COLLEGE of AMERICAN PATHOLOGISTS

September 9, 2024

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1807-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1807-P; Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1807-P entitled "Medicare Program; CY 2025, Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies." 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.

Our comments in this letter focus on the following subjects included in the proposed rule:

1. Medicare Economic Index
2. Development of Strategies for Updates to Practice Expense Data Collection and Methodology
3. CY 2025 Clinical Labor Pricing Update Proposals
4. Potentially Misvalued Services
5. Valuation of Specific Codes
6. Expanding Coverage of Colorectal Cancer Screening
7. QP Determinations and the Alternative Payment Model (APM) Incentive
8. CY 2025 Updates to the Quality Payment Program (QPP
   a. Requests for Information: The Role of MVPs in Transforming MIPS and Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care
   b. MIPS Value Pathways (MVPs)
   c. Data Submission for the Performance Categories
   d. MIPS Performance Category Measures and Activities
   e. Request for Information (RFI) Regarding the Public Health Reporting and Data exchange
   f. MIPS Final Score Methodology; Payment Adjustments and Final Score

1. Medicare Economic Index (MEI)

The CAP appreciates and supports the CMS decision to defer implementation of Medicare Economic Index (MEI) changes to the distribution of relative value unit components (work, practice expense, and professional liability insurance) within the RBRVS. The CAP agrees that CMS should allow for

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the review of data from the Physician Practice Information (PPI) Survey before implementing re-weighting that would result in significant redistribution within physician payment. **The CAP agrees with CMS' proposal to postpone the implementation of the updated MEI weights until additional practice cost data is available.**

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

As the AMA is currently collecting data through the Physician Practice Information Survey (PPI), CMS is not proposing to incorporate the updated 2017-based MEI for CY 2025. Additionally, CMS notes that they have contracted with the RAND Corporation to analyze and develop alternative methods for measuring practice expense for implementation of updates to payment under the PFS. CMS requests general information from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, the CMS requests feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs. CMS believes that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. CMS states that they will "continue to study possible alternatives, and would include analysis of updated PPI data, as part of our ongoing work." Further, the CMS seeks feedback on possible mechanisms to establish a balance whereby their methodology would account for inflation and deflation in supply and equipment costs. CMS seeks comments on how they may continue work to improve the stability and predictability of any future updates, including recurring pricing updates for clinical staff, medical supplies, and medical equipment. The CAP offers the following comments:

- **The CAP shares the CMS concern that the current AMA PPIS effort may fall short of expectations, resulting in contingencies or alternatives being necessary to address the lack of data availability or response rates**
- **The CAP is encouraged that the CMS has contracted with the RAND Corporation to analyze and develop alternative methods for measuring practice costs and related inputs to implement updates to payment under the PFS.**
- **The CAP believes that the CMS should implement scheduled, recurring updates to practice expense inputs for supply and equipment costs. The CAP agrees with the CMS that establishing a cycle of timing to update supply and equipment cost inputs including stakeholder input every year.**
- **The CAP agrees that there must be a balance whereby any methodology to update practice expense costs would account for inflation and deflation in supply and equipment costs.**

3. CY 2025 Clinical Labor Pricing Update

CMS notes that CY 2025 marks the final year of this phase-in of non-physician clinical labor staff costs inflationary updates. During this process, the CAP has advocated for, and the CMS implemented increases to cost estimates to the services provided by histotechnologists and cytotechnologists. While we appreciate these updates, the CAP would point out that inflationary pressure on clinical labor staff costs is an ongoing issue and suggest that the Agency leave open the possibility of a process that allows stakeholders to provide updated cost estimates to the Agency on an ongoing basis. **The CAP encourages the CMS to develop a process by which stakeholders can provide updated non-physician clinical labor costs on an ongoing basis.**

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4. Potentially Misvalued Services

In the proposed rule, CMS discussed comments that they received from a specialty society indicating that they believed that the Fine Needle Aspiration CPT codes 10004, 10005, 10006 and 10021 were potentially misvalued. In the rule, CMS disagrees that these codes are potentially misvalued noting that these services have been recently revalued.
The CAP agrees with the CMS that the FNA services should not be re-evaluated.

5. Valuation of Specific Codes

Chimeric Antigen Receptor (CAR-T) Therapy

In the Medicare Fee Schedule proposed rule the Agency indicated in that they accepted the RUC recommendations for physician work for CPT codes 3X018, 3X019, 3X020 and 3X021 without refinement. However, the Agency did not accept the RUC recommendation for 3X018, 3X019, 3X020 that the practice expense for these services be carrier priced. Instead, these codes are recognized by the Agency as having no recommended direct PE values and the CMS is seeking comment on direct PE values for these codes.

The CAP believes that the RUC should have submitted the non-facility direct practice expense inputs that were developed by a panel of CAP CAR-T experts prior to the September 2023 RUC meeting.

As a reminder, CAR-T therapies involve separate and distinct processes. Importantly, each step is labor intensive and requires the expertise of physicians and other health care professionals, oversight and monitoring. In addition, each patient must be monitored for treatment related complications, such as cytokine release syndrome and neurotoxicity.

Although these processes bear a resemblance to autologous stem cell transplant, there are significant differences: the patient population is frequently sicker, and the collection, handling, and administration of the cells must be performed under stringent conditions. CAR-T services are a treatment of last resort.

The genetic alteration and cell expansion are performed by biotechnology companies operating according to FDA manufacturing processes. Therefore, the codes describe only those steps of this complex process that are currently performed or supervised by physicians. The first code (3X018) describes lymphocyte collection; the second code (3X019) describes the post-collection handling of the lymphocytes and preparation of the cells to be shipped to the manufacturer; the third code (3X020) describes receipt of and handling and additional preparation of the genetically altered lymphocytes before administration; the fourth code (3X021) describes administration of the genetically altered lymphocytes

As described above CAR-T therapy is a complex service that involves a series of detailed steps from the initial collection to the subsequent infusion of cells. Without the services described by 3X018-3X020, the infusion of cells described by 3X021 is not possible. So, the fact that there are currently non-facility direct practice expense costs associated only with the infusion code, 3X021, does not make sense. In fact, the provision of 3X018-3X020 have a significant amount of practice expense associated with each code. The CAP CAR-T expert panel spent time, and in painstaking detail, provided information estimating the clinical labor time and describing the supplies and equipment

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associated with each of these three services. To ensure accuracy our expert panel was made up of CAR-T providers representing different health systems and geographic areas of the country so that the inputs represented the "typical" patient case. The CAP does not want the providers of CAR-T services disadvantaged in any way by not having non-facility direct PE inputs for CPT codes 3X018-3X020.

Therefore, in response to the CMS' request for comment on direct PE inputs for CPT codes 3X018, 3X019, and 3X020, the CAP is submitting non-facility direct practice expense inputs that were developed by a panel of CAP CAR-T physician subject matter experts. These direct practice expense recommendations are based on current patient care practices and AMA RUC/PE guidelines. The attached spreadsheet provides the non-facility direct practice expense inputs for each of these services, with specific details on non-physician clinical labor, supplies and equipment.

The CAP urges the Agency to finalize the proposed physician work RVUs for CAR-T and carefully review and take into consideration our direct practice expense recommendations for CPT codes 3X018, 3X019, and 3X020. (**The direct practice expense information including a spreadsheet and the practice expense summary can be found in the attached appendix).**

Therapeutic Apheresis

In the CY 2024 PFS final rule, CMS flagged CPT codes 36514 (Therapeutic apheresis; for plasma pheresis), 36516 (Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), and 36522 (Photopheresis, extracorporeal) as potentially misvalued. The Agency believed there may have been a possible disparity with the clinical labor type. As a result, the PE clinical labor type was reviewed for these three codes at the January 2024 RUC meeting, with no work review. The PE Subcommittee and the RUC agreed that clinical staff code L042A (RN/LPN) did not appropriately represent the work of an Apheresis Nurse Specialist. There is not a clinical staff code for an Apheresis Nurse Specialist; however, the RUC agreed with the specialty societies' recommendation that the training and experience of an oncology nurse (clinical staff code L056A, RN/OCN) would more accurately reflect the work of an apheresis nurse for these CPT codes. The RUC submitted new PE recommendations for these three codes based on the use of the L056A clinical labor type and were accepted by CMS without refinement. **The CAP agrees with this proposal and urges the CMS to finalize the clinical labor staff type change recommended by the RUC for CPT codes 36514, 36516, and 36522.**

6. Expand Coverage of Colorectal Cancer Screening

CMS is using statutory authority to update and expand coverage for colorectal cancer screening with the following proposals:

- Adding coverage for Computed Tomography Colonography (CTC),
- Removing coverage for the barium enema procedure, and
- Expanding a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

The CAP supports the expansion of colorectal cancer screening coverage.

7. QP Determinations and the Alternative Payment Model (APM) Incentive

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We appreciate the agency's efforts to develop, propose, and implement policies "that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs." As we have previously emphasized, pathologists are integral in any care coordination initiatives – including Advanced APMs – as they apply their expertise to the diagnosis and management of a wide variety of medical conditions and undertake efforts targeted at increasing integration to improve patient care. However, we continue to stress that the development of any APMs must be done in consultation with those specialties involved in the models. Not only have models been developed by Center for Medicare and Medicaid Innovation (CMMI) that dramatically impact 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.

Further, statutory requirements dictate that Qualified APM Participant (QP) thresholds increase in the 2025 performance year from 50 to 75 percent of payments and from 35 to 50 percent of patients. Partial QP thresholds will also increase from 40 to 50 percent of payments and 25 to 35 percent of patients, while the APM Incentive Payment is set to expire at the end of the 2024 performance year. We certainly understand the changes are outside of CMS's current control, but these thresholds represent significant challenges for physicians – and especially pathologists – in reaching QP or partial QP status. Additionally, as we have previously commented, without the incentive payment, providers will be less able to afford continued participation in Advanced APMs (considering operating costs and needed infrastructure) and will be less likely to take on any new participation (given significant transformation investment costs). As these developments further constrain pathologists' ability to participate in Advanced APMs, it is increasingly important to appropriately encourage specialists' participation while reducing reporting burden and meaningfully responding to stakeholder feedback.

Specifically, we acknowledge the proposal to modify criterion of the definition of "attribution-eligible beneficiary." Insofar as this change accurately recognizes Advanced APM participation and addresses challenges to Advanced APM participation faced by specialists, we support the modification. We also support efforts to "simplify and streamline QP determinations." However, as CMS notes, we are concerned that there is more work to be done in this area and we strongly urge CMS to, as expressed, "continue to analyze these developments and issues with the goal to provide for an equitable, rational, transparent, and meaningful methodology for QP determinations across the full range of Advanced APMs."

8. **CY 2025 Updates to the Quality Payment Program (QPP)**

The CAP looks forward to continuing engagement with the CMS on multiple aspects of the Merit-Based Incentive Payment System (MIPS) 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. The CAP continues to support explicit consideration of how non-patient facing providers are enabled to participate and be fairly recognized for the value of care they provide, via accommodations or alternate measures as

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necessary to meet the clause[1] in the Medicare Access and CHIP Reauthorization Act (MACRA) that requires CMS to consider non-patient facing clinicians. The CAP outlines specific concerns below in its comments on the Quality Payment Program (QPP).

A. Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

The CAP appreciates the opportunity to provide input on the design of a future specialty care model built around the MVP framework. Pathology and laboratory medicine implicate many diseases and conditions; pathologists are critical members of health care teams in many settings. Broadly, we recommend that CMS and the Innovation Center focus on aspects of the model which can reduce burden on clinicians, incentivize meaningful participation, and reward high performing specialists. We strongly encourage the Innovation Center to avoid recapitulating the flaws of the current MIPS program by pitting clinicians against each other or imposing unnecessary participation requirements. As well, we emphasize the need for development of models in collaboration with stakeholders, via ongoing engagement with the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and other mechanisms. We have provided additional information below.

First, regarding participant definitions and identification of groups for this model, **we strongly oppose the idea that this model would be mandatory when rolled out**. Mandatory models impose unnecessary burdens on clinicians and do not allow for differences in practice patterns, health information technology, and staffing levels across groups. We suggest that CMS allow clinicians to identify themselves and voluntarily join the model. The burdens associated with MIPS are well-documented; if the ambulatory care model based on MVPs is a significant improvement over MIPS, clinicians will want to join it and if it is designed appropriately, it will be easy for MIPS-eligible groups to join. It is also important to ensure that any model is primarily focused on improving outcomes for patients. Models should not be driven at the expense of patient care.

Additionally, regarding identification of participants via subgroups, CMS has introduced flexibility for formation of subgroups in MVPs such that subgroups are no longer required to be composed of a single specialty. Rather, subgroups can be created in any way that reflects meaningful divisions of a multispecialty practice. For instance, a multispecialty dermatology group with multiple locations could include the dermatologists, pathologists, and Mohs surgeons from the “east side” location in one subgroup and the “west side” location in another. This is significantly more meaningful to the clinicians than grouping all pathologists together, since they practice at different locations and treat different patient populations. Therefore, it would not be possible for CMS to use subgroups as a mechanism to identify certain specialties for an ambulatory care model. Practice patterns of MIPS participants are complex and we encourage recognition of this fact by allowing groups to identify themselves and choose to participate as they deem appropriate for their practice.

Additionally, a well-designed model could incentivize participation of specialists that CMS may not

[1] In carrying out this paragraph, with respect to measures and activities specified in subparagraph (B) for performance categories described in subparagraph (A), the Secretary—
‘‘(I) shall give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient; and
‘‘(II) may, to the extent feasible and appropriate, take into account such circumstances and apply under this subsection with respect to MIPS eligible professionals of such professional types or subcategories, alternative measures or activities that fulfill the goals of the applicable performance category.
In carrying out the previous sentence, the Secretary shall consult with professionals of such professional types or subcategories.

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have originally identified, so we recommend against strict use of Claims or PECOS data to limit participation. CMS is aware of the challenges associated with specialist participation in existing APMs, as outlined in the Calendar Year 2024 rule and later in this rule. Therefore, CMS should consider the maximum amount of flexibility available for groups to voluntarily participate in this new model.

We also suggest that CMS consider exemptions for solo practitioners and clinicians in rural or health professional shortage areas, as well as additional flexibility for non-patient facing clinicians. The latter group requires flexibility in the existing MIPS program and therefore cannot effectively be compared against patient-facing clinicians.

As it relates to selection of measures and activities, it is critical that CMS acknowledge that not all performance categories are relevant to all MIPS participants. In considering the number of activities in an MVP for clinicians participating in the model, we recommend selecting measures that are reliable and would be highly used by model participants as well as measures that drive care integration. 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. 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. Additionally, the CAP encourages CMS to take advantage of the increased participation of clinicians in a model to test measures where appropriate. However, since the most successful quality measures are created by specialty societies with clinical expertise, CMS should also ensure full involvement of current measure stewards and specialty societies.

The payment adjustments in a model based on MVPs will be critical to incentivize participants moving from MIPS into the model. We encourage CMS to base the payment adjustment structure on successful models and demonstrations the Innovation Center has already conducted. Notably, a new model should be maximally accessible to groups who have never participated in a model before. Since this model is explicitly targeting MIPS participants, these practices may not be well-versed in two-sided risk or in the costs and challenges of practice transformation. We suggest that the model should not be mandatory and should be upside-only risk at the beginning, similar to participation in the Shared Savings Program. As well, CMS should consider additional incentive payments to drive practice transformation and payment similar to the advance investment payments (AIPs) in the Shared Savings Program to encourage practices who have never participated in value-based care arrangements to join, especially those caring for underserved populations. In the future, CMS should thoroughly evaluate participants' readiness to move to two-sided risk before transitioning the model.

We also suggest that CMS consider the reasons that these practices are not currently participating in Innovation Center models. MIPS participants, who are often smaller independent and private practices, sometimes lack the resources necessary to fully participate in a model that requires significant investment. The CAP encourages CMS to carefully survey existing models to avoid recapitulating the flaws that prevent these practices from joining.

Similarly, we are encouraged to see consideration of concerns related to consolidation and believe that future models should avoid driving unnecessary consolidation or forcing physicians to change practice patterns when it is not in the best interest of their patients. Any model design features should recognize and allow for participants to practice in the way that best serves their patient population. We also understand CMS' desire to establish a Universal Foundation of quality measures

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that can be used in multiple programs, but the current set is not applicable to all specialties and could increase barriers for participation by small single-specialty practices. CMS can consider working with specialty societies to identify the most parsimonious foundational set of measures within any specialty and to promote broad uptake of those foundational sets across the health care system by federal and private programs.

Finally, with respect to health equity and multi-payer alignment, there are known challenges within the MIPS program related to these areas. We suggest that it is premature to design a model based on attempting to align with other payers when it is unclear how well the model will function for a single payer.

Therefore, while we broadly support the goals of this model to diversify the models available to specialists, we suggest that additional investigation is needed before such a model can be designed, notably in the areas of payment adjustments and avoidance of driving unnecessary consolidation. It is likely that 2026 is too soon for such a model to be rolled out. As CMS continues to develop the model and collaborate with stakeholders on it, we strongly encourage continued work on the current iteration of MVPs, which still have significant challenges for participants.

REQUEST FOR INFORMATION: THE ROLE OF MVPS IN TRANSFORMING MIPS

The CAP understands that an ongoing discussion of sunsetting traditional MIPS aligns with CMS' broader goal of having Medicare beneficiaries in accountable care relationships by 2030 but we highlight several ongoing areas of consideration, many of which CMS has already acknowledged. In addition to some specialties still having limited cost and quality measures (discussed more below), CMS should ensure that other logistical processes and procedures are ready for the sunsetting of traditional MIPS. First, related 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 allows. However, if traditional MIPS sunsets, the QCDR measure process becomes unclear, since the timeline of MVPs in the proposed rule does not align with the timeline of self-nomination for QCDRs with new QCDR measures.

Additionally, we request additional information regarding how feedback will be provided to MVP participants. One of the original benefits of MVPs was enhanced performance feedback from CMS. We look forward to more information on that aspect of MVPs. We also request that CMS codify that the current EMA process will be applied to MVPs and similarly the current Targeted Review process will be applied to MVPs. Finally, we would appreciate additional clarification regarding the role of facility-based scoring once traditional MIPS sunsets. Will facilities be expected to report MVPs? Or will aspects of traditional MIPS be maintained for facilities, given that many clinicians score better via facility-based scoring? These are a few of the issues that remain to be resolved prior to sunsetting traditional MIPS.

Regarding meaningful MIPS participation for clinicians who in the future may not have an applicable MVP, we appreciate CMS' consideration of possible options for specialties where an MVP has not been developed. We offer several thoughts regarding the future of MVP development in these areas. First, we suggest that if there cannot be an MVP for a given specialty, that indicates that the current conception of MVPs is not a good fit for the specialty. Rather than shoehorning the specialty into an MVP that doesn't fit with the established practice of medicine, we recommend waiting until MVPs evolve into a program that does meaningfully capture the specialty in question. Therefore, these

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specialties would remain in traditional MIPS until MVPs evolved or until an APM was available for the clinicians.

CMS MVP Development Options

Option 1: Expanding existing MVPs
With respect to CMS' specific options for development of new MVPs, option 1, expanding existing MVPs, would possibly help address the gaps in the MVP set but could also counteract some of the stated goals of MVPs including the ability to compare participants more effectively within an MVP. For example, oncologists and pathologists participating in a theoretical Advancing Cancer Care MVP could not be compared against each other. This option would also increase the number of measures in a single MVP, possibly significantly, undermining the goal of reduced complexity. For example, if pathology and radiology were included in the Advancing Cancer Care MVP, it would also make sense to include pain management clinicians and palliative care clinicians. This could lead to five or more non-overlapping sets of quality measures within a single MVP. Similarly, if pathology and radiology were included in the Advancing Cancer Care MVP, they could also potentially be captured in the Urological Care MVP and others. This would increase the number of MVPs that include the diagnostic specialties, thereby countering the goal of MVPs to reduce the overwhelming choice of MIPS. The idea of a "patient journey" MVP is intrinsically appealing as it promotes team-based care but would need to be implemented carefully to ensure it meets the overarching goals of MVPs. We would not support this as the primary option for ensuring that the maximum number of specialties are captured in MVPs.

Option 2: Expanding MVP to include subspecialties
The second option, expanding previously finalized MVPs to include subspecialties, does not necessarily address the underlying issue since many of the specialties in question do not have an MVP to expand. That is, expanding a pathology MVP to ensure that all subspecialties (e.g. dermatopathology, hepatopathology, etc.) were included would make sense. However, there is no pathology MVP to expand. Therefore, specialties would have to first be added to other previously finalized MVPs, which was covered above.

Option 3: Develop multiple specialty MVPs
The third option, develop MVPs based on multiple specialty measure sets, could potentially recapitulate the issues that MVPs were designed to address, namely too many unrelated measures and broad measure coverage that does not allow comparisons between clinicians. It may be possible to develop a "Diagnostic Excellence" MVP to cover multiple non-patient-facing specialties, especially as a bridge until each specialty is able to develop their own more relevant MVP. However, we urge caution in constructing such an MVP to ensure that scoring potential is equivalent for all participants and scores are comparable. As CMS acknowledges, this is likely a temporary solution and does not address the underlying issues for these specialties in participating in MVPs.

Option 4: Develop Broad or Cross Cutting MVPs
The fourth option discusses developing MVPs based on broad or cross-cutting measures. We suggest that while CMS may see value in such an MVP, it likely does not address the issues for specialties that currently do not have MVPs. After all, if an MVP could be constructed based on existing measures, there would be no issue. The fact that a number of specialties still cannot have MVPs indicates that the current measure inventory is insufficient; developing an MVP based on broad measures is not a solution to that challenge. These measures also do not apply to all specialties, specifically non-patient-facing specialties.

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Option 5: Develop non-patient facing MVPs
The final option specifically identified by CMS covers developing MVPs for non-patient facing clinicians. This is an ongoing challenge for pathology, and we appreciate CMS' explicit identification of it. As CMS notes, development of "alternative measures or activities that fulfill the goals" of some categories, notably the cost category, may be necessary for such an MVP and would require consultation with the relevant clinicians. The CAP strongly encourages CMS to engage with specialties frequently throughout the development process to ensure that any measures of cost/value are meaningful, and that subsequent MVP(s) are meaningful as well. Per CMS' comments, we believe it may be necessary to consider alternate measures or activities to assess cost. This has been a major sticking point for the development of a pathology MVP, and we are open to other approaches. We remain uncertain whether the current conception of episode-based cost measures will ever be able to adequately capture pathology or other non-patient facing specialties. Alternatively, since clinicians who do not have an applicable cost measure are currently reweighted in traditional MIPS, we suggest CMS reconsider the absolute requirement for inclusion of a cost measure in every MVP. We also support the previously finalized policy to score MVP participants the same as participants in traditional MIPS as it relates to reweighting of performance categories.

Subgroup Participation
CMS also requests feedback on subgroup participation and mandatory subgroup formation for multispecialty groups. Although there is not an MVP that covers most pathologists at this point, many pathologists could be affected by the subgroup policy as they practice in multispecialty groups. First, we request additional insight into an apparent change in CMS' evaluation of MIPS participation. In the current conception of traditional MIPS, eligibility is determined at the individual level; only individuals who meet the low-volume threshold are required to report MIPS. However, with the shift to MVPs and the increased emphasis on subgroup reporting, it seems that CMS is intending for only groups to report MVPs. Will determinations of eligibility still be made at the individual level? If all members of a multispecialty group fall below the low-volume threshold as individuals, will the group still be exempt from reporting, or will they be required to report an MVP and form subgroups?

We appreciate the need to balance increased burden with the desire for meaningful reporting by multispecialty groups. However, we suggest that CMS should not create limitations on subgroup formation *a priori* but wait to see what reporting data looks like after 2026. CMS risks imposing unnecessary requirements on subgroups and groups by attempting to anticipate issues that may not occur.

If CMS decides it is necessary to impose requirements on subgroup formation, we suggest thresholds be set for when enough 'specialty specific claims' would justify the need for subgroup reporting, at least equivalent to the current MIPS participation thresholds. Thus, subspecialties with low volume would not be forced to report via MVPs when they would not have reported via traditional MIPS. As CMS indicated, there would be significant burden concerns related to forcing a small group to create subgroups. Due to the potential for increased burden and the possibility that any data would not be data, small groups should be exempt from the requirement of multispecialty groups to form subgroups for MVP reporting. We also raise logistical concerns regarding use of Claims data to create subgroup restrictions because that information is insufficient to fully capture practice patterns: neither information about what location a clinician practices at within a given TIN, nor subspecialty (dermatopathology, hematopathology, etc.) are available via Claims data.

Similarly, there may be circumstances where multiple subgroups of a single multispecialty group may report the same MVP. For example, consider a large dermatology group with an east side location and a west side location within the same city. The dermatologists, pathologists, and Mohs surgeons

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of each location could each form a meaningful subgroup that promotes team-based care within their location. There is no reason both locations should not report the same MVP.

Finally, the increase in subgroup reporting will increase the complexity of reporting patterns. This will in turn increase the role of clinical data registries to support clinicians reporting MVPs. In order to ensure that registries are able to maximize participation of their clinical clients, registries must be able to know who has registered for what MVP. As of now, registries are reliant on the participants to ensure they have successfully registered for an MVP. With the increased complexity of subgroup reporting, registries will be better able to support their clients if CMS can provide a list of who has registered for which MVPs to third party intermediaries. Similarly, we suggest CMS display the determination of whether a group is considered single specialty or multispecialty on the QPP lookup tool to prevent confusion late in the reporting year.

B. MIPS VALUE PATHWAYS (MVPS)
CY 2025 MVP Development and Maintenance

Development of New MIPS Value Pathways (MVPs)

The CAP acknowledges CMS' desire to continue developing MVPs with a goal of having an MVP for each specialty. However, we emphasize the unintended consequences of including measures and activities that are not in alignment with the primary goal of the MVP. As noted above, capturing multiple specialties in a single MVP reduces the ability to compare groups' performance scores within an MVP, particularly when many of the measures and activities do not apply equally to all specialties. We are not clear why CMS has included pathologist-specific quality measures in the proposed Dermatological Care MVP. Evaluating pathologists solely on dermatology measures does not capture the extent of the practice of pathology and could lead to confusion among single-specialty pathology practices. Furthermore, the presence of only two quality measures in the MVP prevents pathologists from fully participating. **The CAP requests that CMS remove the pathology-specific quality measures from the proposed Dermatological Care MVP.**

MVP Maintenance Process

The CAP appreciates CMS' transparency regarding potential MVP candidates and changes to existing MVPs prior to the proposed rule. We believe it is critical for interested parties to have the opportunity to provide feedback on MVP candidates and to evaluate MVP candidates that may appear in the proposed rule. However, we appreciate the challenge of a live webinar as a mechanism to accept comments especially when the comment volume is low. We therefore support alternative methods of soliciting feedback provided that similar opportunities and time for public review are available. We would not support shortening of the comment period or reduction in opportunities for feedback. **We also emphasize the importance of working with stakeholders on the design of MVPs prior to the public comment period**. Some previously constructed MVPs did not fully consider stakeholder feedback and objections.

MVP Requirements and Scoring
We continue to support policies that align scoring between "traditional" MIPS and MVPs to ensure that clinicians understand their scores and can compare their performance across performance pathways. As one goal of MVPs is to simplify the program for clinicians, we believe it is critical to minimize scoring differences between traditional MIPS and MVPs to make the program as understandable as possible for clinicians.

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With respect to the policy on population health measures, we are supportive of the proposed change to eliminate selection of a population health measure at the time of MVP registration in favor of CMS calculating scores on all available population health measures and taking the highest score. We believe this approach is more fair since, as noted, a clinician or group may not know which population health measure(s) will have sufficient data by the end of the performance period. More importantly, we support a continuation of the policy of reweighting groups who do not meet case minimums for any of the population health measures.

As noted above, we support alignment of scoring policies between traditional MIPS and MVPs. Therefore, we support the proposal to align changes to scoring of cost measures between traditional MIPS and MVPs. This applies to both general scoring of the cost category and specifically scoring of subgroups on the cost category. Additionally, we support the proposal to align changes to scoring and weighting of Improvement Activities between traditional MIPS and MVPs. Overall, the proposal reduces burden on MIPS participants (see further comments below) so we are in agreement with adopting this policy in MVPs and traditional MIPS.

C. DATA SUBMISSION FOR THE PERFORMANCE CATEGORIES
Proposed Minimum Criteria for a Qualifying Data Submission for the MIPS Quality, Improvement Activities, and Promoting Interoperability Performance Categories

Quality Performance Category

The CAP appreciates CMS' understanding of the challenges of data submission and the potential for inadvertent submission of non-scorable data that overrides a valid Extreme and Uncontrollable Circumstances exception (EUC). It is unlikely that submissions without any scorable data are intended to represent the performance of an individual or group for the entire calendar year. Therefore, we are broadly supportive of CMS' proposal to narrow the data that would override an approved reweighting or prior data submission. However, we request clarification regarding the requirements for accepted submission of data for the quality category. The proposed policy states that for the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure. Because QDC codes are still accepted for small practices submitting Medicare Part B Claims data, we wish to clarify whether QDC codes are counted as "numerator and denominator data" for the purposes of overriding an approved reweighting or prior data submission. QDC codes are the appropriate way to submit data for Medicare Part B Claims measures. In the past, however, practices have reported unintentional overriding of an approved EUC due to accidental submission of QDC codes. Therefore, we request clarification whether submission of a single QDC code for a single Medicare Part B Claims measure would satisfy the new narrower definition of data submission for the quality performance category.

Improvement Activities Performance Category

As noted above, the CAP appreciates CMS' understanding of the potential for inadvertent submission of non-scorable data that overrides a valid EUC. Since there is no requirement to submit data on Improvement Activities that were not performed, the CAP believes that CMS should only count submissions that include a response of "yes" for at least one improvement activity. We support the proposed change to data submission criteria.

Treatment of Multiple Data Submissions

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Quality and Improvement Activities Performance Categories

The CAP is supportive of CMS' proposal to codify the policy governing treatment of multiple data submissions to calculate and score each submission received and assign the highest of the scores when submissions are from multiple organizations. While we appreciate the difficulty of calculating and scoring multiple submissions from a single organization, we also encourage CMS to consider mechanisms to do so, rather than taking only the most recent submission.

D. MIPS PERFORMANCE CATEGORY MEASURES AND ACTIVITIES
Quality Performance Category

Data Completeness Criteria

The CAP appreciated CMS' understanding of the challenges associated with increasing data completeness thresholds rapidly. We are therefore supportive of the proposal to maintain the data completeness threshold at 75% for CY 2027 and 2028. However, the CAP urges caution when proposing to raise the data completeness threshold in subsequent years. Rather than setting a time frame when the data completeness threshold can be raised, the CAP suggests that CMS evaluate the actual readiness of practices to submit more data in order to identify remaining barriers and methods to address them. Depending on the progress of interoperability efforts between 2025 and 2028, it is possible that practices will be able to handle an increase in data completeness. Since this is unpredictable, however, we encourage CMS to consider mechanisms to support and incentivize practices' efforts to prepare for increased data completeness and to systematically assess readiness over the next few years.

Selection of Quality Measures

The CAP strongly appreciates CMS' retention of the 6 pathology-specific MIPS CQMs in the Pathology Specialty Measure Set. A stable measure set is critical to streamline options and reduce administrative burden by allowing clinicians to predict reporting requirements for subsequent years. However, t**he CAP asks that CMS remove measure 440, Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician from the proposed 2024 pathology measure set.** The CAP has identified multiple feasibility issues that pathologists face while trying to report on this measure. This measure was written for dermatologists who read their own biopsies, is stewarded by the American Academy of Dermatology (AAD) and has not been tested for feasibility for pathologists because of significant implementation challenges. Notably, AAD has requested that each biopsy be reported separately as an individual denominator instance. This does not align with pathology practice. Multiple specimens are given the same Accession ID and treated as a single case or report. Although we appreciate the addition of a Denominator Exception for measure 440, this measure is out of alignment with pathology practice patterns and is so fraught with implementation issues that the data should not be considered valid to use for benchmark or comparison purposes for pathology practitioners.

For these reasons, the CAP believes that measure 440 be removed from the pathology measure set going forward. **The CAP strongly recommends that measures from one specialty not be added to another specialty's measure set unless and until they have been fully tested in that other population of providers.** Given that the Pathology Specialty Measure Set now contains 6 pathology MIPS CQMs and the fact that QID 491 earned a performance year benchmark for PY 2023, we believe measure 440 is no longer needed and only adds complexity for pathologists and lack of data

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standardization for MIPS.

The CAP also encourages CMS to exercise caution when partially removing MIPS quality measures. While we understand the intent of maintaining measures with specific purposes and their importance in certain MVPs, the overall goal of MVPs is to streamline and simplify MIPS. By creating different sets of quality measures available in "traditional" MIPS and MVPs, CMS risks confusing clinicians wishing to report both options. We also believe that partially retaining quality measures does not align with the intent of the program: this indicates that quality in an MVP is not the same as quality in traditional MIPS. If anything, we suggest that MVPs should be more stringent than traditional MIPS. MVPs are intended to be the most important, parsimonious set of quality measures for a given specialty or condition; a measure that lacks value in the broader traditional MIPS program cannot be considered part of a parsimonious set.

Cost Performance Category

Pathologists and pathology groups are not regularly attributed any of the existing episode-based cost measures. This is appropriate since pathologists are not in control of any of the existing episodes and in fact, we believe that it would be difficult to conceptualize an episode which was entirely attributable to a pathologist. Development of a cost measure for pathologists represents a significant challenge due to the nature of pathology and the collaborative role pathologists play in the health care system. However, we would like to highlight one potential area of concern: although we appreciate CMS' desire to move forward with cost measures, the input of experts via the consensus-based entity, the Partnership for Quality Measurement, should not be ignored. When a measure is deemed "do not recommend" by the Pre-Rulemaking Review (PRMR) group, those critiques should be taken seriously and addressed prior to proposing the measure for the program. To do otherwise discounts not only the expertise of members of PRMR but also the time and effort of volunteers including patients and caregivers who sit on the committee. For instance, the Rheumatoid Arthritis measure was considered "do not recommend" but CMS is still proposing to implement it, without addressing the identified issues.

Improvement Activities Performance Category

Codification of Improvement Activity Removal Factors

While the CAP appreciates that over time, some Improvement Activities (IAs) may require modification to remain current with standards in the field and some IAs may be replaced by more robust activities, we have some concerns about the factors CMS identifies as reasons for removal of IAs. Notably, we request additional clarification regarding how "an alternative activity with a stronger relationship to quality care or improvements in clinical practice" would be identified. If the activity is duplicative, it could be removed under factor 1. However, if the IA considered for removal is not duplicative of an existing activity, it may have an important role. A "stronger relationship to quality care" is not clearly defined and therefore could have unintended consequences of removing activities that are critical to certain specialties.

Similarly, we object to Factor 7, Activity is obsolete. This factor is very unclear; how is "obsolete" defined? How can CMS evaluate the utility of the activity across all specialties, particularly those with limited IA inventories? The term "obsolete" is non-specific and could be used as a reason to deprecate any IA with no further justification. We request that CMS specify more concrete conditions for considering IAs obsolete.

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Changes to the Improvement Activities Inventory

Broadly, the CAP requests that CMS consider the usage of Improvement Activities carefully before proposing any changes the Improvement Activities inventory. Some IAs may be highly used by non-patient facing specialists due to limited availability of IAs and are therefore not obsolete at all for those specialties. The CAP does not support removal of several activities proposed for elimination from the IA inventory in 2025. Notably, IA_ CC_1, Implementation of use of specialist reports back to referring clinician or group to close referral loop, is proposed for removal because it does not align with other performance categories. We suggest that this is not true, as several pathology quality measures such as MIPS CQM 397 and CAP 30, cover provision of accurate and complete specialist reports to referring clinicians in order to close the referral loop. This IA is critical to center the value pathologists provide to the healthcare system by recognizing the importance of their reports. Furthermore, this IA directly aligns with the model under consideration by CMS and the Innovation center as described in section III.J, "Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care". This model explicitly looks to "support participants to close the care loop back to accountable care entities or primary care". IA_CC_1 directly supports that and can therefore hardly be considered obsolete.

Similarly, we object to removal of IA_CC_2 Implementation of improvements that contribute to more timely communication of test results, as this is a critical activity not only for pathologists but for the whole health care system. Patients prioritize timely test results as a major issue with the health care system and improvements that can contribute to faster accurate communication of results to patients would be of direct benefit to them. Quality measure MIPS CQM 440 sets a cutoff of 7 days to return results of skin cancer biopsies to patients; we suggest that time could be significantly shortened by improvements in the system.

Furthermore, we object to removal of IA_ ERP_4 Implementation of a Personal Protective Equipment (PPE) Plan and IA_ ERP_5 Implementation of a Laboratory Preparedness Plan. Although the declared Public Health Emergency for COVID-19 has ended, we suggest that a plan for personal protective equipment and laboratory preparedness will be essential for any future pandemics as well as everyday functioning of the health care system. The idea that implementation and updating of a laboratory preparedness plan is obsolete fails to account for ongoing challenges laboratories face. For instance, as recently as July 23, 2024, the Centers for Disease Control and Prevention (CDC) issued a health advisory about a critical shortage of Becton Dickinson (BD) BACTEC™ blood culture media bottles. More broadly, the Centers for Disease Control and Prevention (CDC) has recently begun to develop a framework for a National Laboratory Response System to define roles and responsibilities in future pandemics. CDC is thereby working to operationalize laboratory preparedness and we strongly oppose any action by CMS to disincentivize it. Laboratory preparedness is vital for the functioning of the health care system whether there is a pandemic or not and declaring this activity obsolete is short-sighted and does not align with the needs of the health care system.

Improvement Activity Scoring and Reporting Policies

In the interest of simplifying the IA category and harmonizing across provider types and settings, we support CMS' proposal to remove category weighting for IAs. We do urge CMS to consider the relative effort of activities when evaluating the IA inventory as a whole. With the elimination of weights, the unequal effort required by different IAs may result in a concentration of MIPS participants reporting a small number of IAs. Therefore, the CAP suggests that CMS add new IAs

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when appropriate to ensure a diversity of IAs with a manageable effort level are available for all clinicians. The CAP also supports reducing the number of activities to which clinicians are required to attest in order to achieve a full score in the IA category. This proposal aligns scoring across traditional MIPS and MVPs, which we believe is important for simplifying the program as a whole.

PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY

E. Request for Information (RFI) Regarding Public Health Reporting and Data Exchange

The CAP commends CMS for efforts to advance the public health information infrastructure across organizations. We also appreciate CMS' consideration of the additional burden posed by increasing or modifying the Public Health Reporting and Data Exchange objectives of the Promoting Interoperability (PI) category and CMS' recognition of the reporting burden that the PI category poses for MIPS eligible clinicians. The CAP has significant interest and experience in promoting public health and data exchange as it relates to laboratories. Therefore, we provide the following responses to this request for information.

- Should CMS shift to numerator/denominator reporting requirements for current and future measures in the Public Health and Clinical Data Exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?
  - CAP Comment: In addition to the burden created by switching to numerator/denominator reporting, we caution against any shifts that could muddy the distinction between Promoting Interoperability measures and Quality measures. The PI category is intended to drive increased interoperability and it is difficult to see how numerator/denominator reporting would achieve that objective.

- Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective? What are the risks of including too many measures under the objective?
  - CAP Comment: To avoid exacerbating workplace burnout, we advocate for ways to reduce burden as much as possible while achieving quality and public health objectives. In this case the value of increasing the burden is unclear. We would need to understand what benefits CMS and hospitals would derive from shifting to numerator/denominator reporting before being able to judge if there is sufficient benefit to the increased burden.

    With respect to the risks, in addition to the aforementioned burden, too many measures dilute the value of any single measure, both in terms of points and in terms of the ability of facilities to identify areas of improvement. Also unclear whether these would all be required measure or optional measures. Currently there are 5 required and 2 optional measures under this objective (all attestation only). Increasing the number could add confusion as well.

- Alternatively, should CMS explore ways to group data types and use cases under a more limited set of Public Health and Clinical Data Exchange objective measure? If so, are there specific scenarios where doing so would make sense? Anecdotal reports suggest that some healthcare providers are attesting to active engagement with public health for the eCR measure if they report cases for at least one notifiable condition (for example, COVID-19).
  - CAP Comment: Clinical laboratories may have problems collecting the required data elements if requirements are expanded to include reporting of laboratory results with some new data elements that have not historically been required and may not be in many information systems currently. Some required data elements are not tracked in many if not

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all information systems (e.g., FDA Unique Device Identifier, the actual zip code of the ordering provider). In addition, several data elements lack enough clarity with conflicting information regarding required vs. optional items for reporting.

Clarify and specify minimum necessary. The Office of Civil Rights (OCR) should release a clarification that public health usage covers the exchange of personal information as part of laboratory orders and results, and that these data fall within the minimum necessary standard

- What potential benefit versus burden trade-offs CMS should consider? How should CMS account for varying levels of public health readiness and capacity for expanding conditions reported electronically, such as in rural areas?
  - CAP Comment: Regarding the potential benefit versus burden trade-off, our position is the same as in the response to the questions above "Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective?"

    With respect to varying levels of readiness, we suggest that new measures be optional (bonus points only) at least at the beginning, and for an extended period of time and with additional incentives for CAHs/rural hospitals.

- What additional levers besides the Promoting Interoperability performance category should CMS explore to improve the completeness of reporting to public health? How should CMS work with other partners to incentivize or require reporting?
  - CAP Comment: Allocate government funding explicitly for the purpose of making such reporting feasible. This could include grants to help hospitals, laboratories, and public health authorities upgrade their systems. Priority for federal funding should be inverse to any resource capability of the laboratory so that financially weaker laboratories are eligible for the most federal resources

- How can the Promoting Interoperability performance category balance robust Public Health and Clinical Data Exchange objective requirements with our desire to reduce burden on MIPS eligible clinicians?
  - CAP Comment: Align incentives to encourage standards usage. Currently, payment programs such as Promoting Interoperability provide financial incentives for using certified EHR technology to achieve certain functions. One measure within the Promoting Interoperability program is to electronically submit laboratory results to public health agencies. However, there is not an associated standard of use, or a data completeness requirement, as part of the measure. Centers for Medicare and Medicaid Services (CMS) could incentivize the use of ONC-identified standards, such as using the USCDI demographic data set when exchanging laboratory orders and results, within Promoting Interoperability or other payment programs. Incentives should be available for all stakeholders, including laboratories and public health, in order to ensure resources are available for needed system upgrades.

    Ensure that laboratories are not penalized if they don't get the correct or full demographic data in the test order. The responsibility for collecting the correct demographic data lies with the ordering physician, and the ordering physician must ensure that data is collected and exchanged accurately and in its totality.

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- How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for MIPS eligible clinicians? What are potential barriers to achieving burden reduction as these new approaches are implemented?
  - CAP Comment: Moving to FHIR-based laboratory data exchange would be costly in that it would require replacement of existing interfaces. Additionally, FHIR is not ready for laboratories, as FHIR does not yet cover the full set of laboratory use cases needed for reporting to PHAs.

F. MIPS FINAL SCORE METHODOLOGY
Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Scoring for Topped Out Measures in Specialty Measure Sets with Limited Measure Choice

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. That is to say, we believe that the current topped out measure policy does not appropriately incentivize maintenance of the highest quality care for patients. Therefore, while we are pleased to note proposed changes to the policy which would mitigate the effects of topped out measures on specialties with limited measure choice, we encourage CMS to continue to evolve the overall goals of the quality performance category away from continuous improvement to a broader definition of quality.

As pathologists have few measures to choose from and cannot report the broadly applicable MIPS quality measures, **the CAP is supportive of the proposed change to the topped out measure policy and 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 prevents equitable scoring opportunities. However, we recommend 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 2025 list would be re-evaluated for the 2027 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.

MIPS PAYMENT ADJUSTMENTS
Establishing the Performance Threshold

Establishing the Performance Threshold Methodology for the 2027, 2028, and 2029 MIPS Payment Years

The CAP appreciates that CMS is taking into consideration the burden placed on clinicians by raising the performance threshold rapidly and is considering the selection of mean or median in three-year intervals. Based on feedback from MIPS participants, constant changes to policies and procedures

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are a significant challenge for practices so we encourage consideration of what other policies can be viewed through a longer time lens.

Based on the provided values for mean and median MIPS scores from 2019 payment year through 2024 payment years, we support continued use of the mean as the performance threshold. While data from payment years 2021 through 2023 are likely unreliable due to the effects of the COVID-19 pandemic, even the median from payment year 2024, the lowest on the list, represents a significant step up from the current 75-point threshold. As noted by CMS, there is considerable value in stability and consistency for clinicians therefore we support the continuation of use of the mean as the performance threshold for payment years 2027, 2028, and 2029.

Establishing the Performance Threshold for the CY 2025 Performance Period/2027 MIPS Payment Year

In the interest of fairness and stability, the CAP supports continued use of 75 points as the performance threshold for the CY 2025/2027 MIPS payment year. As more MVPs roll out and new clinicians and specialties begin reporting them, it is critical to ensure that changes to the MIPS program do not hinder the ability of clinicians who want to report MVPs to do so. We also support CMS' efforts to ensure that small practices and solo practitioners are not disadvantaged. Furthermore, additional analysis of data collected around the time of the COVID-19 PHE is warranted, as noted by CMS, before this data is used to set performance thresholds. We are in agreement that the final scores submitted to CMS in 2020 for CY 2019 may not be wholly representative of performance of all MIPS eligible clinicians.

CALCULATING THE FINAL SCORE
Proposal to Adopt Reweighting Performance Category(ies) Policy When a Third Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS Eligible Clinician's Control

The CAP appreciates CMS' understanding that clinicians cannot be held liable for circumstances outside of their control as it relates to the behavior of third party intermediaries. This is especially critical in the rare circumstances where a third party intermediary terminates services mid-year. Therefore conceptually, the CAP supports this proposal to adopt reweighting policies.

However, we have some concerns with the scope and execution of this proposal. First, we suggest that CMS consider utilizing existing mechanisms for reweighting performance categories when a third party intermediary did not submit data. That is, rather than create a new way that clinicians can submit a request, if the clinician becomes aware during the performance period of an issue that will prevent the third party intermediary from submitting data (e.g. the intermediary terminates service in October), this should be an acceptable reason to apply for an EUC. If the clinician only becomes aware of the issue after EUC applications close at the end of the performance period, he or she can submit a Targeted Review request using the existing process. We believe creating a new process solely for this purpose will be confusing to clinicians.

Second, we suggest that CMS consider codifying a list of acceptable reasons for a clinician to apply for reweighting. For example, termination of a third party intermediary, or a cybersecurity event at an intermediary would be key reasons. This will clarify for clinicians what is meant by "outside the control of the MIPS eligible clinician". Although rare, there could be instances where a third party intermediary does not submit data due to a failure on the part of the clinician or group to provide complete data. This circumstance would not fall under the policy proposed here and we suggest it

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would be worth providing additional specificity.

Finally, we believe that failure to submit data will most often occur when a third party intermediary has terminated services mid-year. However, in the cases where this is not true (for instance, a cybersecurity incident at a third party intermediary), we request that CMS clarify that the third party intermediary will not automatically be put on probation if a clinician submits an application for reweighting. The fact that a clinician submitted a request for reweighting should not affect the standing of the third party intermediary and should be kept confidential.

QP DETERMINATIONS AND THE ALTERNATIVE PAYMENT MODEL (APM) INCENTIVE

We appreciate the agency's efforts to develop, propose, and implement policies "that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs." As we have previously emphasized, pathologists are integral in any care coordination initiatives – including Advanced APMs – as they apply their expertise to the diagnosis and management of a wide variety of medical conditions and undertake efforts targeted at increasing integration to improve patient care. 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 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.

Further, statutory requirements dictate that Qualified APM Participant (QP) thresholds increase in the 2025 performance year from 50 to 75 percent of payments and from 35 to 50 percent of patients. Partial QP thresholds will also increase from 40 to 50 percent of payments and 25 to 35 percent of patients, while the APM Incentive Payment is set to expire at the end of the 2024 performance year. We certainly understand the changes are outside of CMS's current control, but these thresholds represent significant challenges for physicians – and especially pathologists – in reaching QP or partial QP status. Additionally, as we have previously commented, without the incentive payment, providers will be less able to afford continued participation in Advanced APMs (considering operating costs and needed infrastructure) and will be less likely to take on any new participation (given significant transformation investment costs). As these developments further constrain pathologists' ability to participate in Advanced APMs, it is increasingly important to appropriately encourage specialists' participation while reducing reporting burden and meaningfully responding to stakeholder feedback. The lack of incentives and meaningful models for specialists are contrary to CMS's stated goal of having all Medicare beneficiaries in accountable care relationships by 2030

Specifically, we acknowledge the proposal to modify criterion of the definition of "attribution-eligible beneficiary." Insofar as this change accurately recognizes Advanced APM participation and addresses challenges to Advanced APM participation faced by specialists, we support the modification. We also support efforts to "simplify and streamline QP determinations." However, as CMS notes, we are concerned that there is more work to be done in this area and we strongly urge CMS to, as expressed, "continue to analyze these developments and issues with the goal to provide for an equitable, rational, transparent, and meaningful methodology for QP determinations across the full range of Advanced APMs." We encourage CMS to consider other substantial efforts to increase

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options for specialist participation in Advanced APMs.

The College of American Pathologists is pleased to have the opportunity to comment on these issues and appreciates your consideration of our comments. Please direct questions related to items 1-6 of these comments to James Carver at jcarver@cap.org, Maurine Dennis at mdennis@cap.org or Todd Klemp at tklemp@cap.org; item 7, Elizabeth Fassbender at efassbe@cap.org and for QPP issues, Colleen Skau at cskau@cap.org.

CAR-T Practice Expense Appendices

1. CAR-T Direct Practice Expense Spreadsheet
2. CAR-T Practice Expense Summary
3. PE Invoices

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