments and budget-neutral redistribution of payments.**

Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

The CAP appreciates CMS's ongoing efforts to improve the accessibility and usefulness of hospital price transparency information for patients. Pathologists understand how access to price information prior to services can be useful for patients, and we support the Administration's goal of ensuring patients are empowered with meaningful price information when making health care decisions. At the same time, the CAP has consistently stressed the significant difficulty in determining the cost of many pathology services in advance of those services being provided by pathologists. The type of specimen, complexity of the analysis, and need for additional testing are often not known in advance of the initial analysis conducted by the pathologist. As a result, the final combination of pathology services and their associated costs may not reasonably be predictable at the time a patient is attempting to compare prices.

The CAP would again emphasize that while efforts to increase access to price information are important, transparency initiatives are most effective when the information provided is understandable and useful to patients. Providing large volumes of pricing data without appropriate clinical context may create a false sense of precision, confuse patients, or make it more difficult for patients to identify the information most relevant to their care. Indeed, CMS has recognized that the comprehensive machine-readable file (MRF) in particular is not a resource for patients, but for "employers, researchers and innovators, who may be leveraging the data with the goal of stimulating competition, generating new insights, and driving down healthcare costs."

Therefore, as CMS evaluates whether to revisit the number and types of CMS-specified shoppable services, we encourage the agency to remain focused on the original purpose of shoppable services: providing actionable information regarding services that patients can reasonably select and schedule in advance, and for which meaningful comparison shopping may occur. While it may be necessary to update this list to provide the most helpful and up-to-date information, indiscriminately increasing the number of required shoppable services could undermine the very purpose of the consumer-friendly display. Excessive information can overwhelm patients, reduce usability, and make it more difficult for patients to identify the information most relevant to their care.

The CAP also encourages CMS to retain flexibility for hospitals that make available price estimator tools. Price estimator tools can provide information that is considerably more useful to an individual patient because they may account for the patient's insurance coverage, benefit design, deductible status, coinsurance, and other factors that materially affect actual out-of-pocket responsibility. Eliminating deemed compliance for price estimator tools could create burdensome requirements for hospitals while providing little value to patients.

Finally, the CAP supports transparency around what services are and are not included in the price displayed, but we are concerned about any requirement to post more comprehensive information, such as "standard service packages, inclusive of standard codes and ancillary services." As is stated above, there is significant difficulty in determining the cost of many pathology services in advance of services being provided by pathologists. Transparency requirements should not require hospitals or physicians to

predict services or pricing before the diagnostic evaluation has occurred or create an expectation that medically necessary additional testing will be included within an initial estimate. As is currently the case, CMS should instead continue to recommend and encourage hospitals to indicate that services may be billed separately by other entities involved in the patient's care.

The ultimate goal of hospital price transparency should be to provide consumers with clear, understandable, and actionable information that supports informed health care decisions while avoiding unnecessary burden, confusion, or barriers to timely patient care. **In particular, CMS should retain a meaningful definition of "shoppable" that focuses on services patients can reasonably select and schedule in advance; preserve flexibility for price estimator tools; and recognize that the final combination of many pathology services and their associated costs may not reasonably be predictable in advance**. Doing so will better ensure that transparency requirements empower patients without creating confusion, imposing unnecessary administrative burden, or inadvertently hindering timely access to medically necessary care.

Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

The CAP is supportive of CMS identifying options for domestically made PPE products to strengthen the domestic supply chain. We would like to note that there are additional, important PPE items to consider, including (but not limited to) face shields, goggles, respirators, gloves, isolation gowns, shoe coverings, hair nets, beard covers, and bouffant caps. We also encourage CMS to include laboratory supplies in its consideration of “critical medical supplies” as a vital part of emergency public health preparedness for the American people. The CAP thanks CMS for the new types of products that would be recognized within the Medicare program and increase payments for healthcare organizations that purchase from US manufacturers. Many types of PPE and critical laboratory supplies are essential to ensuring safe, high-quality patient diagnosis, care, and pathology practice, particularly during a public health emergency.

Pathologists know firsthand the implications of supply shortages during public health emergencies. During the COVID-19 pandemic, the CAP appreciated working collaboratively with CMS to address supply chain issues using bilateral communication, and the CAP believes in fostering a more resilient domestic supply chain to ensure clinical laboratories have the necessary supplies throughout any future public health emergency. Though the proposed rule does not specifically address laboratory supplies for emergency public health preparedness, the CAP urges CMS to add laboratory supplies to this initiative. During the COVID pandemic, clinical laboratories experienced shortages of the following supplies: pipettes, glass slides, “blue-top” test tubes, specimen acquisition swabs, and transport media. Of note, any items purchased must be of the quality required to perform the specific laboratory function. Including clinical laboratory-related PPE and critical laboratory supplies in the initiative will likely lead to more hospitals being able to participate.

The CAP also strongly encourages CMS to consider including in this initiative all types of clinical laboratories, not only clinical laboratories that operate as hospital departments. Through research done by the CAP, about 11% of pathologists work in independent laboratories, which amounts to a large

number of laboratories that could help strengthen the supply chain. Clinical laboratories are a crucial component of emergency public health preparedness for the testing of many viruses, bacteria, and fungi. Including all types of clinical laboratories in eligibility for the potential options under consideration is the best way to ensure breadth of preparedness, and to further the development of domestically made PPE and critical laboratory supplies.

It is important for hospitals and laboratories to be able to easily discern which products will be labeled as "domestically made". The CAP agrees that the CMS should determine which products will qualify for this program using the terms put forth in the Make PPE In America Act. Also, it will help discern the products that qualify using standards such as NIOSH-approved filtering face piece respirators that demonstrate compliance with the American Society for Testing and Materials (ASTM) Respirator Fit Capability Standard; domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards; and domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards. This will help hospitals and laboratories better understand which products qualify.

For CMS to facilitate this program, we believe that attestation would be sufficient, and CMS could audit selected laboratories to ensure compliance. This would be the easiest way for hospitals and laboratories to participate with the least burdensome requirements and encourage wider participation in the program. Once CMS has finalized the list of items that will be included in this program, they should work collaboratively with stakeholders to develop what threshold must be met and the additional funding that will be provided when a facility exceeds the target threshold. The CAP would be pleased to work with the CMS on implementation in clinical laboratory settings.

We also appreciate that CMS recognizes the burden that reporting could place on hospitals and laboratories and is looking to use processes already in place. In the proposed rule, CMS gives two options for determining the payment to hospitals for the differential cost of buying domestically made PPE. The CAP believes that Approach 1, the claims-based approach, would be the least burdensome option, rather than the cost-report payment approach. Automatically calculating and paying the separate payment adjustment, based on the amount of eligible domestic PPE used in furnishing services during a hospital stay, that a hospital voluntarily bills on the claim for that stay, reduces the work that the hospital would do to receive the additional funding. Along with three new billing codes that would be developed for each approved product, we would ask that the CMS would also create billing codes that apply to laboratory equipment.

Overall, the CAP is supportive of strengthening the supply chain of domestically made products since pathologists were on the frontlines of the supply shortages during the COVID pandemic, and believe that laboratory supplies should be added to this initiative. Adding critical laboratory supplies not only helps build the domestic supply chain, but will benefit the country during the next public health emergency, since pathologists will be the first physicians to test for the pathogens. Extending the initiative to all clinical laboratories – not only those that operate as hospital departments – will help strengthen our public health preparedness and add to the potential value of domestic PPE production.

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The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions on these comments to; Todd Klemp at tklemp@cap.org or Elizabeth Fassbender at efassbe@cap.org, or Andrew Jackson at ajackso@cap.org.

Sincerely,

Qihui “Jim” Zhai, MD, FCAP
President, College of American Pathologists