COLLEGE of AMERICAN PATHOLOGISTS

September 2, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-17701-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: File Code CMS-1770-P; Medicare Program; CY 2023 Payment Policies Under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 29, 2022)

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1770-P entitled "Medicare Program; CY 2023, 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. CY 2023 Clinical Labor Pricing Update Proposals
2. Updates to Prices for Existing Direct PE Inputs
3. Rebasing and revising the Medicare Economic Index (MEI)
4. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers
5. Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services
6. CY 2023 Updates to the Quality Payment Program (QPP)
7. Requests for Information for the Quality Payment Program

1. CY 2023 Clinical Labor Update Pricing Proposals

For CY 2023, CMS received information regarding the pricing of the Histotechnologist (L037B) clinical labor type. The provided data supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that CMS had for the Histotechnologist and matches the $0.64 rate that was initially proposed for L037B in the CY 2022 PFS proposed rule. CMS proposes this $0.64 rate for the clinical labor type L037B and a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) from $0.55 to $0.60 for CY 2023. **The CAP agrees with these clinical labor pricing changes and urges their finalization for CY 2023.** In the future, CMS should update pricing data on a more frequent basis for all direct PE inputs, so adjustments will not be so dramatic. The CAP understands that the real increase in clinical labor costs for physician

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practices is not recognized through an update to the conversion factor and asks CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2023 and all future years.

2. Updates to Prices for Existing Direct PE Inputs

For 2023, CMS proposes to update the prices of eight supplies and two equipment items in response to the public submission of invoices. The proposed prices for these items were generally calculated following its standard methodology of averaging together the prices on the submitted invoices. This includes a number of pathology related supply codes which had significant increases. Within Table 15 the CAP recognized an obvious error in the price of supply SL089 Lysing Reagent (FACS) and it is apparent that this proposed price represents a different supply than what was intended for this supply code. **Therefore**, **the CAP urges the agency not to finalize the proposed pricing update to supply SL089. The CAP also requests that the price updates to supply and equipment codes SL024, SL061, SL469, SA117, SK082, SL030, and EP014 and EP088 be finalized as proposed.**

The CAP appreciates the opportunity to continue to submit invoices as part of its process for developing payment rates for new, revised, and potentially misvalued codes.

3. Rebasing and Revising the Medicare Economic Index (MEI)

In this proposed rule, CMS is proposing to rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership. The proposals change the cost emphasis whereby physician compensation is a lower share, practice expense is higher, and malpractice is lower in the proposed 2017 based MEI compared with the current 2006 based MEI.

The CMS believes that the MEI cost weights need to be updated to reflect more current market conditions and proposes to delay the implementation of the proposed rebased and revised MEI cost weights for both PFS rate setting and the proposed 2023 GPCIs. It believes that this will allow stakeholders the opportunity to review and comment on the proposed rebased and revised MEI cost share weights before CMS uses these weights for purposes of proportioning the work, PE, and MP RVU pools in PFS rate setting and updating the GPCIs.

While the CAP believes that the data currently utilized for the MEI is outdated and should be updated, we urge the agency not to act at this time. We understand that the AMA **is engaged in an extensive effort to collect practice cost data from physician practices. We ask that CMS pause consideration of other sources of cost data for use in the Medicare Economic Index (MEI) until the AMA effort is complete.**

4. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers to Care

A. <u>Reduction of Minimum Age Limitation to 45</u>

In May 2021, the United States Preventive Services Task Force (USPSTF) updated their recommendation for colorectal cancer (CRC) screening. Subsequently the Center for Disease Control and Prevention (CDC) updated their guidance changing the minimum age limitation to 45,

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The CMS proposes to expand Medicare coverage of certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years.

B. Complete Colorectal Cancer Screening (CRC)

Responding to concerns about health equity, low follow-up colonoscopy rates, and patient access barriers, the agency also proposes to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Historically, CMS has treated colonoscopy after a positive non-invasive stool-based CRC screening test as diagnostic colonoscopy. However, government bodies and professional societies have reconsidered their understanding of a complete CRC screening and now consider CRC screening incomplete for individuals with a positive result on a stool-based test until a follow-on screening colonoscopy is also completed.

Accordingly, starting January 1, 2023, the CMS proposes to establish a new Medicare covered CRC screening test (which it refers to as a complete colorectal cancer screening) that includes a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. It would waive the frequency limitations that would otherwise apply for CRC tests for the follow-up screening colonoscopy test when furnished as part of its proposed new complete colorectal cancer screening benefit. The Agency believes that the outcome of their more appropriate and complete approach to CRC screening will be that beneficiary cost sharing for the initial screening stool-based test and the follow-on screening colonoscopy test would not apply and that both tests are paid at 100 percent (no applicable copayment percentage). The CMS cites the May 2021 revised USPSTF recommendation as well as support from organizations with relevant expertise for this proposal.

The CAP applauds the agency for consideration of these proposals to expand Colorectal Cancer Screening. Both lowering the age requirement and the new CRC screening will go a long way to expanding access to these lifesaving tests. We urge the agency to adopt and finalize these proposals.

5. Proposals and RFI on Medicare Parts A and B Payment for Dental Services

In this proposed rule, CMS seeks to cover certain dental services where those services are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services. Certainly, as CMS explains, “unequal distribution of dental services and prohibitive costs” can have serious consequences for Medicare patients, many of whom are at the highest risk for poor oral health. **However, regarding potential future payment models for dental and oral health care services, the CAP urges the agency to take into account the current constraints on PFS funding as future payment models are considered and believes that any expansion of Medicare to include dental services should be through a separate new program independent of the physician fee schedule.** Additionally, as we have commented before, the CAP is supportive of pursuing innovative models but seeks to ensure that physicians, especially the societies that represent physicians participating in and affected by new payment models, have input into their development. The CAP believes it is only with physician input and buy-in that we can ensure effective delivery system reform that will benefit Medicare patients and achieve the value-based care goals we all share.

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6. CY 2023 Updates to the Quality Payment Program

The CAP looks forward to continuing engagement with the CMS on multiple aspects of the Merit-Based Incentive Payment System (MIPS) in order 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 necessary to meet the clause[1] in the Medicare Access and CHIP Reauthorization Act (MACRA) that requires CMS to give consideration to non-patient facing clinicians. The CAP outlines specific concerns below in its comments on the Quality Payment Program (QPP).

Transforming MIPS: MVP Strategy

MVP Vision Overview

MIPS Value Pathways (MVPs) represents a significant transition for the MIPS program to a new framework where measures and activities across the four performance categories would ideally be aligned. As specialty societies move forward with creating MVP candidates, the CAP encourages CMS to be open to innovative thinking and willing to test new ideas rather than reshuffling the current program elements**.** To achieve the goals of improving value, reducing burden and assisting in the transition to Alternative Payment Models (APMs), CMS should consider a variety of possible options for the MVP program now and in the future. We appreciate that CMS is requesting information on a number of topics, both directly and peripherally related to MVPs, and encourage CMS to continue to seek feedback as the program rolls out. Additionally, we suggest that CMS share data on MVPs as soon as possible to assist specialty societies in understanding implementation and use of MVPs as well as potential areas needing revision.

The CAP reiterates previous concerns that the MVP framework does not align with the practice of non-patient facing, diagnostic specialties such as pathology. For example, the CAP is concerned that CMS wants to increase the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of specialty specific measures. This would put pathologists at a significant disadvantage since administrative claims-based quality measures are minimally if at all applicable to pathology practice. Trying to apply the same measure across different specialties would result in intrinsically inequitable performance comparisons among physicians, which is critically important in a budget-neutral program like MIPS. Similarly, subregulatory feedback from CMS has indicated that specialties lacking a Cost measure may not be able to establish an

[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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independent MVP. While this is not explicitly stated in the proposed rule, **we encourage CMS to clarify the requirements for MVPs targeting special-status clinicians in single-specialty practices**.

MVP Development and Reporting Requirements

MVP Development

The CAP applauds CMS's intention to include interested parties in the MVP development process, and reiterates previous comments, consistent with those described in the proposed rule, that CMS should work with specialty societies as critical stakeholders. Specialty societies frequently both develop measures and run clinical data registries, meaning they have expertise that spans not only the clinical knowledge needed to identify best practices but also the practical capacity to implement measures and assist clinicians in reporting them to CMS. In addition, CMS should be explicit in its guidance for what constitutes an MVP. Currently, determining the scope and content of an MVP appears to be a somewhat arbitrary subregulatory process that is not transparent to potential developers or participants.

With respect to the proposed modifications to the MVP development process, the CAP agrees with CMS that opportunities for feedback should be provided frequently to all stakeholders. Therefore in theory the proposal to post a draft version of a candidate MVP for a 30-day feedback period is a good one. However, we highlight two potential areas of concern with this proposal. First, in the current process, MVPs must be submitted to CMS early in the year to ensure sufficient time for review, discussion, and modification prior to inclusion in the proposed rule. Adding a 30-day feedback period and all associated timelines would push the submission deadline back further, and we are concerned that there would be insufficient time between publication of the final rule and MVP submission deadline for developers to assess implications of the rule on their potential MVPs. We encourage CMS to carefully consider timelines for all relevant measure submission and rulemaking activities.

Second, CMS explicitly states that feedback including required changes would not be provided to the original developer of the MVP. **We strongly encourage CMS to reconsider the proposal to exclude developers from seeing potential changes**, as it seems contrary to the intention of soliciting participation from all interested parties. Given that feedback may include suggestions for additional clinical input or testing data, participation from developers would be critical. Although timelines are a concern, we suggest that CMS modify the process to allow for a window of review by the original interested party or parties who submitted the candidate MVP.

MVP Maintenance Process and Engagement with Interested Parties

As described above, the CAP believes in the importance of including all stakeholders in the MVP development and maintenance processes. However, we have some concern about the subregulatory nature of these processes. The maintenance process for existing MVPs was carried out as an informal process wherein CMS accepted comments but did not publish specific concerns or requests for feedback. The comments CMS received were never publicly shared and there was no indication at the time whether CMS intended to share feedback with the MVP developers. Therefore any potential issues highlighted for existing MVPs remain unknown to the majority of stakeholders, including those who will be expected to deploy these MVPs in 2023. We encourage CMS to share all feedback received with the MVP developer and publish comments as part of the updates to MVPs in the proposed rule. The subregulatory nature of the proposed process leads to confusion and

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potentially to distrust of the process.

With respect to the proposal to add a public webinar subsequent to receiving feedback to review any feasible and appropriate changes, we support the idea in theory, although we reiterate concerns described above related to timelines. More importantly, we also encourage CMS to share all feedback, not just that deemed feasible and appropriate, even if it is aggregated in groups to collect common themes.

Furthermore, for both MVP development and maintenance, we stress the importance of continuing meaningful engagement with all stakeholders. Several MVPs currently on track for rollout in 2023 were developed via a subregulatory process without explanation from CMS and with limited engagement from stakeholders, and feedback from stakeholders was not explicitly taken into account. Of particular importance is soliciting and incorporating feedback from those whose intellectual property such as quality measures would be included in the MVP.

Subgroup Reporting

The CAP appreciates the additional detail provided by CMS to clarify subgroup composition and registration requirements. First, with respect to defining a single or multispecialty group, **we support use of Medicare Part B claims data as the appropriate data source for determining a group's specialty type or types.** This data is familiar not only to clinicians but other stakeholders in the process and is an appropriate data source.

As it relates to subgroup registration, we agree with commenters who previously expressed concerns that CMS's potential requirement for subgroups to be primarily composed of a single clinician type might discourage team-based care and/or hide performance of some specialties. We therefore applaud CMS for flexibility related to subgroup composition rather than moving forward with the 75% threshold considered last year. We also understand the desire of CMS to better track the clinician composition of the subgroups. While the proposed subgroup description appears low burden, **we encourage CMS to ensure that subgroup registration does not add administrative burden to the program in the future, and more importantly that subgroup descriptions are not used as a way to approve or deny the formation of subgroups** but continue to be informational only.

Additionally, we support the proposal that subgroups be assessed on Cost, population health and outcomes-based administrative claims measures based on their affiliated group. Given the current limitations of subgroup formation, this appears to be the only way to ensure accurate data.

More broadly, however, we express concern with the idea of subgroups as a potential fix for specialties that do not have a relevant MVP. Elsewhere, including the 2022 proposed and final rule, and the 2022 CMS Quality Conference, CMS has expressed a desire to limit the number of MVPs and focus MVPs on the "patient journey." While such an MVP is in theory an important way to recognize the value of team-based care across the continuum, focusing MVPs on such broad topics paradoxically limits their utility. Since subgroups are only permitted for multi-specialty groups, a single-specialty practice could be inadvertently excluded from a patient journey MVP if they by themselves are unable to report on all the necessary components. For instance, a patient journey MVP may be reportable by subgroups who can receive the Cost and population health measures of their group but a single specialty group who cannot report the Cost measure would not be able participate in this MVP. **We encourage CMS to view subgroups as one potential tool to ensure all clinicians have the opportunity to participate in MVPs, but to also develop MVPs in a manner that allows participation by all clinicians who desire to do so in their preferred**

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practice arrangement, multispecialty or single specialty.

MIPS Performance Category Measures and Activities

Quality Performance Category

The CAP would like to highlight a perceived discrepancy in the scoring provisions of the rule. Under IV.C.10.c.(1)(b)(i), Submission Criteria for Quality Measures, Excluding the CAHPS for MIPS Survey Measure, CMS states that "To incentivize the voluntary adoption of high priority measures, a MIPS eligible clinician may earn bonus points for reporting such a measure (§ 414.1380(b)(1)(v)(A))". However, bonus points for reporting high priority measures were removed starting in 2022, which CMS acknowledges later in the rule at IV.C.10.e.(2) that "we removed transition policies such as quality bonus points that had been established for scoring the quality performance category". **Given the value of high-priority measures and their expanded definition, we encourage CMS to reinstate their bonus points.**

The CAP supports CMS' proposal to maintain the data completeness criteria threshold at 70% for CY 2023. Furthermore, the CAP suggests CMS consider keeping the data completeness criteria threshold at 70% for subsequent years due to the increasing complexity of the program. As MVPs roll out, it will be critical to ensure that all clinicians in MIPS are scored equitably on actual performance and not disadvantaged by programmatic requirements.

The CAP strongly supports addition of the MIPS CQM "Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma" to the MIPS program and to the pathology specialty measure set. This measure is currently in use as a QCDR measure in the Pathologists Quality Registry, where it has seen high levels of use. The measure has been designed to work with a CAP Clinical Practice Guideline, released in August of 2022, therefore it represents the most up-to-date clinical information.

However, the **CAP requests CMS not to finalize the 2023 pathology measure set as proposed. First, the CAP asks that CMS remove the proposed Screening for Social Drivers of Health measure from the proposed 2023 measure set.** While this measure represents an important step forward in promoting health equity and achieving higher quality care for patient-facing clinicians, it does not align with pathology practice. As non-patient-facing clinicians, pathologists do not regularly interact with patients and are not in a position to screen for social drivers of health. Therefore, this measure cannot be attributed to pathologists, as it is out of their control, and would create additional confusion and complexity if included, however well-intentioned.

Second, t**he CAP asks that CMS remove measure 440, Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician from the proposed 2023 pathology measure set.** As provided in writing to CMS, 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 indicated that in cases where multiple types of specimens are present in the same report (i.e. a re-excision and biopsies of nearby tissue), only biopsies should be included this measure. Practically speaking, this does not align with pathology practice. Multiple specimens from the same patient on a single date of collection are given the same Accession ID and are assessed and verified at once, not as individual

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specimens. Similarly, AAD has requested that each biopsy be reported separately as an individual denominator instance. As described above, this does not align pathology practice. Multiple specimens are given the same Accession ID and treated as a single case or report. Although we are supportive of the addition of a Denominator Exception as proposed 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 the proposed expansion of the pathology measure set to include an additional pathology-specific measure, we believe measure 440 is no longer needed and only adds complexity for pathologists and lack of data standardization for MIPS.

The CAP has discovered that CMS is not applying the EMA process automatically to practices who are unable to report on a minimum of 6 measures or on a high priority/outcome measure. The CAP has also discovered that when a practice reports less than 6 measures via Medicare Part B claims, CMS does the look-back on Medicare claims to see if the practice could have reported on other measures to determine if EMA should be applied. However, when the data is submitted via a qualified registry, the burden is placed on the practices to provide CMS with a list of all CPT codes billed as part of their Targeted Review to have CMS apply EMA and correct their scores. Given that practices report zero cases in the numerator and denominator to CMS, we encourage CMS to thoroughly apply EMA before final scores are released. **For these reasons, the CAP urges CMS to apply the EMA process automatically to all practices who are unable to report a minimum of six measures as determined by Medicare Part B claims.** Otherwise, the practices are subject to erroneous scoring and are unable to achieve the maximum MIPS final score.

In addition, determination of clinically-related measures should be subject to rulemaking and comment, because the subregulatory process for determining these has led to erroneous groupings. We identified the following pathology clinically related measures for Medicare Part B Claims and MIPS CQM collection types in CMS' 2022 EMA and Denominator Reduction Guide:

Clinical Topic	MIPS CQM	Medicare Part B Claims
Pathology (C)	**249:** Barrett's Esophagus **250:** Radical Prostatectomy Pathology Reporting **395*:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **396*:** Lung Cancer Reporting (Resection Specimens) **397*:** Melanoma Reporting	**249:** Barrett's Esophagus **250:** Radical Prostatectomy Pathology Reporting **395*:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **396*:** Lung Cancer Reporting (Resection Specimens) **397*:** Melanoma Reporting
Pathology – Skin Cancer (C)	**397*:** Melanoma Reporting **440*:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	**397*:** Melanoma Reporting

These are not necessarily clinically related measures. While these clusters may appear related in scope, the diversity of pathology practice settings and case mixes mean that not all pathologists examine specimens that pertain to all measures in the cluster and are therefore are unable to report on one or more of the clustered measures. In other words, just because a pathologist can report on one measure, does not mean he/she can report on the others. The CAP asks that CMS not include these clusters as part of the EMA process for future MIPS performance years.

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The CAP asks that CMS take the above into account before finalizing the EMA pathology clinically related measure clusters for future MIPS performance years. Further, the CAP urges to use the formal rulemaking process for publishing the EMA clinically related measure clusters. This would allow appropriate input from specialty societies and MIPS eligible clinicians, so that measure clusters are actually related for reporting purposes.

Improvement Activities Performance Category

The CAP appreciates CMS' continued policy to allow non-patient facing clinicians and groups to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit (regardless of the weight of the activities) to meet the IA submission criteria. However**, we request that CMS not finalize removal of IA_PSPA_20, Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes**. We understand CMS considers it duplicative of IA_PSPA_19 but constant changes to IAs adds burden and complexity to the program. We request that IA_PSPA_19 and IA_PSPA_20 be maintained as-is to reduce confusion and achieve the same aim.

We support the inclusion of the proposed new Improvement Activity IA_ERP_XX, COVID-19 Vaccination Achievement for Practice Staff. However, we request clarification on this IA and on IAs more broadly regarding reporting by non-patient-facing clinicians. The specifications of IAs do not describe an eligible population, so it is unclear which IAs can be used by which clinicians. While the QPP Help Desk has indicated that all IAs can be reported by all clinicians unless otherwise indicated, we have found this not to be true. In the past, several pathology practices were informed it was inappropriate for non-patient facing clinicians to report certain IAs although that was not detailed in the IA description. Similarly, the description of COVID-19 Vaccination Achievement for Practice Staff contains the phrase "100% of office staff"; it is not clear whether laboratory staff would be included in this description and therefore whether this IA would be reportable by pathologists. We request clarification on this specific IA and that additional guidance be included to indicate eligible clinician types.

Promoting Interoperability Performance Category

The CAP appreciates the CMS' recognition of the non-applicability of the PI category to pathologists by CMS and support the continuation of the automatic reweighting policy for non-patient facing clinicians for the PI category.

MIPS Final Score Methodology

Quality Measure Scoring

CMS is proposing to remove the 3-point floor for measures that can be scored against a benchmark (these measures would receive 1-10 points), for measures without a benchmark that have been in the program for more than 2 years (large practices would receive 0 points for these measures), and measures that do not meet the case minimum requirements (large practices would receive 0 points for these measures). **The CAP opposes these proposals and asks that CMS maintain the 3-point floor for quality measures, especially in light of the removal of bonus points for high-priority and outcome measures.** The CAP believes that the continuation of the 3-point floor is necessary to not disadvantage clinicians as the program gets more complicated and as MVPs are introduced as a new pathway for reporting MIPS. Maintaining the 3-point floor would also counter the presence of several topped out and non-benchmarked measures and allow clinicians who report

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these measures to not be penalized for something that they do not control.

The CAP is also supportive of CMS's proposal to maintain the performance threshold at 75 points, especially given that the Exceptional Performance bonus is no longer available in CY 2023. However, with the removal of the 3-point floor, it should be recognized that the performance threshold is now harder for practices to achieve.

Third Party Intermediaries

QCDR Measure Testing Requirements

Since the original proposal requiring full testing of QCDR measures by their second year of use, CMS has recognized the challenge that the COVID-19 public health emergency has posed for QCDRs attempting to test measures. Clinicians continue to devote their time and energy to diagnosis and treatment of COVID-19 and obtaining testing data remains a major burden. **The CAP therefore supports the proposal to delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year.** However, measure testing is a lengthy process and data collection for some testing efforts may have already begun. Given the continued uncertainty regarding the COVID-19 PHE, we therefore request that CMS consider a two-year delay rather than continuing to implement a series of one-year delays. Additionally, the National Quality Forum continues to update and refine testing recommendations; an additional two-year delay would allow time for QCDRs to understand and implement new NQF recommendations, particularly relating to reliability testing.

Measure testing is an added—but as-yet unmeasured—cost of the MIPS program to physicians. Specialty societies that create and steward measures must bear the operational and financial costs of undertaking measure testing. Most measure stewards have identified challenges in engaging practices in testing/reporting measures for which there is no immediate need or incentive for the practice. The CAP recommends that CMS offer clinicians and groups an incentive for participation in QCDR measure testing. Similarly to how CMS proposes that clinicians and practices that choose to report new measures would earn a minimum of seven or five points, CMS should award bonus points in the quality performance category to clinicians and practices that choose to assist in measure testing. Alternatively, CMS could consider an Improvement Activity to promote practice participation in testing of QCDR measures.

The CAP continues to believe that CMS's measure testing requirement will impose unreasonable and undocumented cost and other burdens on physicians via their specialty societies and QCDRs and that such costs will impede measure development, lead to increases in registry participation fees for clinicians, and may cause QCDRs to cease measure development altogether. This requirement fails to recognize the many steps used in developing QCDR measures to ensure their reliability and validity. For these reasons, we continue to believe that this rule is contrary to MACRA's requirement to encourage the use of QCDRs for reporting measures.

Public Reporting on the Compare Tools hosted by the U.S. Department of Health & Human Services

As the CAP has stated in prior comments to the CMS, we believe that all physicians should have an opportunity to review their personal information that will be included on the CMS Physician Compare website prior to posting. Prior review by physicians will give physicians the opportunity to improve their processes when deficiencies are identified; and is aligned with the stated program goals of

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improving health care quality. The CAP encourages the CMS to develop educational tools for patients viewing the Physician Compare website, especially with MIPS as it moves to MVPs. The CAP believes it will be important to note when a physician could not participate in a specific performance category listed due to circumstances beyond his/her control, (e.g. Cost or PI due to lack of applicable measures). The absence of this explanatory information is potentially misleading and could imply a lack of interest in quality when the issue is in fact the lack of applicability of the program measures to that physician. **The CAP reiterates the need to indicate clearly on the website when a program measure does not apply to a particular physician.**

Advanced APMs – Generally Applicable Nominal Amount Standard

Here, CMS proposes to "permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the applicable QP Performance Period, beginning with the 2023 QP Performance Period." According to CMS, the nominal amount standard of 8 percent has worked well and making the change permanent will provide continuity in policy into the future. The CAP agrees and supports making the 8 percent permanent. We continue to believe it is important to focus on increasing opportunity and incentives for specialty physician involvement in Advanced APM before unnecessarily pursuing increased financial risk. This is even more true than when we commented on this issue earlier, given the loss of the APM Incentive Payment and the concerns around the incentive structure in the MIPS versus Advanced APM tracks explained above.

7. Requests for Information for the Quality Payment Program

A. RFI on Quality Payment Program Incentives Beginning in Performance Year 2023

The CAP is committed to increasing the availability and adoption of innovative payment models that afford an opportunity for the voluntary participation of pathologists. However, the number of Advanced Alternative Payment Models (APMs) in which pathologists are able to participate remains limited. Additionally, moving forward – as CMS acknowledges – "the statutory incentive structure under the Quality Payment Program for eligible clinicians who participate in Advanced APMs stands in contrast to the incentives for MIPS eligible clinicians." Specifically, the consequences of the loss of the APM Incentive Payment, which was a critical component in rewarding high-quality treatment of patients and in increasing participation in Advanced APMs, cannot be underestimated. Without the incentive payment, providers will be less likely 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 startup/investment costs). Not only does it appear this will further constrain pathologists' ability to participate in Advanced APMs if they are interested, but like CMS, we are concerned about what this could do to "the availability and distribution of funds in the budget-neutral MIPS payment pool."

Thus, to CMS's more general point, the CAP believes any administrative action beginning in the 2024 performance period and 2026 payment year should maintain the availability of traditional MIPS while increasing opportunity and incentives for specialty physician involvement in Advanced APMs. Importantly, as we outline below, incentives for physicians to participate in Advanced APMs should recognize that high-value care is provided by both small practices and large systems, and in both rural and urban settings. As we emphasized in earlier comments, pathologists are integral in any care coordination initiatives – including Advanced APMs – as they apply their expertise to the

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diagnosis and management of a wide variety of medical conditions and undertake efforts targeted at increasing integration to improve patient care.

1. *What are your primary considerations going forward as you choose whether to participate in an Advanced APM or be subject to MIPS reporting requirements and payment adjustments? What factors are the most important as you make this decision?*

   Response: The primary consideration many independently-practicing pathologists consider when choosing whether to participate in an Advanced APM or be subject to MIPS reporting requirements is the effect on practice consolidation. The considerations can vary slightly for employed pathologists working in larger or multispecialty practices. Larger multispecialty (usually hospital-owned or affiliated) practices have the resources to make sophisticated ROI calculations as the primary consideration around participation in MIPS versus Advanced APMs. However, smaller and independent practices often lack the infrastructure needed for effective participation in Advanced APMs.

   Traditional MIPS, though burdensome, allows single specialty pathology practices to obtain full incentives. Many pathologists in independent practice choose to stay in MIPS for that reason. The CAP believes the replacement of traditional MIPs with MVPs and Advanced APMs incentivizes larger, multispecialty practices, as the clinical alignment envisioned by these programs is often achieved via physician employment or practice consolidation. Indeed, consolidation among physician practices and between hospitals and physician practices has accelerated in the past decade, with participation in APMs cited as reasons for consolidation (March 22 MedPAC Report to Congress; Chapter 4). Further, health system ownership and greater integration in physician practices appear to be associated with greater APM participation.

   In addition, scale remains an important factor in participation; organizations with high patient volumes can better afford high fixed-cost investments and operational changes needed for success in Advanced APMs. Although economies of scale suggest that group practices may improve quality and contain costs via centralized operations, recent research found that although vertical integration (i.e., consolidation) is associated with better performance on quality measures, it did not significantly reduce use, mortality, spending, or prices (Beaulieu et al; Short and Ho; Curto et al). Thus, CMS must make participation in APMs voluntary and continue to incentivize participation in ways that are meaningful for independent practice, or physicians will likely choose to remain in traditional MIPS.

2. *If you are participating in an Advanced APM now and have been or could be a QP for a year, will the end of the 5 percent lump-sum APM Incentive Payments beginning in the 2025 payment year (associated with the 2023 QP Performance Period) cause you to consider dropping your participation in the Advanced APM, which would mean forgoing QP determinations, thereby ensuring you are subject to MIPS reporting requirements and payment adjustments?*

   Response: Larger organizations, as opposed to individual physicians, are likely to make the decision on whether to drop participation in an Advanced APM based on the end of the 5 percent lump sum APM Incentive Payment beginning in the 2023 performance year/2025 payment year. Larger multispecialty (usually hospital-owned or affiliated) practices have the resources to make sophisticated ROI calculations as the primary consideration around participation in each program (unlike smaller independent practices). If participation in MIPS, despite unknowns about the actual positive payment adjustments is likely to have a more positive ROI for the system, that will be a major consideration.

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3. *Going forward, attaining QP status for a year through sufficient participation in one or more Advanced APMs will enable an eligible clinician to, for a year: (1) continue receiving any financial incentive payments available under the Advanced APM(s) in which they participate, subject to the terms and conditions applicable to the specific Advanced APM(s); (2) be paid under the PFS in the payment year using the a higher QP conversion factor (0.75 percent rather than 0.25 percent) beginning in payment year 2026; and (3) not be subject to MIPS reporting requirements or payment adjustments. Do these three conditions provide sufficient incentives for you to participate in an Advanced APM, or would you instead decide to be subject to MIPS reporting requirements and payment adjustments?*

   Response: The incentives for attaining QP status through sufficient participation in Advanced APMs are not sufficient incentives for independently practices pathologists to participate in an Advanced APM. APMs generally require clinical alignment that is often achieved via physician employment or practice consolidation. As we have emphasized above, the primary consideration many independently-practicing pathologists consider when choosing whether to participate in an Advanced APM or be subject to MIPS reporting requirements is whether it is possible to remain in independent practice.

   Additional incentives are needed for independent practices to effectively participate in Advanced APMs *in their current practice arrangement.* This may include state and federal funds to support practice transformation and incentives for collaboration over consolidation. Incentives for physicians to participate in Advanced APMs should recognize that high-value care is provided by both small practices and large systems, and in both rural and urban settings.

4. *Are there other advantages of MIPS participation that might lead a clinician to prefer MIPS over participation in an Advanced APM, such as: (1) quality measurement that may be specific to a particular practice area or specialty area; or (2) the desire for more precise accountability through public reporting of quality measure performance in the future?*

   Response: As noted above, it can be inferred that CMS is accelerating practice consolidation and the movement to larger, multispecialty practices. An estimated 5,000-8,000 pathologists are in single specialty pathology practices, and would benefit from staying in traditional MIPS, despite its challenges. Needed innovation in payment and delivery reform must recognize the wide range of practice types and sizes that exist today so all physicians can participate in the move to a more patient-centered system that rewards high-quality care and reduces costs.

B. Advanced APMs – RFI: Potential Transition to Individual QP Determinations Only

We thank CMS for the opportunity to weigh in on the potential change to Qualifying APM Participant (QP) determinations. We offer general comments about the suggested changes, as well as specific considerations for each of the reasons CMS cited for the potential transition. First, as a general comment, CMS does not describe data to support their assertion that any of the issues raised are happening with appreciable frequency. The scenarios described are potentially concerning. However, it is not clear how common any of these scenarios are and whether the rate of occurrence merits a complete redesign of the system for determining APM eligibility. For instance, if specialists are being removed from participant lists in a single APM, that should be addressed within that APM rather than by a broad programmatic change. Particularly given CMS' expressed concerns about clinicians leaving APMs and the growing complexity of the Quality Payment Program (QPP) program, CMS should focus on incentives for clinicians to voluntarily join APMs rather than change

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how clinicians are assigned to APMs. The proposal to transition to solely individual QP determinations will no doubt drive some clinicians out of APMs and increase the complexity of the program for physicians. Indeed, CMS finalized the policy to make the QP determination at a group level noting that it "promotes administrative simplicity and collaboration among group members instead of promoting barriers." The QPP regulations are already exceedingly complex and difficult for most physicians to understand and interpret. Significant administrative infrastructure is currently needed to help physicians interpret regulations and make decisions about participation pathways. Making these rules even more complex and nuanced will disenfranchise physicians from full participation in the QPP.

Any changes to QP determination should facilitate full participation in APMs by specialists who desire to do so, as highlighted by another RFI in this proposed rule. Additionally, changes to QP determination should not compromise the ability of clinicians to practice in the setting that provides the best care for their patients, whether that is a single-specialty practice, a multi-specialty practice, or a hospital system. We do not think moving to a system of individual QP determination accomplishes these goals. Nor has CMS defined any other way in which this change would promote better patient outcomes.

Furthermore, the CAP understands the importance of making APMs available to all clinicians, including those whose APM entities do not meet the patient or payment threshold in a particular year. We support a proposal that would enable the transition of pathologists to become QPs in APMs if that is the payment model that best serves their patients and clinical care team partners. As above, we do not think moving solely to individual QP determination is that proposal. Rather we suggest leaving the default as QP determination at the APM entity level and introducing the ability of clinicians to appeal their QP determination if they so choose during a defined window after the first snapshot.

If CMS does decide to move forward with individual QP determination, the transition should occur in stages, including a field-testing period where clinicians are made aware of their individual and entity-level determinations. Clinicians should be given an opportunity to appeal the determination, whether they are assessed as an individual QP or not. Furthermore, CMS should publicly release sufficient data to ensure that such a policy does not disproportionately disadvantage clinicians in small or single-specialty practices or rural and underserved areas

Below we provide comments about the specific scenarios CMS cites for considering a move to individual QP determination only.

1. *APM entities are removing specialists from their participant lists*

   As noted above, CMS does not cite specific data indicating the prevalence of this issue, including whether it is specific to a certain APM or set of APMs, or certain types of specialists. We are not currently aware of this practice as it pertains to pathologists. If this is occurring, it is likely because the APM entity is concerned that the specialists are not being meaningfully evaluated by the metrics in the APM. It is unlikely that an APM entity does not value the contribution of these clinicians (no APM entity would continue employing clinicians who were not contributing). Rather, removing them from participant lists suggests that their contribution is not being measured by the APM. As noted elsewhere in our comments, we suggest that CMS work with the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and all relevant stakeholders to design specialty-focused APMs and APMs that meaningfully capture a diverse variety of specialties' contributions to team-based

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care. For the APM pathway to truly be successful, more options are needed that would provide a meaningful opportunity for pathologists' participation. Of the Advanced APMs currently available under the Quality Payment Program, pathologists only participate in a handful to a very limited extent and none meaningfully value pathology. Additionally, the fact that CMS has yet to take up any of the models recommended by PTAC demonstrates the complexity in creating appropriate physician developed APMs as envisioned under MACRA. Of note, however, any models submitted to PTAC must provide evidence of consultation and concurrence from specialties participating in their models prior to their submission so that PTAC is making recommendations on models that are truly physician-focused and enable meaningful contribution by their participants to enhance the care of patients. This would serve the dual purpose of reducing the practice of APM entities removing specialists from their participant lists and also increasing the number of clinicians who could be determined to be QPs individually. While CMS states that a comprehensive network that includes a range of specialists is essential for the success of APMs and ACOs, it is clear that current models do not incentivize this network. If current models did so, APM entities would not be proactively removing specialists from their participant lists. Therefore APMs must change to include specialists even if CMS proceeds with the proposal to change QP determination level.

Furthermore, if CMS has evidence of a specific APM entity unfairly removing specialists from the participant list, CMS could propose administrative action to be taken against the entity. However, proposing a whole-scale change to QP determination is a blunt tool for dealing with a narrow problem.

2. *Increase the threshold for theoretical QPs whose APM entity doesn't meet the threshold*

   As described above, the data supporting this issue are not cited so the scope of the problem is unclear. If it is limited to one APM, that would indicate redesign of the APM in question rather than of the eligibility system. APMs are designed to operate on a group level; the metrics in APMs need to be evaluated at the group level, particularly cost metrics. Changing QP determination across the board goes against this model, against the idea team-based care, and moves participation in APMs closer to MIPS where eligibility is determined on an individual basis. If it is the intent of CMS to move APMs closer to MIPS, perhaps hoping to ease the transition, that should be stated as an explicit goal of the policy and should be justified accordingly.

3. *Decrease the number of clinicians who are being assigned QP status but do not furnish most of their services through an APM entity*

   While we appreciate CMS' concerns about providers unfairly benefiting from their colleagues' work, it will be difficult to differentiate clinicians who are do not furnish most of their services through an APM entity from clinicians who simply do not furnish services captured by the APM measures. As CMS notes when it finalized the policy, "many of the eligible clinicians participating in the APM Entity may play a role in the actual diagnosis, treatment, and management of many beneficiaries in the APM Entity population" and each of these individual eligible clinicians "could potentially view themselves as being instrumental in providing quality care to the beneficiary that is in line with the objectives of the APM, regardless of whether their individual services are counted towards APM-specific attribution methods." Further, CMS acknowledges that most of what attributes a beneficiary to an APM is evaluation and management (E/M) visits. Since CMS is aware most E/M visits are not

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furnished by specialists, they are in essence acknowledging that valuing specialists in APMs is difficult. Thus, it is not a fair assumption that clinicians who are assigned QP status but do not conduct E/M visits are unjustly receiving financial rewards. CMS expressed concern that APM entities were unduly removing specialists from their participant lists; the concern expressed here seems in direct contrast to that previous concern since CMS appears to be indicating that clinicians who cannot be directly attributed to the APM should be removed as a QP. That is, specialists are difficult for APMs to evaluate, yet CMS suggests moving to a model in which all clinicians must be directly evaluated by an APM to participate.

Furthermore, this policy does not consider the breadth of roles and responsibilities of clinicians within an APM. As CMS itself earlier noted, a provider who is not furnishing direct services may be making other important contributions to practice such as consultation or training of new clinicians. Determinations of who is making a valuable contribution to an APM entity should be left to the APM entity. As described above, APM entities can remove clinicians from participant lists if they choose. CMS should not assume that clinicians who furnish a minority of services through that APM are not contributing in other ways; if they were not contributing, it stands to reason they would be removed.

C. MVPs and APM Participant Reporting Request for Information

We thank CMS for the opportunity to weigh in on the transition from MIPS and MIPS Value Pathways (MVPs) to advanced payment models (APMs), a long-standing goal of the Quality Payment Program. We share CMS's broad concern that specialty clinicians such as pathologists are not receiving meaningful feedback from APMs, even when they are considered Qualified Participants through their APM Entity. We also understand the desire to align MVPs and APMs more closely in order to ensure a glide path from the former to the latter.

However, we are concerned that CMS is underestimating the availability of APMs for certain specialty physician groups and therefore potentially neglecting an important step in the process. Generally, the already-approved MVPs do not directly align with existing APMs. Therefore, the data collected from MVPs will mostly not be relevant to aid in a transition to APMs with the exception possibly of kidney care MVPs/APMs. Even the proposed Advancing Cancer Care MVP does not overlap entirely with the patients included in the new Enhancing Oncology Model APM so meaningful comparisons may be challenging. Per the recently released MedPAC data book (July 2022), the vast majority of clinicians participating in accountable care models were in accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). In fact, of the clinicians who qualified for the 5% Advanced APM bonus, over 75% were in MSSP, and four other APMs made up most of the rest of the eligible clinicians. Just 3.4% participated in an APM other than the top four or MSSP. Therefore, it should not be assumed that specialty clinicians, even those who are fully participating in relevant MVPs, could transition to a specialty specific APM that meaningfully accounts for their performance. Especially given that the measures available for reporting through the APM Performance Pathway (APP) are not specialty-specific, this further reduces the likelihood that a specialist in an APM or ACO would have relevant data available. Without meaningful representation in APMs, obtaining additional specialty-specific data from MVPs would not drive the transition.

Additionally, we are concerned that the stated goal of driving all clinicians into APMs is a one-size-fits-all approach that does not account for the distinct needs of the different specialties and practice settings. CMS should consider maintaining a variety of payment models to ensure that clinicians can choose the practice setting that best serves the needs of their patient population. Indeed, elsewhere

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in this rule, CMS expresses a very valid concern that APMs are removing specialists from their participant lists due to the fact that specialists are not formally measured in the APM. Although there is no doubt that specialists are critical to patient care, the fact APM measures do not apply to them potentially leads to their removal from clinicians' lists.

Therefore, we urge caution in pushing specialists into APMs which do not fully value their essential contribution to patient care. The lack of specialty specific APMs combined with the clear intention of MVPs to span specialties and cover multispecialty groups will drive consolidation in the health care system. In fact, studies show overall consolidation is increasing and as a result, health care costs are increasing as well. The replacement of traditional MIPs with MVPs and advanced APMs incentivizes larger, multispecialty practices. The clinical alignment envisioned by these programs often is achieved via physician employment or practice consolidation. To avoid consolidation pressure or undesirable changes to their practice patterns, many pathologists in independent practices are choosing to stay in traditional MIPS. Consolidation among physician practices and between hospitals and physician practices has accelerated in the past decade, resulting in higher prices in commercial markets. The resulting integration of health care across clinicians and participation in APMs, which aim to improve quality while constraining spending, are cited as reasons for consolidation. Indeed, health system ownership and greater integration in physician practices appear to be associated with greater APM participation. Although economies of scale suggest that group practices may improve quality and contain costs via centralized operations, recent research found that although vertical integration (ie, consolidation) is associated with better performance on quality measures, it did not significantly reduce use, mortality, spending, or prices (Beaulieu et al; Short and Ho; Curto et al).

Although Medicare and Medicaid are not subject to precisely the same economic pressures as private payers, it seems unlikely that CMS would be insensitive to overall increases in health care costs. Furthermore, consolidation will likely hit the most vulnerable populations hardest, such as rural populations and those in already medically underserved areas.

To improve the glide path from MVPs to APMs, CMS should consider all options, not just how to increase data available to primary care and specialty providers. Establishing a viable transition pathway between MIPS and APMs, two fundamentally different payment models, requires movement on both sides. That is, MVPs can be brought more in alignment with APMs, but APMs should also be assessed to determine flexibility for movement closer to MVPs that meaningfully account for specialist participation including non-patient-facing and diagnostic specialties. CMS should explicitly create more specialty specific APMs working in conjunction with all stakeholders. Furthermore, stakeholder input should be solicited on existing APMs, including the quality measures. A process should be established to update measures and activities in existing APMs that are not meeting quality improvement and/or cost targets. These same considerations apply to measures in the APP as well. It is not clear how measures are selected for inclusion in the APP, either the limited set available to all participants or the CMS Web Interface set for MSSP ACO participants. Given the high number of MSSP participants as described above, flexibility in measures available to these clinicians will be critical. Indeed, the recent MedPAC report details a number of specialty types included in the MSSP.

If full participation in APMs remains the long-term goal, CMS can also consider additional incentives for clinicians who transition from MIPS to APMs. Similar to the burdens associated with joining an ACO, thoroughly described by CMS elsewhere in the proposed rule, clinicians who leave MIPS for APMs will incur some cost and burden associated with the transition. CMS should assess available options for incentivizing this transition such as the advance investment payments (AIPs) suggested for inexperienced ACOs. While there may eventually be reduced burden for APM participation as

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compared to traditional MIPS, the effort to undertake the transition is substantial and with the sunset of the 5% APM bonus, financial incentives are reduced. In fact, elsewhere in the proposed rule, CMS expresses concern about clinicians transitioning back into MIPS from APMs. Therefore, a close consideration of possible incentives, monetary and non-monetary, for moving into APMs is necessary.

Additionally, CMS should consider a significant change to the MVP process. Instead of MVPs being considered a path to APMs, each MVP could be the first step towards an APM. That is, CMS could potentially establish a process by which any MVP that is approved for use has a clear multi-year plan by which the MVP will be converted into an APM contingent upon meeting certain participation targets and other goals. This would allow clinicians to truly glide from a system they are familiar with, MIPS, to a new payment model, APMs, without sudden abrupt changes. It would also promote development of meaningful specialty specific APMs based on gaps identified in the MIPS program and measures already fully developed for MIPS while slowly ratcheting up risk requirements. A clear plan developed in conjunction with the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and all relevant stakeholders, standardized across MVPs/APMs would ensure a uniform product and also allow physicians to have ownership over their payment models. Furthermore, such a process should be developed to maintain the most critical parts of MVPs; for instance, a multispecialty MVP must include a minimum number of quality measures for each of the covered specialties. An APM developed out of that MVP should maintain this feature to ensure maximal participation. Other potential features to maintain would be automatic determination of eligibility; this could be deployed along the transition path from MVP to APM. Such a plan would bring MVPs and APMs into closer alignment. If MVPs are maintained as a totally separate entity from APMs, they will never be a glide path because there is nothing to glide “to”; as noted above, there is not an APM for every specialty type and a specialty-specific MVP will not ease the transition of a specialist from MIPS into, for instance, an ACO/MSSP or BCPI.

Critically, in order for this process to work smoothly, CMS must commit to meaningfully engaging with the expertise of PTAC as well as all relevant stakeholders.

The bottom line is that the critical issue between MVPs and APMs is not solely a lack of data. That is, it is not that specialists need more data from APMs; additional data will not be meaningful under the current system because specialists are not measured in APMs. If there is a current need for data, it is in practice patterns to understand where gaps in MVPs and APMs are. Current MVPs are not evenly distributed across specialties, due in part to the available cost measures. CMS should clarify the intention of MVPs; if they are intended solely as a glide path to APMs, an explicit path between the two should be established.

D. Request for Information on Third Party Intermediary Support of MVPs

We thank CMS for the opportunity to provide feedback on this important issue. Implementation of MVPs represents a new challenge for third party intermediaries and flexibility will be key to ensuring a smooth and successful roll out.

We believe that third party intermediaries should not be required to support all quality measures within an MVP, and furthermore that third party intermediaries should not be required to support all MVPs that CMS asserts are relevant to their clinicians. The choice of whether to support MVPs and measures within those MVPs should be left to the intermediaries based on their clinical expertise and capabilities, working with other intermediaries and measure developers. Below, we offer support for

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this position in contrast to the potential reasons why third party intermediaries would be asked to support all measures.

First, it is possible CMS is considering this policy based on a desire to standardize MVPs and ensure they are implemented identically by all third party intermediaries. However, based on the current requirements for MVPs, there will be multiple versions of a single MVP even if all third party intermediaries were required to support all measures/activities. Because Qualified Registries (QRs) and other intermediaries cannot support QCDR measures, any MVP that contains QCDR measures will have both a "QCDR" and a "public use" version. Half of the current proposed MVPs, including those already finalized as well as those proposed in the 2023 NPRM, contain QCDR measures. QCDR measures often represent the newest and most cutting-edge clinical evidence, with the greatest opportunity for improvement, so their inclusion in MVPs is vital to targeting areas of improvement. However, since only approved QCDRs may support QCDR measures, any MVP containing QCDR measures will be different when supported by a QR versus a QCDR and standardization will not be achieved.

Second, CMS may be considering this policy as part of the broader goal of MVPs to simplify MIPS. CMS has suggested that clinicians find the number of measures/activities overwhelming, thus MVPs streamline the program for clinicians. However, requiring third party intermediaries to support all measures would actually be counter to this goal. Because some intermediaries would be required to support new measures and potentially even measures that do not apply to their clientele, this policy could introduce additional confusion into the program rather than simplify it. This rationale applies to both support of all measures and support of all applicable MVPs. Some third party intermediaries may find that a limited number of measures in an MVP apply to some of their clients, therefore they would be required to support this MVP (and potentially all of the measures in it) even if the majority of the MVP was not applicable. For instance, if four measures out of twelve in MVP applied to the participants in a given QCDR, that registry would be required to support eight measures that were irrelevant to their clientele, introducing additional complexity to the measure selection process for clinicians and unnecessary additional burden on the intermediary. Furthermore, CMS has suggested that the number of MVPs will remain limited and eventually will be focused on "patient journey" MVPs. While such an MVP is in theory an important way to recognize the value of team-based care across the continuum, requiring third party intermediaries to support all of a patient journey MVP would likely require them to support measures that did not apply to their clinicians, thus introducing additional confusion.

Third, CMS may be considering this policy in an attempt to standardize the data and collect a larger pool of measures, which statistically helps establish more reliable benchmarks and a wider performance range. However, differences in intermediaries and expertise could lead to inconsistent poor-quality data. It is not likely that all intermediaries would be able to implement all measures the same way. Some third party intermediaries use sophisticated data tools such as natural language processing to extract data. An intermediary with little experience in this realm would likely not be able to implement the measure in the same way, resulting in inconsistent data or poor data quality. Measure stewards have expertise in not only measure development but measure implementation; it should be left to stewards to decide if other intermediaries have the necessary clinical and technical capabilities to implement their measures as opposed to mandating all intermediaries support their measures.

Furthermore, measure stewards have invested significant time, money, and clinical expertise in developing measures, which are therefore the intellectual property of the stewards. Without the contribution of specialty societies developing measures, the measures available to eligible clinicians

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may be poorly refined and inaccurately capture quality performance. Requiring intermediaries to support all measures could in essence be forcing measure stewards to license their intellectual property to other users who would profit from the time and expense of developers. CMS previously abandoned a plan to require QCDRs to license their measures to CMS after valid concerns were raised regarding this idea. The current proposal generates similar issues, and we express the same concerns as we presented related to the previous proposal. While we remain willing to license our QCDR measures to other QCDRs, and in fact have discussed licensing with two other QCDRs, the proposal requiring all third party intermediaries to support all measures in an MVP unfortunately approaches the territory previously covered by the 2019 licensing proposal.

By eliminating the mandate for all third party intermediaries to support all MVPs that apply to any of their clientele, CMS could partially mitigate the issue. If intermediaries can choose whether to support MVPs, they will choose those whose measures they feel sure of implementing correctly that best support their clientele. A third party intermediary is best served by supporting all MVPs that their clinicians want to report, so it is unnecessary for CMS to mandate this.

In conclusion, third party intermediaries have the clinical and operational knowledge, and the personal relationships to know whether supporting an MVP and/or all of its measures is best for their members and to evaluate who should be allowed to support measures any intermediary has developed. CMS clearly understands that measure developers have the subject matter expertise to create and implement complex quality measures. Therefore, it should be clear that developers have the necessary expertise to decide whether they can implement a measure they did not develop, and to determine whether another intermediary can implement measures they did develop. We look forward to working with CMS on how to most successfully implement MVPs in a manner that maximizes use while reducing complexity of the program, ensuring data quality and preserving the intellectual property of all stakeholders.

E. Request for Information on Value of Adding CME Accreditation Organizations as Third Party Intermediaries

We thank CMS for the opportunity to comment on this potential expansion of third party intermediary type. Broadly speaking, we do not think that allowing CME accreditation organizations to become third party intermediaries aligns with long-term program goals. Specifically, creation of a new type of third party intermediary would not reduce clinician confusion but would likely add to it, and the complexity of the program.

As CMS notes, completion of the two Improvement Activities that could be directly supported by CME accreditation organizations would not be sufficient for most clinicians to get full Improvement Activity credit. Combined with the need to report Quality measures and Promoting Interoperability activities, this would necessitate use of another third party intermediary, resulting in additional burden and confusion. Additionally, creating a new type of third party intermediary could lead to confusion about what exactly these groups support; for instance, a clinician may not be aware until it is too late that only certain Improvement Activities can be reported through these organizations. We therefore do not see an immediate benefit to expanding the types of third party intermediaries. In short, a CME vendor reporting some of MIPS would not actually reduce administrative burden on practices.

Furthermore, adding CME accreditation organizations as third party intermediaries runs counter to CMS' increasing requirements on other types of third party intermediaries over the past few years. CMS should clarify that all reporting vendors of the MIPS program are subject to equivalent

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requirements. QCDRs are required to adhere to significant administrative, legal, and data validation requirements as vendors of CMS in the MIPS program, plus a significant level of clinical expertise on staff. Indeed, registries are required to support all relevant categories of the MIPS program, instead of being able to select only the ones that might be easiest or most cost effective. Creating a new type of intermediary with lower requirements is discrepant and unfairly provides a business advantage to CME organizations. This applies even more to the possibility of allowing CME accreditation organizations to submit MVPs; holding them to a lower bar than other intermediaries would jeopardize the data quality across the program.

Conversely, if a CME accreditation organization meets all the requirements to become a third party intermediary as they stand now, the organization should be permitted to do so without the need for a new type of intermediary. If CMS has received significant feedback from CME accreditation organizations who would like to become QRs and QCDRs but are confronted by programmatic barriers, we suggest CMS consider whether those barriers are necessary to ensure program integrity. If they are not, CME accreditation organizations could be permitted to become QRs and QCDRs through the same process as all current intermediaries. If the barriers seem necessary to ensure data quality or program integrity, it is likely that creating a new category of third party intermediary would also damage those same attributes.

F. Patient Access to Health Information Measure

1. *Moving beyond providing the information and technical capabilities to access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?*

   The CAP agrees with the CMS that there are advantages to having informed and educated patients having access to their health information via a variety of platforms. However, the CAP has concerns with respect to the implementation of promoting of patient access and use of their health information, as we see the potential for harm to patients. There is a myriad of situations in which automatic release of final reports to a patient portal can have disastrous psychological and practical consequences, and a case-by-case implementation of an exception is impractical or unworkable. For example, results may have already gotten to the patient before a physician realizes that the result may be harmful to the patient and/or the patient's family, particularly when the diagnosis or result produced by a pathologist, or the laboratory was not anticipated.

   The CAP would also like to note logistical concerns with patient portals that the CMS should be cognizant of in any policies designed to promote patient access and use of their health information. Specifically, some patient portals or similar apps may be incapable of suppressing reports if the pathologist believes that the immediate release of the result would cause patient harm. Similarly, the immediate release of health information on patient portals may threaten patient privacy. For example, some patient portals do not have the flexibility to hide some results from those who have proxy access (such as a parent or legal guardian) while still showing them to the patient. This would threaten patient safety if, for instance, the patient were a minor and the results concerned sexually transmitted infections or pregnancy tests. The immediate release of such results on the patient portal would also risk violating state law, as some states may require that all sexually transmitted infection results and pregnancy tests can only be shown to the adolescent between the ages of 13 and 18 (and not the patient's parents or legal guardian). Other patient portals which block results based

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on state law do not have the capability to allow a physician to release a result to the portal even after legally required counseling has occurred. In addition, some LIS/EHR systems do not adequately handle the concept of preliminary reports, which could cause a harmful premature release of non-validated results to a portal. Finally, patient portals have difficulty navigating conflicting state and federal reporting requirements, especially in the context of special rules for pediatric patients.

In sum, we urge the CMS to be mindful of the potential harm to patients in any policies designed to promote patient access and use of health information. Such policies must contain sufficient guardrails against such harm and must also consider the issues with patient portals and LIS/EHR systems. In any policy seeking to promote patient access to health information, the CMS also should consider a broader ability for pathologists and ordering clinicians to make certain exceptions and allow a delay for the opportunity for care team clinicians to create an integrated response before patient communication for the best care coordination.

2. *Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access?*

   The CAP is supportive of CMS in its promotion of patient access of health information. However, the concerns that the CAP has with the implementation of policies designed to promote patient access to health information would also apply to allowing patients add information to their records. Moreover, patients may add incorrect or misleading information which may worsen patient outcomes as well as cause lab result interpretation and billing challenges. If the patient data are not standardized, it is also possible that laboratories may misinterpret the patient data.

3. *Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?*

   Patients may add incorrect or misleading information which may worsen patient outcomes as well as cause lab result interpretation and billing challenges. If the patient data are not standardized, it is also possible that laboratories may misinterpret the patient data. To prevent these scenarios from occurring, we encourage the CMS to be mindful of such scenarios and also to work with medical associations to develop best practices with respect to a patient's addition of information to their records.

G. Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

1. *Refined potential future Definition of dQMs. Do you have feedback on the potential refined definition of digital quality measures (dQMs)?*

   The CAP is concerned by the definition of digital quality measures (dQMs) because of the implications it has related to clinical registries. The updated definition states that dQMs are "self-contained measure specifications and code packages". This term could be interpreted as software that functions completely independent of any other software.

   Additionally, Laboratory Information Systems (LIS) are not considered certified electronic health record technology (CEHRT) because they do not meet the required criteria (drug to

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drug interactions, electronic prescribing, etc.). Therefore, clinical quality measures (CQM), which all CAP pathology measures are, can only be calculated outside of CEHRT as opposed to electronic clinical quality measures (eCQMs).

Lastly, most anatomic pathology data is non-standard, narrative text which cannot be sufficiently and accurately captured by LOINC. Therefore, some level of manual intervention is required for data abstraction/quality measurement compared to other types of clinical data for electronic clinical quality measures.

2. *Do you have feedback on potential considerations or challenges related to non-EHR data sources?*

   The CAP supports CMS' decision to widen the list of acceptable data sources to include "clinical registries". However, the "meat" of anatomic pathology data is non-standard, narrative text. Current semantic standards such as LOINC, do not sufficiently and accurately capture pathology data in the narrative text. Therefore, pathology data cannot be transmitted entirely electronically without manual intervention.

   The CAP is concerned that the value of clinical registries will be depreciated based on CMS' clarified definition of dQMs as, essentially, independent, calculative tool. Clinical registries are an important piece of the healthcare ecosystem. One of the main functions of clinical registries is that it collects and stores data. If the data is not initially stored in clinical registries, then where would the data be stored?

   Lastly, the CAP understands the importance and supports standardized data. However, the current CMS' guidelines and requirements for standardized data should not be a "one-size fits all."

3. *Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?*

   The CAP is not able to provide sufficient feedback on this section because the FHIR implementation guides do not apply to CQMs which pathology measures are comprised of because LISs are not considered CEHRT.

4. *Are there additional venues to engage with implementors during the transition to digital quality measurement?*

   The CAP supports CMS engagement with other implementors, specifically non-patient facing specialties like the CAP, to identify ways to better capture non-standardized data in preparation for transition to dQMs and FHIR.

5. *What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?*

   The CAP is not able to provide feedback on data flow options for FHIR-based eCQM reporting because LISs are not considered CEHRT.

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6. *Are there other critical considerations during the transition?*

   The CAP has outlined several critical considerations related to the standardization of data and transition to FHIR eCQM reporting in the sections above.

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 1-5 of these comments to Maurine Dennis at mdennis@cap.org or Todd Klemp at tklemp@cap.org; and for items 6-7 contact Colleen Skau at cskau@cap.org and Elizabeth Fassbender at efassbe@cap.org.

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