COLLEGE of AMERICAN PATHOLOGISTS

September 14, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1848-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; CY 2027 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 [CMS–1848–P] RIN 0938–AV82

Dear Administrator Oz:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making on the revisions to Medicare payment policies under the Medicare Physician Fee Schedule (PFS) for 2027, published in the July 16, 2026, Federal Register (Vol. 91, No. 135 FR, pages 43842-44557).

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.

The following sections provide detailed comments on the specific topics addressed in the proposed rule, including:

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11. Strategies to Improve Payment Transparency, Accuracy, and Congruency Across Payment Systems
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1. Priority Recommendations

The CAP has concerns regarding several proposals that could adversely affect pathology and laboratory medicine. While more detailed comments are provided in the subsequent sections, the priority CAP recommendations include:

MHCC Request for Revaluation of Physician Work Time Based on Empiric [Claims] Data (CPT codes 88305 and 88307):

The CAP urges CMS not to revise the physician times or work RVUs for CPT codes 88305 and 88307 or any other codes in the CPT code 88305 family for CY 2027. The CPT code 88305 family encompasses heterogeneous pathology services that are essential to diagnosing cancer and other serious diseases. Any changes to the physician times or work RVUs for these services require careful, clinically informed evaluation. The MHCC's analysis does not establish that these codes are misvalued because it does not account for the heterogeneity of these services or evaluate the time and intensity of the typical service, and it raises unresolved issues involving claim attribution and dates of service that may distort its specialty and provider-day findings. Likewise, the Urban Institute's two-minute estimate, which was based on a small convenience sample and acknowledged methodological limitations does not provide a reliable basis for revaluation. At most, these data raise questions warranting further evaluation; they do not establish that the codes are misvalued or identify the source of the apparent discrepancy. If CMS determines that further review is warranted, the Agency should adhere to the established potentially misvalued code and public comment process. If that review indicates that physician time or work requires reconsideration, the RUC provides the appropriate clinically informed process for that evaluation.

Software as a Medical Service (SaMS) Laboratory Analyses:

The CAP urges CMS not to finalize its proposal to remove SaMS laboratory analyses performed on laboratory tests from the CLFS. Regarding SaMS technologies more broadly, CAP commends CMS on its recognition of the distinctive characteristics of these services but urges CMS also to recognize that SaMS technologies are distinct from physician services, do not share a valuation basis with physician services, and should not compete with physician services for statutorily constrained PFS resources. Instead, CMS should work with

stakeholders to develop a dedicated payment framework that is budgetarily separate from the PFS and avoids inappropriate effects on physician payment. Such a framework should promote cost transparency without shifting financial burden to physicians, other practitioners, or beneficiaries, while supporting sustainable reimbursement, investment, and adoption.

2. **Maryland Health Care Commission (MHCC) Request for Revaluation of Physician Work Time Based on Empiric [Claims] Data (CPT codes 88305 and 88307)**

The MHCC nominated 13 CPT codes as potentially misvalued, including CPT codes 88305 and 88307. Using data from the 2023 Maryland All-Payer Claims Database (MD-APCD), MHCC suggested that the physician times and work RVUs assigned under the PFS may not accurately reflect clinical practice and recommended that CMS review all codes in the CPT code 88305 family. CMS is seeking comments on whether it should revise the physician times for these services for CY 2027 or in future rulemaking and whether any revisions should be accompanied by corresponding changes to the work RVUs.

The CAP urges CMS not to change the physician times or work RVUs for CPT codes 88305 and 88307 or any other codes in the CPT code 88305 family for CY 2027. The CPT code 88305 family encompasses heterogeneous pathology services involving a wide spectrum of specimen types and clinical diagnoses across multiple organ systems. These services are essential to diagnosing breast, lung, colorectal, hematolymphoid, and other malignancies, as well as other serious diseases. Any changes to the physician times or work RVUs for this code family therefore require careful, clinically informed evaluation. The MHCC analysis does not provide such evaluation.

<u>The MHCC Analysis Does Not Account for Service Heterogeneity or Evaluate the Time and Intensity of the Typical Service</u>

CPT code 88305 includes 63 specimen types in its descriptor, while CPT code 88307 includes 39. MHCC does not describe the services represented among the provider days exceeding its thresholds. Therefore, it is not possible to determine the extent to which its findings reflect a typical distribution of services reported under these codes or are restricted to a limited subset with particular characteristics.

MHCC's concerns focus on only a small fraction of the provider-days analyzed. MHCC identified 1,763 provider-days on which the cumulative intraservice time associated with CPT code 88305 exceeded eight hours, representing 2.9 percent of the 60,221 provider-days analyzed. Provider-days exceeding 24 hours accounted for less than 1 percent. For CPT code 88307, MHCC identified 40 provider-days, or 0.4 percent, exceeding eight hours. MHCC also does not report the number or percentage of billers associated with these apparently aberrant provider-days. Without information regarding the services or billers

responsible for these observations, it is not possible to determine whether they reflect a broader issue with the service as typically provided or isolated circumstances with particular explanations.

Specimen heterogeneity affects not only the time required to furnish these services but also their intensity. Section 1848(c)(1)(A) of the Social Security Act requires physician work RVUs to reflect both physician time and intensity. Dr. William Hsiao's foundational research underlying the resource-based relative value scale similarly recognized that relative valuation requires the combined and simultaneous consideration of physician time and intensity, as reflected in the overall physician work associated with a service. MHCC, however, makes no effort to evaluate service intensity and instead examines cumulative time alone.

MHCC neither demonstrates that the provider-days exceeding its thresholds are representative of the typical CPT code 88305 or 88307 service nor evaluates the intensity required to furnish these heterogeneous services. Therefore, its analysis cannot establish that the physician times or work RVUs associated with the typical service are inaccurate.

Unresolved Claim-Attribution Issues May Distort Specialty and Provider-Day Findings

MHCC points to the "regular" billing of CPT codes 88305 and 88307 by gastroenterologists and dermatologists as a basis for suggesting that these services may be misvalued. The CAP's review of the CMS *CY 2025 PFS Final Rule 2023 Utilization Data Crosswalked to 2025* file indicates that dermatologists accounted for 12.7 percent of CPT code 88305 utilization billed globally or for the professional component, while gastroenterologists accounted for 0.5 percent. The apparent difference between MHCC's characterization and the CAP's findings may reflect a relatively low threshold for what MHCC considers "regular" billing overrepresentation of dermatologists and/or gastroenterologists in the claim subset in question, or methodological differences in how MHCC identified and attributed services to providers. MHCC does not define "regular," report the number of physicians involved, or describe the distribution of provider-days across specialties, making it impossible to determine the reason for this apparent discrepancy.

The possibility of methodological differences raises a broader concern regarding MHCC's provider-day calculations. Under Medicare reassignment rules, a physician may authorize another eligible physician or entity to submit claims and receive Medicare payment for services the physician personally performed. As a result, the physician or entity identified for billing and payment purposes may not be the physician who personally performed the service.

This indeterminacy is compounded by the composition of the MD-APCD, which combines Medicare, Medicaid, and commercial claims data. Requirements for reporting provider

identifiers, as well as the completeness and consistency of those identifiers in data submitted to the MD-APCD, may differ among payers. MHCC does not explain how it addressed these differences or verified that the rendering physician was consistently identified across all payers.

MHCC does not provide sufficient information for the CAP to determine whether its calculations distinguish the physician who personally performed a service from another physician or entity that billed and received payment for the service, whether through Medicare reassignment or under an organizational NPI. If MHCC attributed services to another physician or entity that billed and received payment through Medicare reassignment, or to an organizational NPI, the services may have been attributed to the physicians who did not personally perform them. This could combine services performed by multiple physicians into a single provider-day, overstate utilization attributed to certain specialties or providers, and produce apparently excessive cumulative service times that reflect pathology billing and payment arrangements rather than the work performed by any individual physician.

Claim Dates of Service May Not Reflect When Pathology Services Were Actually Performed

A separate concern is how MHCC determined the day on which the physician work occurred. MHCC does not provide sufficient information regarding this aspect of its provider-day methodology. In pathology, the date of service reported on a claim may not correspond to the day or days on which the pathologist performs the professional work because pathology-specific billing rules govern the date reported on the claim.

It is therefore important to distinguish between the claim date of service and the date of sign-out. The claim date of service is the date reported for billing purposes, while the sign-out date generally reflects when the pathologist completed, authenticated, and released the pathology report. Furthermore, the work necessary to complete the analysis and report almost always occurs over multiple days, with the sign-out date generally being a better, though still incomplete, indicator of when bulk of the professional work was performed than the date the specimen was obtained from the patient.

If the MD-APCD does not include pathology report sign-out information or another reliable measure of when the professional work occurred, MHCC would not have been able to calculate accurate provider-day totals. Reliance on claim dates of service could concentrate work performed over multiple days onto a single provider-day, assign work to the wrong day, and produce apparently excessive cumulative service times. This methodological limitation further calls into question whether MHCC's provider-day totals provide a reliable basis for evaluating the physician times assigned to CPT codes 88305 and 88307.

The Urban Institute's Acknowledged Unreliable Two-Minute Estimate Cannot Support Changes to Physician Time or Work RVUs

For CPT code 88305, MHCC relies on a 2016 Urban Institute study that reported a median observed intraservice time of two minutes. However, the study identified CPT code 88305 as a highly heterogeneous service and acknowledged that its small observed sample likely did not capture the time necessary to perform all elements of the service. The authors explained that CPT code 88305 may involve one or multiple tissue samples and that the required elements vary depending on the nature of the request and tissue source.

The two-minute median was derived from 23 direct observations in a convenience sample from three health systems. The authors cautioned that the sample should not necessarily be viewed as representative. The study also identified limitations involving service volume, code identification, consistent observation, and quality control.

The Urban study did not include clinical review by pathologists to determine whether the observed services reflected the range of work typically reported under CPT code 88305 or whether the resulting estimate captured all relevant elements of the professional service.

Given the heterogeneity of CPT code 88305 and the Urban Institute study's small convenience sample, lack of documented expert clinical review, and acknowledged methodological limitations, the two-minute estimate cannot be assumed to represent the intraservice time required for the typical CPT code 88305 service. CMS should not rely on the estimate when considering whether changes to physician time or work RVUs are warranted.

CMS Should Not Revise the CPT Code 88305 Family Without a Clinically Informed Review and Meaningful Public Comment

As noted at the outset, any changes to the physician times or work RVUs for this clinically important code family require careful, clinically informed evaluation. MHCC's analysis does not meet that standard. Nevertheless, CMS raises the possibility of revising the code family for CY 2027 without proposing specific changes to the physician times or work RVUs for CPT codes 88305 and 88307 or any other codes in the CPT code 88305 family.

As established in the CY 2015 PFS final rule, page 67608, the potentially misvalued code process includes CMS publishing a proposal and providing a meaningful opportunity for "public comment before establishing final values for the codes." This process is particularly important for clinically heterogeneous services with significant implications for patient care. CMS should not circumvent this established process by finalizing revisions that stakeholders have not had an opportunity to evaluate and address.

The CAP urges CMS not to revise the physician times or work RVUs for CPT codes 88305 and 88307 or any other codes in the CPT code 88305 family for CY 2027. For the reasons discussed above, the MHCC's limited analysis and the Urban Institute's acknowledged unreliable two-minute estimate do not establish that these codes are misvalued or identify the source of the apparent discrepancy. At most, these data raise questions warranting further evaluation. If CMS determines that further review is warranted, the Agency should adhere to the established potentially misvalued code and public comment processes. If that review indicates that physician time or work requires reconsideration, the RUC process provides the appropriate clinically informed and comparative process for evaluating the time and intensity of the typical service and its relativity to other services across the PFS. As a member of the RUC, the CAP stands ready to provide the pathology expertise necessary to support an accurate evaluation of the physician work involved.

3. Software as a Medical Service (SaMS) Laboratory Analyses

The rapid development of software-based medical technologies, including artificial intelligence, raises important questions regarding how these services should be classified and paid by CMS. Focusing on laboratory services, CMS identifies distinct algorithmic analyses which by themselves produce a clinically actionable test result and are separate from those requiring a CLIA-certified laboratory's examination of human material (i.e., are not clinical laboratory tests as defined in and subject to CLIA regulations). For purposes of this proposal, CMS refers to these stand-alone algorithmic analyses as "SaMS laboratory analyses performed on laboratory tests." CMS believes that SaMS laboratory analyses performed on laboratory tests can be performed by non-CLIA-certified laboratories or other entities and therefore do not meet the statutory framework requiring payment as clinical diagnostic laboratory tests (CDLTs) under the Clinical Laboratory Fee Schedule (CLFS). Therefore, for CY 2027, CMS proposes to transition 10 HCPCS codes described as SaMS laboratory analyses performed on laboratory tests from the CLFS to the PFS.

The CAP urges CMS not to finalize its proposal to remove SaMS laboratory analyses performed on laboratory tests from the CLFS. More broadly, the CAP does not believe that the PFS provides an appropriate payment framework for SaMS technologies.

SaMS technologies are ordered by physicians, but they are not furnished by physicians as professional services. Since physicians do not render or profit from SaMS technologies, SaMS technologies are conceptually more closely aligned with CLFS than with PFS in their budgeting and payment principles. However, neither the PFS nor the CLFS is the ultimate (long-term) payment framework solution for SaMS, performed on laboratory analyses or elsewhere in patient care.

Incorporating SaMS technologies into the PFS would require them to compete with physician services for limited Medicare payment under a budget-neutral system. At the same time, PFS budget neutrality may not provide stable or sustainable reimbursement for the continued development, maintenance, and improvement of these technologies. Both outcomes could adversely affect patient care by undermining physician payment and limiting the development and availability of beneficial new technologies.

The resources associated with SaMS technologies also differ fundamentally from the physician work and practice expense inputs underlying the resource-based PFS. CMS acknowledges that it lacks transparent information regarding the costs of SaMS technologies, particularly their proprietary algorithmic components. Without such information, CMS cannot appropriately and consistently value SaMS technologies under the PFS. CMS's proposal to contractor-price the SaMS laboratory analyses performed on laboratory tests, rather than assign them RVUs, further illustrates their poor fit within the existing PFS methodology. The proposal may also create significant uncertainty for laboratories regarding which professionals are authorized to review and sign out these analyses, including whether sign-out may be performed only by physician laboratorians or also by doctoral level nonphysician laboratory professionals.

Subjecting SaMS technologies to PFS budget neutrality and beneficiary cost sharing would not resolve the lack of cost transparency identified by CMS. The history of Medicare payment for CDLTs and the structure of the CLFS demonstrate that cost containment does not require shifting financial liability to beneficiaries, physicians, or other practitioners. The CLFS generally neither imposes beneficiary coinsurance nor subjects' payment rates to PFS-style budget neutrality. CMS should instead work directly with manufacturers, laboratories, physicians, and other stakeholders to develop mechanisms that address the lack of cost information.

Rather than attempting to adapt existing Medicare payment systems that were not designed for SaMS technologies, the CAP urges CMS to work with stakeholders to develop a dedicated payment framework that appropriately accounts for the distinct characteristics and costs of these technologies and remains budgetarily separate from the PFS. Until such a framework is developed, CMS should not remove the identified services from the CLFS.

CMS should also enhance its process for determining which individual services meet its definition of a SaMS laboratory analysis. The inclusion of CPT code 81416 illustrates the challenges of the current process. CPT code 81416 requires a laboratory to perform next-generation sequencing on a patient specimen in addition to the subsequent analysis. Reliance on the code descriptor alone, therefore, may not fully capture the laboratory resources and processes required to furnish the service. It should also be noted that CPT code 0208U (a Proprietary Laboratory Analyses [PLA], where algorithmic analysis is only

performed and part of the concurrent laboratory analysis), was deleted from CPT in January 2022.

The CAP urges CMS to establish a clinically informed expert process for evaluating whether individual services meet its definition of a SaMS laboratory analysis performed on laboratory tests.

4. Table D-B5 (CY 2027 PFS Estimated Impact on Total Allowed Charges by Specialty)

Table D-B5, CY 2027 PFS Estimated Impact on Total Allowed Charges by Specialty, reports substantial decreases in estimated total allowed charges for pathology and independent laboratories between CY 2026 and CY 2027. For pathology, estimated allowed charges decline from $1.178 billion to $777 million, a reduction of approximately 34 percent. For independent laboratories, estimated allowed charges decline from $551 million to $380 million, a reduction of approximately 31 percent. These decreases affect both facility and non-facility services.

The CAP has been unable to identify any proposal, utilization assumption, or methodological change in the proposed rule that would explain reductions of this magnitude. The reported figures also appear disproportionate to the corresponding estimated payment effects presented in the same table. Because reductions of this size would have significant implications for pathology and laboratory services, the CAP is concerned that the values reported in Table D-B5 may reflect a methodological or reporting error.

The CAP requests that CMS review the pathology and independent laboratory estimates in Table D-B5 and explain the policies, data, and methodology responsible for the reported decreases. If the estimates are erroneous, CMS should promptly publish corrected values so that stakeholders can correctly evaluate the proposed rule's effects before CMS finalizes its policies.

5. Current Procedural Terminology (CPT) Request for Information (RFI)

CMS seeks comment on the continued use of CPT as the national coding standard for physician and other health care professional services. **The CAP supports CPT as a uniform, clinically grounded, and continuously maintained system for describing health care services across payers and settings.**

The CAP respectfully disagrees with characterizing CPT as a monopoly and instead views it as a uniform national standard from which the health care system benefits. Maintaining a single national nomenclature provides concrete advantages to the Medicare program. It establishes a common vocabulary that allows services to be reported consistently across the

health care system, and Medicare claims to be processed, audited, and compared on a uniform basis.

Indeed, pathologists have seen firsthand the challenges that arise from the increasing complexity associated with multiple coding, registration, coverage, and billing requirements simultaneously. For example, the requirement in certain circumstances that molecular pathology claims also contain DEX Z-codes has been disruptive, administratively burdensome, and cost prohibitive for many pathologists and laboratories. For providers and patients, competing coding systems increase billing uncertainty and may delay access to medically necessary diagnostics.

Importantly, the CPT process also incorporates broad clinical input from a range of stakeholders, including national medical specialty societies. As an active participant in this process, the CAP has direct experience contributing pathology expertise to the development and maintenance of codes that accurately describe current medical practice and emerging technologies.

It is also important to preserve the distinctions among coding, coverage, and payment. The CPT Editorial Panel establishes codes to describe services but does not determine Medicare coverage, medical necessity, or payment. Similarly, the RUC recommends the relative resources required to furnish services, while CMS retains sole authority to establish Medicare payment amounts.

Existing alternatives do not serve the same function as CPT. In particular, ICD-10-PCS is designed to classify hospital inpatient procedures and does not describe the full range of physician services across settings. Replacing CPT would create disruption throughout Medicare and the broader health care system in the absence of an alternative capable of performing the same functions.

The CAP supports continued use of CPT as the national coding standard for physician and other health care professional services and encourages CMS to work with the AMA and medical specialty societies to evaluate the existing framework and identify potential improvements.

6. Evaluation and Management (E/M) Visit Complexity Add-On (HCPCS code G2211)

The CAP urges CMS not to finalize either MOD1 or MOD2 as proposed. Neither modifier has been valued based on the physician work and practice expense required to furnish a clearly defined service. If CMS believes additional payment is warranted, it should use established CPT/RUC processes to codify and value the associated resources. Additional support for ACO participation should be provided through the applicable ACO arrangement, and outside the PFS's budget-neutrality framework.

MOD1 Does Not Resolve the Underlying Concerns With G2211

The CAP continues to be concerned that the resources purportedly recognized by HCPCS code G2211 are already accounted for in the valuation of the evaluation and management (E/M) code set. Continuing to pay separately for G2211 risks duplicative payment and increased expenditures that must be offset through PFS budget neutrality. CMS's proposal to replace G2211 with a modifier, referred to in the proposed rule as MOD1, does not resolve these underlying concerns. Applying a percentage-based modifier not tied to identifiable physician work or practice expense would further depart from the resource-based foundation of the PFS.

Although CMS states that MOD1 recognizes resources not captured by the underlying E/M codes, the proposed valuation does not identify or quantify the additional physician work or practice expense involved. CMS derived the 16 percent adjustment to maintain aggregate G2211 spending under the proposed modifier structure, rather than evaluating the resources associated with MOD1 across the various eligible levels of E/M services. This non-resource-based methodology does not provide an adequate basis for assessing the accuracy or relativity of the resulting payments.

The CAP urges CMS not to finalize MOD1 as proposed. If CMS believes that additional payment is necessary, it should clearly define the intended service and use the established CPT and RUC processes to codify and value the associated physician work and practice expense.

CMS Has Not Established a Resource-Based Valuation for MOD2

CMS also proposes MOD2 for eligible participants in the Medicare Shared Savings Program or the LEAD Model. CMS proposes to value MOD2 at 32 percent of the associated E/M visit based on its conclusion that furnishing longitudinal care within an accountable care relationship involves greater complexity and responsibility than furnishing comparable care outside such a relationship.

CMS has not adequately identified or quantified the additional resources required to provide care through an accountable care organization (ACO) to justify the proposed 32 percent adjustment. CMS also does not explain why MOD2 should be valued at twice the percentage rate proposed for MOD1. Allowing eligible practitioners to report MOD2 for both assigned and unassigned beneficiaries further weakens the purported connection between the additional payment and the ACO's accountability for a beneficiary's cost and quality of care.

The CAP urges CMS not to finalize MOD2 as proposed. If CMS believes that higher relative payment is appropriate, it should clearly define the intended service and use

the established CPT and RUC processes to codify and value the associated physician work and practice expense.

ACO Support Should Be Provided Outside the PFS

Any additional resources associated with ACO participation may already be supported through existing ACO incentives. Shared-savings payments are contingent on satisfying applicable quality and financial performance requirements. MOD2 may duplicate that support by providing additional reimbursement through the PFS regardless of ACO performance. **If CMS determines that additional support for ACO-related activities is necessary, the CAP recommends that CMS provide it through the applicable ACO arrangement and outside the PFS's budget-neutrality framework.**

7. **Valuation of Specific Codes for CY 2027 - Fine Needle Aspiration (CPT codes 10005 and 10006)**

Following a specialty society's request to re-review CPT codes 10005 and 10006, the RUC reviewed these services at its January 2026 meeting. The RUC recommended work RVUs of 1.35 for CPT code 10005 and 1.00 for CPT code 10006, along with updated direct PE inputs that included an invoice pricing the portable ultrasound at $83,750.

CMS proposes accepting the RUC-recommended work RVUs and direct PE inputs with one modification. Rather than increasing the price of the existing portable ultrasound item (EQ250), which is used by numerous other HCPCS codes, CMS proposes creating a new "Fine Needle Aspiration portable ultrasound" equipment item (ER130) priced at $83,750 and assigning it to CPT codes 10005 and 10006.

The CAP supports the proposed work RVUs and modified direct PE input and urges CMS to finalize them as proposed.

8. **Updates to Practice Expense (PE) Methodology – Indirect PE**

For CY 2027, CMS is proposing 3 changes to the PE RVU methodology. CMS proposes to:

- Modify step 8 to calculate indirect PE based on both work RVUs and clinical labor RVUs for all services except 010- and 090-day global period codes;
- Remove steps 12 through 17 that rely on the IPCI from the calculation of the PE RVUs over a 2-year transition period, and;
- Add a new step to apply a stabilization adjustment to the PE RVUs (proposed step 19)

Modify step 8

Step 8 of the PE RVU methodology calculates the service-level allocators used to assign indirect PE to individual services. For most services, the indirect PE allocator is based on the service's direct PE RVUs and work RVUs. CMS proposes to modify the allocator to also include clinical labor PE RVUs. The proposed change would apply to all services except those with 010- and 090-day global periods.

The CAP cannot determine whether CMS incorporated the proposed modification into its calculation of PE RVUs for the proposed rule. In the separately published sample Calculation of PE RVUs under Methodology for Selected Codes worksheet, CMS continues to indicate that the second component of the indirect PE allocator for CPT code 99213 is based on the work RVU and does not appear to incorporate the clinical labor PE RVU as proposed.

The CAP urges CMS not to finalize the proposed modification to Step 8. CMS should instead publish expanded documentation and allow stakeholders to fully assess the impact and provide informed comments.

Remove steps 12 through 17

Steps 12 through 17 refer to the Indirect Practice Cost Index (IPCI), which is used to adjust the allocation of indirect PE to recognize differences in practice costs across specialties. CMS believes that the data used to develop the IPCI is outdated and may distort PE allocation. Therefore, CMS proposes to remove the IPCI from the PE RVU methodology over a two-year transition period.

Although CMS has identified concerns with the data used to develop the IPCI, it has not presented evidence demonstrating that eliminating the IPCI will improve the allocation of indirect PE. CMS-commissioned RAND studies of practice expense have emphasized the need to develop improved and recurring sources of practice expense data. Eliminating a data-driven component of the PE methodology without updated data to support an alternative approach appears inconsistent with that objective.

The CAP urges CMS not to finalize the proposed removal of Steps 12 through 17. CMS should first provide evidence demonstrating that the proposed changes would more accurately reflect the indirect PE associated with individual services.

Proposed step 19

CMS proposes to add Step 19 to the PE RVU methodology to mitigate year-to-year volatility in PE RVUs. The proposed stabilization adjustment would generally prevent PE RVUs from increasing or decreasing by more than 5 percent from the prior year. CMS proposes to exclude new, revised, or reviewed codes from the adjustment.

The CAP recognizes the benefits of payment stability and predictability. However, CMS should be careful not to override the accurate revaluation of resources. Increases in PE RVUs may reflect validated changes in resource costs necessary to furnish high-quality patient care.

In addition, a percentage-based stabilization adjustment may result in the unequal recognition of shared direct PE inputs across services. An increase in the cost of a resource may represent a larger percentage change for a service with relatively low PE RVUs. As a result, such a service may be subject to the 5-percent limitation even though the same increase may be fully recognized for a service with higher PE RVUs.

To ensure that direct PE resource costs are fully reflected in PE RVUs, the CAP recommends that CMS exempt increases to direct PE inputs from the stabilization adjustment when supported by higher supply or equipment prices validated through the invoice submission process.

9. Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential

For CY 2026, CMS revised its PE methodology to recognize differences in indirect practice costs across sites of service. Interested parties have argued that a binary site of service distinction cannot adequately account for the variable specifics of physician employment and practice arrangements. In response, CMS is seeking data on the indirect PE costs incurred by hospital-employed and facility-based physicians, including whether the current 50 percent allocation is appropriate or could be lower, potentially as low as zero.

Indirect PE costs incurred by hospital-employed and facility-based physicians

Indirect PE costs do not disappear simply because a physician is employed by hospitals, health systems, or other entities. Physicians may continue to require billing, scheduling, compliance, administrative support, and other professional infrastructure. The responsibility for these costs will vary across the spectrum of employment and contractual arrangements. CMS should not assume that these costs are borne entirely by the hospital under every contractual arrangement. A zero percent allocation would not recognize this variation and could materially undercompensate physicians for the indirect costs associated with furnishing PFS services.

The CAP recommends that CMS not further reduce the current indirect PE allocation for facility services. Given the wide range of employment and contractual arrangements, CMS should not broadly assume that facility-based physicians do not incur indirect costs.

HCPCS modifier to identify employment

CMS is seeking comments on whether to establish a new HCPCS modifier to identify physicians and other professionals employed by hospitals, health systems, or other entities and use the modifier to reduce facility PE payments.

An employment-status modifier would impose an essentially binary classification, not reflective of the variety of employment and contractual arrangements. It would also create a substantial administrative burden, because physicians may have multiple arrangements that change over time.

The CAP urges CMS not to adopt an employment-status HCPCS modifier. Accurately validating and administering such a modifier across varied and changing employment arrangements would be operationally infeasible and require disclosure of sensitive employment information.

10. Updates to Prices for Existing Direct PE Inputs

CMS proposes to update the prices for the Liposorber system (EQ174) and Universal Detection Kit (SA117) based on publicly submitted invoices.

The Liposorber system is used with CPT code 36516 and is proposed to increase by approximately 618 percent, from $7,800 to $56,000. The proposed increase would bring the price of the Liposorber system more closely in line with the current market prices.

The Universal Detection Kit is used with CPT codes 88364, 88365, 88367, 88369, and 88373 is proposed to increase by approximately 5 percent, from $6.05 to $6.38.

The CAP supports the proposed price updates for the Liposorber system (EQ174) and Universal Detection Kit (SA117) and urges CMS to finalize both updates as proposed.

11. Strategies to Improve Payment Transparency, Accuracy, and Congruency Across Payment Systems

CMS developed a public-use file that conceptually divides services not billable with modifiers 26 or TC into professional and technical RVUs. CMS believes the file could support payment comparisons across settings and future site-neutral policies. It seeks comment on the file's usefulness and ways to improve transparency for excluded global surgical services.

The CAP does not oppose such comparisons and notes that most pathology services already have separate global, professional, and technical values. However, RVUs reflect scaling and budget-neutrality adjustments and therefore do not directly measure underlying resources or costs.

The CAP recommends that CMS publish both RVUs and the underlying dollar-denominated resource costs before scaling and budget-neutrality adjustments. Doing so would support more meaningful comparisons across payment systems and allow interested parties to assess the extent to which PFS payments have kept pace with practice costs over time.

In closing this section, the CAP urges CMS to carefully consider the cumulative effect of the proposals discussed in this section on pathology practices, independent laboratories, physicians, and the patients who rely on timely and accurate diagnostic services. The CAP supports policies that improve payment transparency and accuracy, appropriately recognize the physician work and practice expense required to furnish pathology and laboratory services, and ensure that new technologies are evaluated through processes that are clinically informed, methodologically sound, and transparent to stakeholders. Where CMS identifies areas requiring further review, the CAP encourages the agency to rely on established public comment and RUC processes so that proposed changes can be evaluated with appropriate clinical expertise and adequate opportunity for stakeholder input.

The CAP appreciates CMS's consideration of these comments and remains committed to working with the agency to support Medicare payment policies that advance high-quality patient care, preserve access to essential pathology and laboratory services, and maintain the integrity of the resource-based Physician Fee Schedule. The CAP would welcome continued dialogue with CMS and stands ready to provide clinical, technical, and policy expertise as the agency evaluates these issues and develops future Medicare payment policy.

12. **Clinical Laboratory Fee Schedule (CLFS): Consolidated Appropriations Act (CAA), 2026**

    The CAP understands that the CLFS provisions in this proposed rule primarily implement data reporting and payment requirements enacted in the 2026 CAA, along with minor technical changes. Nevertheless, we believe it is important to reiterate our longstanding position that the continued success of the Protecting Access to Medicare Act (PAMA) depends on the collection of comprehensive and representative data from all types of laboratories, including hospital outreach laboratories, independent laboratories, and physician office laboratories. As demonstrated by the nearly $4 billion in payment reductions imposed on many of the most commonly ordered Medicare laboratory tests – and Congress's repeated intervention to moderate those reductions through subsequent legislation – payment rates derived from unrepresentative data fail to reflect the entire laboratory market and ultimately jeopardize beneficiary access to laboratory services. Accurate CLFS rates are essential to preserving access to high-quality diagnostic testing, particularly as laboratories continue to face workforce shortages, inflationary pressures, and growing demand for diagnostic services.

To this end, we appreciate CMS's changes to the definition of "applicable laboratory" in the CY 2019 Medicare PFS rulemaking, which we are hopeful will capture a broader and more representative segment of the laboratory market. At the same time, the CAP remains concerned about ongoing confusion among laboratories regarding their PAMA reporting requirements. Despite communication and education efforts from CMS, the CAP, and other laboratory stakeholders, many laboratories continue to face uncertainty regarding whether they meet the definition of an "applicable laboratory" and are therefore required to report. We have also heard from our members that, while the CMS tool to report was generally straightforward and instructions were clear, the more significant challenge was extracting the required data from laboratory information and billing systems. Laboratories reported that this process required substantial manual review and auditing to ensure accurate submissions, making compliance a significant operational and administrative undertaking.

These concerns are compounded by reports indicating CMS itself does not know which specific laboratories meet the definition of "applicable laboratory" and are therefore required to report. If laboratories remain uncertain regarding their reporting status while CMS likewise cannot readily identify reporting entities, the result is an environment that creates unnecessary administrative burden, compliance uncertainty, and the risk of inconsistent reporting.

As CMS evaluates the recently completed data reporting period, the CAP encourages the agency to provide full and transparent information regarding the reported data before any resulting payment rates take effect. The public should be able to review the composition and representativeness of the reporting, meaningfully assess and corroborate CMS's calculations, and understand and prepare for the anticipated impact of those data on CLFS rates. Additionally, the CAP supports CMS's enforcement of the obligation to report. Incomplete participation in prior reporting periods contributed directly to the unrepresentative data and skewed payment rates described above, and the integrity of the CLFS depends on all applicable laboratories reporting. At the same time, enforcement should distinguish between a refusal to report, and good-faith errors made by laboratories navigating genuine uncertainty. As discussed above, many laboratories cannot readily determine whether they meet the definition of an applicable laboratory, and CMS itself reportedly cannot identify which laboratories are required to report. In these circumstances, civil monetary penalties of up to $10,000 per day per violation should be reserved for knowing failures to report and intentional misrepresentations, consistent with CMS's stated intent to consider the specific circumstances of each case before assessing penalties. We look forward to continuing to work with CMS and the laboratory community to support compliance with PAMA's reporting requirements and to ensure that the resulting CLFS rates are based on accurate, representative, and transparent data.

13. **Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability**

The CAP supports improved interoperability and appropriate efforts to reduce unnecessary laboratory testing. Better exchange of pathology reports among physicians, hospitals, laboratories, and other care settings has the potential to not only reduce unnecessary testing but to improve care coordination and decrease patient burden. At the same time, CMS appropriately recognizes that diagnostic laboratory testing is critical to determining a patient's course of treatment and there are cases where more frequent testing is clinically justified. Accordingly, before moving forward with any actions aimed at addressing interoperability and duplicate testing concerns, CMS should first establish a clear, clinically meaningful definition of a "duplicate laboratory test" and work collaboratively with pathologists, ordering physicians, laboratories, and other stakeholders on future policies in this area. Such an approach would help ensure that efforts to reduce duplicate testing do not inadvertently impede access to medically necessary diagnostic services while advancing the shared goal of improving care through greater interoperability.

Potential Mechanisms for Addressing Duplicative Payment

A clear, clinically meaningful definition of a "duplicate laboratory test" would ensure that any future policies target only truly unnecessary utilization rather than medically appropriate repeat testing. Many repeat claims are clinically appropriate and represent good medical practice rather than unnecessary utilization. Repeat testing is often necessary to monitor changes in a patient's condition, guide treatment decisions, confirm or clarify initial findings, or address technical and operational issues that affect test performance. Examples include:

- Serial monitoring of chronic diseases, such as diabetes, anticoagulation therapy, renal disease, cancer, or other ongoing conditions that require periodic laboratory assessment
- Changes in the patient's clinical status, including acute deterioration, new symptoms, hospitalization, infection, trauma, or other evolving clinical circumstances
- Monitoring response to treatment, therapeutic effectiveness, or disease progression, including assessment of whether interventions are achieving the desired clinical outcome
- Testing performed on a recollected specimen after the original was rejected for integrity, collection, transport, or adequacy failures (e.g., hemolyzed, contaminated, or insufficient specimens); analytical reruns of the original specimen are not billed
- Confirmatory testing performed by a different, separately codable methodology to verify unexpected, equivocal, or clinically significant results before diagnosis or treatment decisions are made (common in infectious disease, toxicology, and molecular diagnostics); rerunning the same test to confirm an initial result is not billed
- Reflex testing, in which predefined follow-up testing is automatically performed when an initial result meets established clinical criteria

- Testing performed using different analytical methodologies when additional sensitivity, specificity, characterization, or confirmation is needed
- Testing performed by different laboratories when specialized technology, subspecialty expertise, proprietary methodologies, or reference laboratory capabilities are required
- Repeat testing required to satisfy guideline-recommended monitoring intervals, laboratory quality standards, or established coverage policies
- Follow-up testing needed to evaluate abnormal results, investigate new clinical questions, or support differential diagnosis as additional information becomes available

Two similar tests performed close together are not necessarily duplicates. Two claims for the same CPT code may appear identical administratively but represent entirely different clinical circumstances. A laboratory claim contains the procedure code, applicable modifiers, the diagnosis codes provided with the order, the ordering practitioner's NPI, the date of service, and units. It contains no field for clinical narrative, specimen condition, prior results, or the reason a test was repeated. Claims data alone generally do not reveal whether the patient's condition changed, the specimen was inadequate, the initial result was inconclusive, a different methodology was required, or the repeat test was otherwise medically necessary. As a result, policies that rely solely on claims-based information risk conflating clinically appropriate repeat testing with unnecessary duplication. Without first establishing a clinically meaningful definition of duplicate laboratory testing, any payment policy risks denying payment for services that are reasonable and necessary and supported by current standards of medical practice.

Critically, if CMS ultimately employs mechanisms designed to address duplicative laboratory testing, it should recognize that laboratories performing diagnostic testing generally cannot determine whether testing ordered by a treating clinician represents unnecessary duplication. Performing laboratories frequently do not have access to the patient's complete medical record, cannot reliably view laboratory results obtained through other laboratories or health systems; and typically perform testing based upon a valid physician order. The clinical justification for repeat testing resides with the ordering practitioner and in the patient's medical record, not on the laboratory claim. The only signals available on a laboratory claim are the existing CPT modifiers: modifier 91 for medically necessary same-day repeats, which by its own terms excludes reruns for quality control, specimen or equipment problems, or confirmation of an initial result, none of which are billed, and modifiers 59/XU for distinct services, together with the diagnosis codes transcribed from the order. CMS should not attempt to close this gap by requiring performing laboratories to append a new modifier or attestation regarding the justification for repeat testing, as this would require laboratories to certify clinical information they do not possess. It would also be inappropriate to deny/reduce payment or seek recoupment from a performing laboratory based upon information unavailable to that laboratory at the time testing was performed.

Additionally, the CAP does not oppose carefully targeted utilization controls that are supported by clinical evidence and allow for appropriate exceptions; **however, we specifically oppose broad Medicare Administrative Contractor (MAC) edits, inappropriate frequency limitations, and automatic definitions of duplicate testing based on arbitrary time periods**. These approaches are inherently imprecise and risk restricting beneficiary access to medically necessary care. Diagnostic testing frequently must be tailored to a patient's unique clinical circumstances, and rigid utilization controls cannot adequately account for the complexity of medical decision-making. While CMS notes that frequency limitations exist for certain narrowly defined services, such policies should not be expanded absent compelling clinical evidence, broad stakeholder input, and a clear demonstration that the limitations can be implemented without impeding access to appropriate care.

Broad MAC edits, inappropriate frequency limitations, and automatic definitions of duplicate testing also risk creating significant unintended consequences, including delayed diagnosis, interruptions in patient care, increased appeals and administrative burden, provider uncertainty regarding coverage, and a chilling effect on medically appropriate repeat testing. Moreover, MAC edits and other retrospective payment mechanisms do little to influence clinical decision-making at the point of care because they are applied only after a service has been ordered and furnished. Such mechanisms may reduce payment, but they do not address the interoperability limitations and information-sharing deficiencies that often contribute to repeat testing in the first place.

Any policy designed to address duplicative laboratory testing should therefore be narrowly tailored, evidence-based, and focused only on demonstrably unnecessary utilization. CMS should avoid approaches that broadly encompass clinically appropriate care while relying on exceptions or appeals processes to preserve beneficiary access. Policies should be designed from the outset to distinguish between inappropriate duplication and medically necessary repeat testing, rather than presuming testing is duplicative unless a provider can establish otherwise.

Finally, existing coding and billing policies already distinguish medically necessary repeat testing from inappropriate duplicate billing. CPT modifier 91 separates billable medically necessary same-day repeats from reruns performed for quality control, specimen or equipment problems, or confirmation of an initial result, which are not billed. Modifiers 59/XU identify distinct specimens and encounters. NCCI medically unlikely edits and procedure-to-procedure edits limit units of service and unbundling for laboratory codes. The national coverage determinations for laboratory tests adopted through negotiated rulemaking, together with MAC local coverage policies, set frequency and medical necessity parameters, including the vitamin D testing LCD the RFI cites, and the ABN process addresses tests expected to exceed those limits. In the hospital outpatient setting, most laboratory tests have

been conditionally packaged under the OPPS since CY 2014, limiting duplicative payment exposure there. Before adopting new payment mechanisms, CMS should identify what gap these existing policies fail to close. Additionally, any clarifications to billing instructions or other guidance must recognize the practical limitations faced by performing laboratories, including their inability to routinely determine whether prior testing was performed elsewhere and their reliance on valid physician orders. Accordingly, billing instructions should not impose new responsibilities on laboratories to identify potentially duplicative testing when the information necessary to make that determination is often unavailable to them. Instead, CMS should prioritize efforts that improve interoperability as a more targeted and effective means of reducing unnecessary testing while preserving access to medically necessary care.

Laboratory and Imaging Interoperability

Pathologists convey diagnostic information through the pathology report, which serves as the clinical deliverable. Consequently, interoperability of the pathology report is critical to conveying complete pathology diagnostic interpretation. The ordering clinicians and patients review the pathology report and generally do not request or examine laboratory images that provide information for the pathologists' consideration. Pathology diagnosis focuses on testing biospecimen(s) provided by patients, consisting of tissue, cells, and/or fluid. The pathology diagnostic process does not begin with an image, as with specialties such as radiology. The biospecimen is processed and a glass slide or less frequently a digitized image thereof together with relevant data are interpreted by a pathologist. Based on the analysis of the slide or digitized image together with relevant data, the pathologist provides their final interpretation in the pathology report. Accordingly, while pathology images may be created and used for diagnosis or pathologist-to-pathologist consultation, they are not routinely requested or viewed by ordering clinicians or patients for clinical decisionmaking. The report conveys the diagnostic interpretation.

Digital pathology—which involves acquiring, managing, and interpreting pathology information from digitized glass slides or whole slide imaging—is not the standard of care in pathology practice. National adoption remains limited due to significant infrastructure demands, including the cost of scanners, digital storage space, high-performance computing, and related health IT systems. The CAP collected data in its 2025 Practice Leaders Survey that indicated only 15% of practices report using digital pathology (whole slide imaging) for the purposes of primary diagnosis. The majority of those 15% of practices using digital pathology for the purposes of primary diagnosis did so for less than 50% of their surgical case volume. Evidence indicates adoption varies significantly by practice setting, with academic medical centers and reference laboratories more likely to digitize slides, but even in those situations, laboratories report that the digitization is used for facilitating research, providing consultations, and discussing cases at tumor boards, rather than required for primary diagnosis.

The CAP strongly encourages CMS and HHS to explore different types of federal subsidies both to help develop consensus-based standards for pathology data interchange and assist pathologists and laboratories to afford the infrastructure needed to implement digital pathology

once standards emerge. Some practices may use research or grant funds to assist in implementing digitization, since insurance reimbursement does not incentivize digitization of slides. While interoperability has benefits for patients, clinicians, health systems, and public health, currently laboratories often bear the substantial share of the sizeable costs of making pathology diagnostic data interoperable.

While CMS' focus in this RFI is on laboratory and imaging data, interoperability challenges are not unique to those domains. Similar barriers affect the exchange of clinically relevant information throughout the healthcare system, such as operative notes, discharge summaries, etc. The challenges related to information availability often reflect broader health information exchange limitations throughout the healthcare system. Therefore, failures are not attributable only to a particular laboratory, pathologist, imaging provider, or facility. Any federal strategy should recognize that laboratory and imaging interoperability challenges exist within a broader ecosystem of fragmented health information exchange.

In addition to these general comments, the CAP provides the following answers to the questions that CMS included in this section.

1. Because image exchange can involve substantial technical and operational costs, should HHS or CMS consider incentives to support adoption and implementation, and if so, what form should those incentives take?

CAP Comment: *Yes. Because pathology interoperability lacks standards for implementation, federal subsidies should initially focus on development of consensus-based, freely available standards. For example, the Food and Drug Administration invested in the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD)[1] – a successful public-private partnership. The CAP was pleased to participate in this initiative to help promote standards in collaboration with the FDA and device industry. Greater investments in standards development and consistent use of open-source standards by medical device developers are essential. Full implementation of digital pathology is premature until these standards exist and are widely used.*

The CAP also supports federal incentives to encourage adoption and implementation of interoperability capabilities. As CMS considers policies to advance laboratory interoperability, the agency should prioritize positive incentives that support implementation rather than penalties or added regulatory burdens. Incentives could include federal subsidies, grants, technical assistance programs, workforce training initiatives, and investments in digital infrastructure that facilitate standards-based exchange. These investments are crucial to help enable quicker diagnosis and facilitate specialized consultations.

Laboratories continue to face substantial workforce, technology, and operational costs

[1] U.S. Food and Drug Administration. Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD). FDA Diagnostic Data Program. https://www.fda.gov/medical-devices/diagnostic-data-program/systemic-harmonization-and-interoperability-enhancement-laboratory-data-shield.

associated with implementation of interoperability capabilities. While targeted investments may be particularly valuable in rural and underserved communities, interoperability requires significant investments across all pathology practice settings, including independent laboratories, community hospitals, academic medical centers, and large healthcare systems. Incentives can help laboratories adopt and implement interoperable technologies, adopt and implement digital infrastructure, participate in standards-development and implementation efforts, and prepare for evolving interoperability frameworks as standards continue to mature. As discussed further below, laboratory interoperability standards and implementation approaches remain under active development, making continued investment and stakeholder engagement particularly important.

2. Given variability in conformance to existing laboratory and imaging exchange standards, would interested parties find value in expanded conformance testing tools, certification approaches, or implementation guidance?

CAP Comment: *As mentioned above, standards development remains a necessary focus of work and would benefit from additional federal investment and consensus-building. Federal efforts should focus first on semantic interoperability resources rather than additional validation tools. Requiring use of standards is premature and may cause harm by freezing pathology practice in the current lack of implementable standards. More implementation experience is needed before imposing new certification requirements. The CAP encourages HHS to support collaborative pilot programs that identify operational barriers, test standards implementation, and develop best practices for interoperability. The Office of the National Coordinator for Health Information Technology's (ONC's) behavioral health data exchange pilot programs may also be a useful model.[2] CMS and HHS could establish similar pilot programs focused specifically on laboratory interoperability to evaluate standards implementation, facilitate exchange across care settings, identify workflow challenges, and develop scalable approaches for nationwide adoption. Such efforts could complement additional investment in SHIELD and the Advanced Research Projects Agency for Health's (ARPA-H's) work to advance medical imaging data exchange infrastructure.[3]*

The CAP supports implementation guidance and pilot programs, and believes these approaches are likely to provide greater near-term value than new certification requirements. Laboratory interoperability standards and implementation approaches continue to evolve. Efforts to build consensus about standards must include pathologists to ensure meaningful development and implementation within routine laboratory workflows. For example, the CAP is currently working with stakeholder organizations and technology companies to promote interoperability in digital pathology through the Digital Imaging and Communications in

[2] Office of the National Coordinator for Health Information Technology. ASTP/ONC Announces Selection of Nationwide Pilot Programs to Improve Behavioral Health Data Exchange. Published August 8, 2024. https://healthit.gov/news/astp-onc-announces-selection-of-nationwide-pilot-programs-to-improve-behavioral-health-data-exchange/.

[3] Advanced Research Projects Agency for Health. ARPA-H Launches Program to Create Medical Imaging Data Exchange Platform. Published September 19, 2024. https://arpa-h.gov/news-and-events/arpa-h-launches-program-create-medical-imaging-data-exchange-platform.

Medicine (DICOM®) standard. Although development and use of the standard are still embryonic in pathology, DICOM holds promise to advance interoperable digital pathology by moving toward standardized approaches and away from proprietary solutions.[4] Although conformance testing tools can be helpful, their effectiveness depends on the maturity of the underlying standards. Given the continued evolution of laboratory interoperability standards and implementation approaches, additional harmonization, testing, and implementation experience are needed before new certification requirements are considered.

3. How should CMS account for cases in which repeat imaging occurs because prior imaging results were not available for timely, standards-based reuse? Should CMS consider payment, quality, or participation policies that create accountability for the initial imaging provider, furnishing entity, or facility when failure to make results reusable contributes to avoidable repeat imaging? Are there penalties or disincentives for non-compliance we should consider?

CAP Comment: *This question has limited applicability to pathology practice where the pathology report is the primary clinical deliverable to the clinician and patient – not a digital image. Pathology images may be used for pathologist-to-pathologist consultation. Clinicians and patients, however, rely on the pathology diagnostic interpretation contained in the pathology report.*

Accordingly, reimbursement focuses on providing timely and clinically actionable pathology reports to the ordering clinician and patient. Therefore, payment reductions, penalties, or other disincentives for failing to deliver digital pathology imaging is not relevant to a pathologist conveying a complete pathology interpretation. As such, CMS should not employ these types of disincentives for failure to provide pathology diagnostic images. Further, interoperability failures may occur outside the direct control of laboratories and pathologists. Laboratories and diagnostic providers already furnish the diagnostic information requested by the ordering clinician through pathology reports.

If CMS wishes to encourage additional interoperability capabilities beyond existing requirements, those activities should be supported through incentives and investments rather than penalties. Moreover, repeat testing is sometimes clinically appropriate and may not be avoidable. As discussed in our comments in the previous section (X.3. Potential Mechanisms for Addressing Duplicative Payment) and initial comments in this section, repeat testing may be clinically justified based on changes in a patient's condition, advances in scientific knowledge, the availability of new diagnostic information, or the need to evaluate a new specimen. Indeed, access to prior results does not necessarily eliminate the clinical need for repeat testing. For example, repeat testing may occur when clinicians are unable to determine whether previously generated results are sufficiently comparable to support a

[4] The CAP is playing a leadership role in a DICOM working group (WG-26) designed to support and develop the DICOM standard for pathology. Digital Imaging and Communications in Medicine (DICOM). Working Group 26: Pathology. DICOM Standards Committee. https://www.dicomstandard.org/activity/wgs/wg-26.

particular clinical decision. Even when laboratory data are available, differences in methodologies, test characteristics, reference intervals, reporting practices, or other factors may affect how results are interpreted and applied in patient care.

4. For laboratory interoperability specifically, what barriers continue to impede exchange despite the availability of established standards, and what policy levers could help address those barriers? Should we consider incentives to support laboratory adoption and implementation of health data standards?

CAP Comment: *Laboratory interoperability standards are in the embryonic stages. Further development is required prior to widespread promotion and adoption. Although important standards-development efforts are underway, laboratory interoperability standards and implementation approaches continue to evolve. Interoperability also depends on semantic interoperability, meaning that laboratory information is represented and interpreted consistently across organizations. Variations in local test names, result components, the report content structure, terminology implementation, and coding practices can create barriers even when data can be exchanged electronically. In addition, laboratory results that appear similar may not always be clinically interchangeable because of differences in testing methodologies, analytical platforms, or reference intervals.*

The CAP also notes that interoperability challenges frequently arise outside the direct control of laboratories and pathologists. Laboratories often have limited responsibility for or control over laboratory data once it has been transmitted and incorporated into downstream systems. Even when laboratories and ordering clinicians are within the same healthcare organization, pathologists often are not involved in determining where and how to store data labeled in an electronic health record (EHR) as "laboratory data." In addition, the data often lack the key information that an ordering clinician or pathologist will need to determine whether results are clinically interchangeable. CMS should understand and account for divisions of responsibility/authority when developing interoperability policies. Requirements should not hold laboratories accountable for functions or workflows that occur after laboratory data have been successfully transmitted. Similarly, the CAP also encourages CMS to consider policy levers that encourage EHR developers, healthcare institutions, health information networks, and other stakeholders to improve interoperability of the pathology report. Existing interoperability programs demonstrate that information exchange can occur when organizations elect to participate and invest in implementation. These challenges highlight the continued need for harmonization and implementation experience. Indeed, HHS has noted that variation in how standards are adopted and implemented can limit the usefulness of exchanged information,[5] *underscoring the need for continued harmonization and implementation support rather than only imposing additional requirements.*

Financial incentives would help develop standards and address several remaining barriers to

[5] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. *Harnessing Electronic Health Record Data for Clinical Research*. Published July 21, 2026. https://aspe.hhs.gov/sites/default/files/documents/df5a3f5d1703624dcccb758418c5ad2a/Harnessing%20EHR%20Data%20for%20Research_Final.pdf.

laboratory interoperability, including implementation costs, workflow variation, and limited adoption of exchange mechanisms. The CAP encourages CMS to incorporate financial support and positive incentives into any interoperability strategy. Positive incentives are likely to be more effective than penalties in promoting adoption while avoiding unintended consequences for patient access to laboratory services. Federal support is particularly important because adoption of interoperability capabilities remains uneven across the healthcare system. Recent HHS analysis found that lower-resourced hospitals engage less frequently in interoperable exchange compared to their higher-resourced counterparts and there is inconsistent adoption of clinical content standards by EHR developers and health systems.[6]

5. Should CMS establish a minimum data standard for result shareability, for example, a United States Core Data for Interoperability (USCDI+) supplement for imaging and laboratory results, requiring all participating entities to deliver both a structured Fast Healthcare Interoperability Resources (FHIR) R4 Diagnostic Report resource and a human-readable Portable Document Format/Archive (PDF/A) rendition to the ordering health care provider's designated endpoint as a condition of Medicare payment? How should CMS address health care providers who have not yet implemented FHIR-native workflows, especially in rural areas?

CAP Comment: *The CAP supports standards-based interoperability and is engaging initiatives to develop consensus on standards. The CAP contends, however, that workable, clinically meaningful standards do not exist for pathology diagnostic information. CMS should avoid conditioning Medicare payment use of the standards mentioned and implementation of interoperability capabilities that lack meaning for pathology diagnostic information and that laboratories do not fully control. Conditioning payment on premature standards risks freezing laboratory operations and practice at an inopportune time. FHIR does not incorporate essential information necessary for laboratory use cases, and significant implementation challenges remain. Moving to a specific FHIR-based approach could require substantial modifications to existing interoperability infrastructure and interfaces, resulting in significant implementation costs and operational disruption, particularly for smaller and/or independent laboratories. Moreover, the ability to exchange laboratory data through a standardized format such as FHIR does not ensure that results can be consistently interpreted, compared, and applied across organizations. As discussed in response to Question 4, effective interoperability also depends on semantic interoperability, including the consistent representation and interpretation of laboratory tests and results.*

Additionally, interoperability often depends upon actions taken by multiple stakeholders, including receiving systems, healthcare organizations, health information networks, and vendors. Consequently, provider-focused requirements or disincentives may be less effective

[6] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. *Harnessing Electronic Health Record Data for Clinical Research*. Published July 21, 2026. https://aspe.hhs.gov/sites/default/files/documents/df5a3f5d1703624dcccb758418c5ad2a/Harnessing%20EHR%20Data%20for%20Research_Final.pdf.

than policies that promote institutional adoption, vendor interoperability (including EHR and laboratory information systems), and broader health information exchange capabilities efforts. Laboratories should not be penalized for factors outside their direct control.

The CAP encourages CMS to recognize that interoperability capabilities are generally deployed and maintained at the health system, institutional, network, and vendor levels rather than by individual healthcare providers. Individual providers typically do not build interoperability infrastructure; rather, they rely upon tools and systems implemented by hospitals, reference laboratories, healthcare systems, health information technology developers, and other vendors.

14. CY 2027 Updates to the Quality Payment Program

The CAP looks forward to continuing engagement with the CMS on the Quality Payment Program (QPP), including multiple aspects of the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) to determine how to appropriately measure providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. Through the years, the CAP has advocated to ensure flexibility for pathologists in a way that recognizes and accounts for the value pathologists contribute to patient care as non-patient facing clinicians in an inherently patient-facing program. These considerations will be especially important as CMS moves forward with implementation of MIPS Value Pathways (MVPs). Below, the CAP provides feedback in response to proposals on the QPP.

TRANSFORMING THE QUALITY PAYMENT PROGRAM: MIPS VALUE PATHWAYS (MVPS)

Proposal to Update Timeline for Full MVP Implementation
CMS requests feedback on the timeline of full MVP implementation, including the proposal to phase out traditional MIPS as a reporting option starting in the CY 2029 performance year. CMS has previously established optional MVP reporting, allowing individuals and groups to report via multiple mechanisms if desired. The CAP appreciates CMS' desire to transition all Medicare beneficiaries to accountable care relationships and increase participation in APMs. The CAP also supports value-based care as the future of quality healthcare for Medicare beneficiaries. However, while we appreciate the lower burden of MVP reporting compared to reporting of traditional MIPS, several operational concerns remain regarding full MVP implementation. Most notably, the current timeline of development and approval for QCDR measures does not align with the timeline of MVP development and modification, representing a serious mismatch in the ability of QCDRs to introduce meaningful quality measures. For instance, if the CAP were to propose a new QCDR measure for CY 2029, that measure could not be part of the Pathology MVP in 2029, because self-nomination of QCDR measures occurs after the CY 2029 proposed rule is released. In the absence of traditional MIPS, it is unclear what would happen to this measure; MIPS-eligible clinicians could not report it so there would be no benefit for a registry to support it. Furthermore, CMS has incentivized reporting of new measures by setting a floor of 7 points for measures in their first year of use, which has been invaluable to the CAP in terms of earning benchmarks for QCDR measures. However, if traditional MIPS no longer exists and a QCDR measure cannot be in an MVP in its first year of use, the 7-point floor is significantly

devalued.

We suggest that full MVP implementation should not occur before this issue and other similar timing issues are resolved. Furthermore, the process of adding measures to MVPs or modifying MVPs remains slow and opaque. Although CMS provides an opportunity to suggest modifications to existing MVPs, these recommendations are not always accepted. The lack of constructive feedback on why recommendations were not accepted represents a barrier to meaningful engagement between CMS and measure developers and stewards. Finally, we appreciate that CMS will apply the same scoring policies to MVPs as to traditional MIPS and we strongly recommend that CMS apply the Eligible Measures Applicability (EMA) process to MVPs, especially given the limited set of quality measures available in MVPs. **Therefore, we suggest that CMS address programmatic issues with MVPs prior to full MVP implementation and delay full MVP implementation accordingly to ensure issues are resolved**.

The CAP also appreciates CMS' suggestion to potentially create a process by which clinicians could attest that no MVP is applicable. We furthermore suggest that such a process allow clinicians to attest that no population health or cost measures are applicable. Although CMS calculates scores on these measures without data submission by MIPS-eligible clinicians or groups, allowing clinicians to attest that no measures apply would reduce the chance of inaccurate attribution and provide clinicians with greater peace of mind. Given that scores for these measures are not available until at least 6 months after the end of the performance period, the lack of feedback represents a source of uncertainty for clinicians, which could be alleviated by an attestation process. Similarly, given the limited set of Improvement Activities available in each MVP, we suggest that CMS implement a process by which a group could attest that none of the included Improvement Activities are applicable.

Finally, CMS' proposal to include virtual groups in MVPs allows for continued participation of more MIPS-eligible clinicians. However, the CAP notes that CMS includes language regarding the need for virtual groups to register twice, once as a virtual group and once for the MVP. We suggest that once full implementation of MVPs occurs, participants will not need to register for MVPs and such a process should be phased out. It is unclear what benefit would be derived from groups or individuals registering for MVPs once they are the only available reporting option. In general, we recommend that CMS consider scoring and reporting policies that maximize the ability of MIPS-eligible clinicians to participate in MVPs while lowering the administrative burden associated with participation.

CY 2027 MVP Development and Maintenance

MVP Maintenance Updates to Previously Finalized MVPs

As background, the CAP notes that when it comes to development of new quality measures, the QCDR measure pathway has been a successful and highly used way to introduce new quality measures into the program more rapidly than the MIPS CQM process. While the CAP appreciates CMS providing an opportunity to comment on candidate MVPs prior to proposal in the notice and comment rulemaking process, we remain unclear on measure selection criteria after public comment since no feedback is provided on recommendations for existing MVPs.

We continue to recommend inclusion of our two new QCDR measures in the 2027 MVP: CAP 43,

Complete Reporting of Gastrointestinal Metaplasia, and CAP 44, Molecular Assessment for Endometrial Carcinoma. Along with the existing measures in the MVP, these new measures will expand the diseases addressed and represent opportunities for improvement for pathologists. We understand the CMS' desire to limit the number of measures in each MVP. However, the diversity of clinical areas covered by independent pathology practices necessitates a diversity of measures; for instance, there are currently no measures in the MVP that cover gynecologic pathology at all.

More broadly, we do not recommend selecting measures solely based on performance gap; this is a difficult metric to track completely since utilization of any one measure is optional. It is self-evident that clinicians who are not performing the quality action for a measure may simply choose not to report it. Thus the lack of gap may not be a full representation of nationwide performance. We suggest using gap as only one of several factors to select measures. Other factors include how well aligned measures within a model are, how closely linked to patient outcomes they are, and whether they drive integration across the care team.

Request for Information: Fast Healthcare Interoperability Resources®-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs
The CAP supports CMS' goal of increasing interoperability and believes that digital quality measures (dQMs) are a significant improvement over the current iteration of electronic clinical quality measures (eCQMs), which have rigid and limiting requirements that reduce their feasibility for many medical specialties. However, we continue to encourage CMS in conjunction with the Office of the National Coordinator for Health Information Technology (ONC) to maximize the utility of dQMs by ensuring that a standards system for dQMs is flexible, comprehensive, freely available, and easily understood by measures developers and end users. The CAP's analysis continues to indicate that the FHIR standard does not capture all essential pathology data in narrative pathology reports, which could be problematic for constructing measures on this standard.

Broadly speaking, laboratories face substantial workforce, technology, and operational costs associated with development and implementation of new standards. While we appreciate CMS' recognition that targeted investments may be necessary in rural and underserved communities, interoperability requires significant investments across all pathology practice settings, including independent laboratories, community hospitals, academic medical centers, and large healthcare systems. The CAP suggests that incentives can help laboratories participate in standards-development and implementation efforts and prepare for evolving interoperability frameworks as standards continue to mature. Laboratory interoperability standards and implementation approaches remain under active development, making continued investment and stakeholder engagement particularly important. Given the lack of standards applicable for pathology and laboratory data, CMS should prioritize positive incentives that support implementation rather than penalties or added regulatory burdens.

On the organization side, prior to full conversion of quality measures to the FHIR standard, organizations must first assess the existing FHIR capabilities to understand where gaps are, identify a plan for closing those gaps, then develop a timeline on which that development can occur. Until there is a better sense across the ecosystem of measure developers and end users

of where gaps in FHIR standards exist, it is premature to suggest that all measures could be converted to FHIR. The process of implementing FHIR is multi-step and multistakeholder: it is not entirely within the control of any one party to deploy FHIR. To ensure success of the dQM transition the CAP suggests a stepwise process in which CMS would solicit volunteers for a pilot demonstration with defined endpoints, metrics for success, and a roadmap clearly establishing milestones to achieve conversion of measures to the FHIR standard. At the conclusion of such pilot projects, CMS should make publish the results of the pilot, barriers and facilitators, and a cost analysis for the conversion.

Below, we provide specific input on the topics identified by CMS regarding FHIR in digital measurement:

- Transition Approach and Design: First, regarding the proposed transition approach and period, we request additional information on how measures will be prioritized for this transition. The RFI indicates that not all quality measures will undergo the transition to FHIR on the same timeline. Will the first cohort be limited to existing eCQMs or the FHIR-based measures that were available for review and comment earlier in 2026? If not, how will target measures be identified? We suggest that CMS first solicit input from stakeholders on which measures could reasonably be prioritized, then clearly and publicly describe which measures have been selected for this initiative and why. Similarly, we request that CMS clarify whether the two-year transition period applies only to the first cohort of measures or whether the same process will be applied to subsequent sets of measures.
    - Regarding scoring implications, we recommend that CMS create separate benchmarks for FHIR-based quality measures as opposed to the current CQL-based measures. Currently, different versions of the same measure (e.g. Medicare Part B Claims versus registry) have different benchmarks. We recommend this approach continue in the future, at least long enough to ensure that FHIR-based measures have the same feasibility and scoring ranges as CQL-based measures.
- Factors Affecting Readiness for FHIR-Based Reporting: The CAP strongly recommends that CMS in conjunction with ONC create and disseminate easily accessible resources regarding the transition to FHIR-based measures based on real world experience transitioning some initial measures to the FHIR standard. Resources should be aimed at different groups and individuals, including measure developers, clinicians and end users, and administrative and IT staff among others. Although there are several FHIR Implementation Guides (IGs) available that touch on digital measurement, these are not aimed at a measure user audience.
    - For instance, the RFI references several IGs including the Data Exchange for Quality Measures (DEQM) FHIR implementation guide and the US Quality Core Implementation Guide. These IGs are not accessible to lay users and the relationship between them is unclear. We recommend that in addition to the IGs for technical audiences, CMS and ONC establish plain language resources for other audiences.
    - Additionally, the CAP recommends that CMS solicit feedback from a broad variety of stakeholders to identify potential issues. Although some FHIR-based dQMs were available for public comment earlier in 2026, the questions were

highly technical in nature and did not request input on barriers and/or readiness. Prior to implementing a mandatory transition, an environmental scan to capture barriers, attributed parties and possible resolutions should be conducted.
    - Additionally, CMS and ONC should evaluate readiness of electronic health record (EHR) vendors for the transition to FHIR-based quality measures. Although some vendors indicate "FHIR-readiness", in practices this often means availability of a FHIR Application Programming Interface (API) rather than structuring all data in conformance with the FHIR standard. EHR vendors must be held accountable for their essential role in promoting interoperability and should not be permitted to pass all associated costs of this important transition on to practices.
- CMS should study the cost of transitioning measures to the FHIR standard and disseminate that information. Estimating the anticipated cost is necessary for those considering transitioning a measure. High costs may lead to measures being abandoned rather than implemented with FHIR. CMS should consider funding mechanisms to preserve key measures (e.g., measures embedded in an MVP) as well as potential financial mechanisms to assist specialties in the early steps of their transition. Current estimates suggest converting measures to FHIR will be a costly process especially for societies who do not have technical staff and psychometricians in house.
- General Solicitation of Comments: As noted above, the CAP is supportive of CMS and ONC's ongoing efforts to improve interoperability. However, the integrity of clinical data and clinical quality measurement are paramount and must be maintained during the implementation of any new standards. Additionally, the burden of transitioning clinical quality measures, with the accompanying risks, must be weighed carefully against the benefits of a new standard, particularly in the case of a standard such as FHIR that may not adequately capture all available clinical data. The CAP suggests that transitioning to mandatory MVP reporting and to FHIR-based measures at the same time may represent a significant burden for IT and administrative staff especially at small practices. Although we understand the desire to align the transition, two years is a relatively limited amount of time for either transition, much less both. We look forward to continuing to work with CMS on development of the FHIR standard in a manner that is appropriate for pathology and LIS, acknowledging the unique structure and function of these systems.

MIPS PERFORMANCE CATEGORY MEASURES AND ACTIVITIES

Quality Performance Category

Proposal to Designate MIPS Core Measures

As background, within the practice of pathology, there is tremendous diversity of subspecialty. A gastrointestinal pathologist and a dermatopathologist may not see any cases in common, and a genitourinary pathologist would see a different set of cases altogether. Therefore the quality measures that are meaningful to one subspecialty of pathology may not be meaningful to another subspecialty. In fact, another subspecialty may not even meet the case minimum. This is part of the reason that pathologists overwhelmingly report as groups rather than individuals; in order to meet the case minimum for 6 different quality measures, several subspecialties likely must be represented. There are few if any areas within pathology for which 6 relevant quality measures exist, and pathologists cannot report cross-cutting measures since the majority are non-patient-

facing physicians. CMS has recognized this challenge by including the pathology MIPS CQMs on the list of topped-out measures with limited measure availability for two years. The CAP greatly appreciates this recognition; pathology practices, especially small practices, struggle to meet the performance threshold due in part to the limited number of measures. The CAP continues to develop measures to address the relatively narrow set of measures available to pathologists.

The breadth of subspecialties within pathology, however, means that there are no measures that all MIPS-eligible pathologists could report on. Even assuming group reporting by all pathologists, it is difficult to know whether any measures could be considered "core" or foundational to the specialty. Some practices may see twenty-five cases of one specimen type but several thousand of another specimen type; thus while they meet the case minimum for the former, it would not be central to their practice. It is also difficult to determine which measures would be the most meaningful for patients; a patient with melanoma would consider the Melanoma Reporting measure the most important while a caregiver whose father has prostate cancer would prioritize Radical Prostatectomy Pathology Reporting. One measure is not more important than the other *a priori*.

Given the limited number of quality measures available to pathologists, we suggest that pathology and any other specialty identified by CMS as having limited measure availability be exempt from the core measures requirement. The reasons stated for implementing core measures, including increasing the comparability of scores, do not apply when there is already a small set of measures for a specialty. To increase meaningful comparative data, the CAP recommends that CMS assign each measure a category that describes what it is measuring. Scores on the categories can be reported and may be more meaningful to patients. Quality measures are often technical and while they represent clinical best practices, they may not be meaningful to patients. Furthermore, since measures cannot be reported by all clinicians, comparisons of individual measure scores will always be incomplete. However, by grouping measures, CMS can report to patients on the general performance of clinicians or groups

Furthermore, the CAP continues to promote use of Qualified Clinical Data Registries (QCDRs), which provide the maximum support and flexibility for clinicians participating in MIPS. CMS should not take actions that disincentivize use of QCDRs. If CMS intends to move forward with establishing core measures for MVPs, we recommend that multiple measure types, including QCDR measures, be available.

Proposal to Remove High Priority Measure Designation and High Priority Quality Measure Retention Consideration

In conjunction with the designation of core measures, CMS is proposing to eliminate the designation of high priority measures. However, as noted above, the CAP does not believe that the core measures identified for pathology are a complete representation of the care that is central to the clinical focus of the specialty. These three measures are important but by no means cover the entire breadth of pathology practice, especially since all three focus solely on oncology. Therefore the CAP believes the high priority designation should be maintained and still used to assess whether measures are retained in the MIPS program.

Proposal to Implement Data Submission Requirement for MIPS Core Measures

The CAP appreciates that CMS is considering a mechanism by which clinicians who do not have an applicable core measure can attest to this fact. However, clinicians who have limited measures to choose from are likely to need EMA applied as well. Currently, EMA is not reliably applied to scores but often requires submission of a Targeted Review. We recommend that the processes be combined: a clinician who attests that he or she does not have a core measure should automatically be evaluated for EMA and vice-versa. In general, we continue to encourage CMS to examine opportunities to reduce administrative burden on practices. We recognize the need to balance burden reduction with fairness to practices but we continue to hear from practices about the substantial effort required to participate in the MIPS program. Therefore we recommend that CMS consider all possibilities to reduce the need for attestation, registration, or other administrative tasks for practice.

Along those lines, **the CAP supports the proposal to exempt small practices from MIPS core measure reporting requirements**. Particularly as it relates to the pathology core measures, our data indicate that small practices often do not meet the case minimum for QID 396, Lung Cancer Reporting (Resection Specimens). Given that there are only three core measures, eliminating one of them would represent a significant challenge for small practices. Therefore we believe that small practices should be exempt from the requirement to report a core measure as small practices are particularly vulnerable to being unable to report a core measure.

Improvement Activities Performance Category

Proposals to Adopt New Improvement Activities

As has been mentioned in previous comment periods, the CAP remains concerned about the relatively limited number of Improvement Activities (IAs) that are available for non-patient-facing clinicians, particularly those who do not use Certified EHR Technology (CEHRT). This concern is even more significant with the move towards full MVP implementation since MVPs have a more narrow set of IAs available.

Therefore, the CAP is pleased to see the proposal to include IA_CC_XX (Use of Data to Improve Practice Workflows) and IA_CC_XX (Understand and Improve Diagnostic Performance) in the Care Coordination subcategory 2027. **We strongly support this proposal** and these new IAs as relevant and meaningful for pathologists. In the case of “Understand and Improve Diagnostic Performance”, this IA can improve patient safety by decreasing diagnostic errors by emphasizing the importance of ongoing constant monitoring of diagnostic performance across the care continuum. The “Use of Data to Improve Practice Workflows” IA is particularly important to promote uptake of evidence into clinical practice via concrete actions at individual practices. These IAs represent important foundational activities to improve clinical practice and quality in the long term.

Proposals to Remove Existing Improvement Activities

Although the CAP understands CMS’ desire to keep a parsimonious set of IAs to enable clinicians to easily identify and select relevant activities, we caution against combining/removing too many IAs into a single activity. In order to be understandable and meaningful, IAs must be straightforward. Combining a large number of activities into one IA defeats this goal.

Additionally, the CAP does not support removal of IA_PSPA_2 “Participation in MOC Part IV”.

Although CMS has indicated that this IA is no longer relevant or useful in current clinical practice, maintenance of certification is an optional improvement activity that demonstrates ongoing clinician education and practical quality improvement.

MIPS FINAL SCORE METHODOLOGY

Scoring the Quality Performance Category

Scoring Topped Out Measures

While the CAP understands CMS' belief that measures with high performance do not demonstrate room for continuous improvement, and are therefore topped out, we have long held that continuous improvement should not be the only metric of success in the quality performance category. Just as most consumers would not find it acceptable to have airline flights that were only 98% safe, many patients would not be satisfied with healthcare that was only 98% safe or accurate. Nor would consumers accept that safety should no longer be measured simply because a single metric had been achieved. We believe that the current topped out measure policy does not appropriately incentivize maintenance of the highest quality care for patients. We continue to encourage CMS to continue to evolve the overall goals of the quality performance category away from narrowly-defined continuous improvement to a broader definition of quality that recognizes maintenance of high quality over consecutive years.

In the meantime, **the CAP is supportive of CMS' analysis used to identify the list of topped out measures impacted by limited measure choice**. This aligns with our own internal analyses examining the challenges faced by large practices with limited measures when they are topped out.

Proposal of Measures Impacted by Limited Measure Choice to be Subject to Defined Topped Out Benchmark for the CY 2027 Performance Period/2029 MIPS Payment Year

As pathologists have few measures to choose from and cannot report the broadly applicable MIPS quality measures, **the CAP is supportive of the inclusion of pathology measures in the list of measures impacted by limited measure choice**. We appreciate CMS' desire to ensure fair scoring of all specialties and recognition that the limited measures available to pathology and certain other specialties prevent equitable scoring opportunities. However, we continue to suggest that CMS consider setting a two-year time frame for evaluation of measures on the list impacted by limited availability. That is, a measure proposed for inclusion on the 2027 list would be re-evaluated for the 2029 performance period. Constant change to policies and procedures is a significant challenge for practices and a single year may not be enough time for practices to change their reporting structure if they have moved away from topped out measures.

Additionally, the CAP is supportive of CMS' proposal to score topped out core measures according to the defined topped out benchmark. In the interest of fair scoring, this assists practices who must report a topped out measure as a core measure. However, the CAP also continues to believe that QCDR measures should be included in both the limited measure choice list and in core measure sets.

Request for Information: MVP Scoring

The CAP understands CMS' desire for MIPS to provide comparable, understandable scores

across clinician and specialty types as well as the desire for scoring to be fair and accurate. We support these overall goals and recognize that some changes may need to be made as full MVP implementation progresses. However, we caution CMS strongly against any changes that could pit specialties against each other or disadvantage one specialty systematically.

Additionally, as noted above, pathology has a limited number of measures available for use and pathologists in single-specialty practice cannot report cross-cutting measures. Therefore, the scores of pathologists and pathology groups are relatively fair and comparable to each other, and relatively meaningful to patients reviewing the scores. Given this, we recommend avoiding policies that could skew or redistribute scores within in an MVP such that a set of comparable clinicians is disadvantaged. If one specialty performs better than another or significantly better than average, this fact should not be hidden or removed via scoring policies.

The CAP also suggests that any significant changes to MVP scoring should not be introduced until a majority of clinicians have participated in MVPs for several years. In order to determine if changes to scoring of MVPs are necessary, CMS must first observe widespread use of MVPs across a spectrum of specialties. If a specific need for normalization is identified during optional reporting of MVPs, changes should be deployed prior to full MVP implementation to ensure policies are working and not unfairly penalizing any specialty, provider type, or reporting option (e.g. Group vs Individual). Any significant changes to scoring, such as normalization, could have unintended consequences so it would be necessary to compare normalized scores to corresponding traditional scores. In order to do so, multiple years of traditional and normalized scores would be needed. We acknowledge that results of an assessment prior to full MVP implementation may not exactly match the situation once MVPs are the sole reporting option, but an estimation of impact based on voluntary reporting of MVPs is better than no data.

Below, we provide specific input on the topics identified by CMS regarding future MVP scoring:

- Prior to MIPS payment adjustment determination, should we consider normalizing scores, such that MIPS eligible clinicians reporting a given MVP would have their scores compared to other MIPS eligible clinicians reporting the same MVP? If so, should normalization occur at the final score level or at a performance category level?
    - Given the fact that single-specialty pathology practices only report on two performance categories, we do not recommend normalizing scores at the category level unless only Quality scores will be normalized.
    - The CAP urges caution with an approach of normalize scores within each MVP to result in similar distributions of scores across MVPs. In general, we recommend against any approach that would suggest certain scores were comparable when in fact they were not. That is, because pathologists only report on two performance categories, it may not be accurate to compare their scores to clinicians who reported on four performance categories because the data source and quantity is different.
- While we are considering scoring fairness within and across specialty-based MVPs as a primary goal for the future of MVP scoring, we are also interested in other goals to consider. For example, should we consider whether MVP scoring policies provide more meaningful rewards for the high performing clinicians via larger positive payment adjustments?

- As noted above, the primary concern with the suggested change is that there is not adequate baseline understanding of how MVPs perform across physician specialties. Until a majority of physicians have participated in MVPs for several years, the need for changes to scoring is not apparent. The CAP suggests that sufficient maturation of MVPs is a prerequisite for identifying any opportunities for improvement in MVPs.
- While the CAP is aware that the +9% bonuses originally described the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) have not materialized due to overall high performance of providers within MIPS, we suggest that physicians providing high-quality care should not be penalized unduly. That is, the fact that most individuals and groups are receiving a positive payment adjustment suggests that most individuals and groups are providing high-quality, cost-effective care as measured by MIPS. Artificially adjusting scores would devalue the care provided and would provide an inaccurate picture of the care provided by these individuals or groups.
- CMS also requests input on scoring approaches that may increase scoring fairness within and across MVPs while reducing a clinician's ability to predict their performance category or final score. We suggest that the ability to predict scores is important for individuals and groups to understand their performance throughout the year. Already the lack of feedback on cost measures presents a problem for groups who receive Cost category scores. Altering scoring methodology such that scores were less transparent or predictable, within a year or year to year, may complicate the program for participants.

THIRD PARTY INTERMEDIARIES GENERAL REQUIREMENTS

Conditions for Approval: Proposal to Provide Performance Feedback Reports at the Level of Data Submitted

The CAP supports the concept of providing actionable feedback to individuals and groups throughout the year. In addition to the direct emails four times a year, the CAP's Pathologists Quality Registry also displays near-real-time performance and is available to clinicians at all times. We believe this provides the most meaningful feedback to MIPS participants.

The CAP is concerned that mandating feedback reports at the level of data submitted will increase clinician confusion and may not be feasible throughout the year. Many clinicians do not decide whether to submit as an individual or a group until late in the year, depending on scores, final eligibility determinations, and other practice-specific factors. Since all data is transmitted to the Pathologists Quality Registry attributed to an individual NPI within a TIN, there is no need to select reporting option prior to submission. In fact, participants can view their performance scores at the individual and group level throughout the year. Sending multiple feedback reports at multiple reporting levels would be confusing for clinicians. Therefore we suggest that this policy is unnecessary given that Qualified Clinical Data Registries (QCDRs) usually provide the information on the performance dashboard.

Conditions for Approval: Proposal to Update Qualified Posting

The CAP understands the potential confusion created by third party intermediaries changing

information after the Qualified Posting is publicly available and supports proposals to reduce confusion as well as prohibit poor behavior by third party intermediaries. However, there may be some circumstances outside of the control of the intermediary which would necessitate updates to the Qualified Posting. For instance, if a technology vendor were to go out of business mid-year, that would necessitate a change that the third party intermediary was not responsible for. We support the overall proposal, although we recommend that CMS permit exceptions in true emergency situations, subject to CMS' discretion.

CALCULATING FINAL SCORE

Proposal to Use Alternative Data Sources to Determine Clinician Eligibility for the Automatic EUC

As background, the CAP believes strongly in the ongoing necessity of Extreme and Uncontrollable Circumstances Exceptions (EUC) as natural disasters continue to compromise the ability of some practices to provide high-quality care and to report MIPS measures and activities. This program has been essential for practices particularly in hurricane- and wildfire-prone areas. In the past, the CAP's Pathologists Quality Registry has supported clinicians applying for EUCs by providing resources and directing practices to the appropriate CMS page. However, the fact that a practice needs an EUC often means the practice's facilities, including IT and/or internet facilities, have been compromised. Some practices are not able to apply for EUCs until much later in the year.

The CAP continues to support CMS' policy of applying automatic EUCs to practices in FEMA-designated major disaster areas. However, we recognize the challenges posed by utilization of Provider Enrollment, Chain and Ownership System (PECOS) data as outlined by CMS. Therefore, we support CMS' proposal to use additional current and reliable data such as the zip code on billed claims to make EUC determinations.

ADVANCED APMS

QP Determination
As background, the CAP supports efforts to increase specialist participation in APMs, especially Advanced APMs. The transition to value-based care is critical for the entire healthcare system. However, we continue to stress that the development of any APMs must be done in consultation with those specialties impacted by the models. Not only have models been developed by the Center for Medicare and Medicaid Innovation (CMMI) that dramatically change providers' clinical decision-making without considering the input of those specialties, but CMMI has not tested as proposed any specialist-developed APMs recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which was meant to provide an important opportunity for specialists to develop their own models and submit them for review and recommendation. More innovative payment and delivery models must be developed in an open and transparent fashion with the input of those specialties impacted by the models.

Regarding determination of who is participating in an Advanced APM, or determination of Qualifying APM Providers (QPs), the CAP supports clear straightforward determinations that

reduce burden on individual clinicians and advance value-based care across the healthcare system. Previously, the CAP expressed hesitancy about determinations done solely at the NPI level since that is contrary to the team-based care approach of the healthcare system. Therefore, we were pleased to see CMS acknowledging the need for determinations at the NPI and TIN level. This seems to be the least confusing option that will capture the most APM participants.

We understand CMS' concerns regarding financial incentives of QP status, particularly as the differential conversion factors for QPs vs non-QPs (MIPS-eligible clinicians) increase over the next few years. Furthermore, we acknowledge the desire to align QP determination with MIPS determination. However, we have significant reservations regarding the burden this would place on individual clinicians to understand both APM participation and simultaneously MIPS participation, the different requirements of each program, the different incentives of each program, and the administrative burden to participate in each program. Additionally, as noted previously regarding individual QP determination, simply because an individual clinician does not meet the patient or payment threshold to be considered a QP does not mean that he or she is not making critical contributions to team-based care.

We believe that continuing QP determination at the NPI and at the TIN level is the most understandable method to do QP determinations. We recognize that this may result in some payments to TINs who are not in Advanced APMs. However, CMS states that this is relatively low number of TINs currently. Additionally, TINs with one or a small number of NPIs who are QPs at another, separate practice will only receive incentives for that NPI, not for all NPIs at the practice. This small bonus can serve as a demonstration of the benefits of being in an APM and hopefully encourage TINs to look for ways to join Advanced APMs. More importantly, however, we believe the administrative burden and confusion generated by requiring an individual to track his or her status at each practice and simultaneously understand MIPS and APMs is too significant an issue to justify the change to QP determinations at the NPI/TIN level.

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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 tklemp@cap.org, James Carver jcarver@cap.org, Elizabeth Fasbender EFASSBE@cap.org, Colleen Skau CSKAU@cap.org, or Han Tran HTRAN@cap.org

Sincerely,

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