



COLLEGE of AMERICAN PATHOLOGISTS

June 27, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Medicare Program; “Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models”.
Proposed rule. CMS-5517-P; RIN 0938-AS69

Sent via Electronic Submission to <http://www.regulations.gov>

Dear Acting Administrator Slavitt:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-5517-P entitled “Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models”. The CAP is a national medical specialty society representing 18,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals, and federal and state health facilities.

The CAP is looking forward to continued engagement with the CMS on this challenging program in order to determine how to measure appropriately providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. The CAP believes considerable accommodations or alternate measures will be necessary to meet this clause¹ in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments in MIPS followed by APMs including Physician-Focused Payment Models (PFPMs).

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.



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

1. MIPS Eligible Clinicians
2. Definition of Non-Patient-Facing MIPS Eligible Clinicians
3. MIPS Eligible Clinician Identifier
4. MIPS Category Measures and Reporting
5. MIPS Composite Performance Score Methodology
6. Review and Correction of MIPS Composite Performance Score
7. Public Reporting on Physician Compare
8. MIPS proposed Rule estimated Impact on total allowed charges by practices size
9. Incentive Payments for Participating in Advanced APMs
10. Physician Focused Payment Models (PFPM) Definition
11. PFPMs as Advanced APMs
12. PFPM Criteria
13. PTAC Recommended Models

MIPS Program Details

The CAP appreciates that the CMS is proposing to retain the eight current PQRS pathology measures developed by the CAP for the Quality category. Continued inclusion of these measures will allow most pathologists to report on applicable measures. The CAP also suggests that measure types be updated to reflect that diagnosis is a patient outcome with respect to pathology services. As a diagnostic specialty, pathology contributes to understanding the patient's condition in order to provide appropriate medical care. Diagnosis is an important outcome, essential to achieving an ultimately positive patient result. A correct diagnosis ends the diagnostic odyssey. This essential aspect of patient care should be incorporated into the traditional definitions of outcomes. As such, we ask that the following measures be designated outcome measures consistent with efforts at the National Quality Forum:

- Measure #99 Breast Cancer Resection Pathology Reporting
- Measure #100 Colorectal Cancer Resection Pathology Reporting
- Measure #249 Barrett's Esophagus
- Measure #250 Radical Prostatectomy Pathology Reporting
- Measure #395 Lung cancer reporting (biopsy/cytology specimens)
- Measure #396 - Lung cancer reporting (resection specimens)
- Measure #397 Melanoma reporting



II.E.1.a MIPS Eligible Clinicians

The CMS proposes to define MIPS eligible clinicians (“ECs”) for the first and second year for which MIPS applies to payments (and the performance period for such years) as a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined CMS-5517-P TLP 4/25/16 49 in section 1861(bb)(2) of the Act), and a group that includes such professionals. The CAP agrees with the CMS proposed definition of eligible clinicians. The CAP requests that the CMS specifically address the eligibility of pathologists who work in independent laboratories. Pathologists working in independent laboratories were **specifically excluded from the PQRS because they were considered suppliers; however their status with regard to MIPS is unclear. Please provide clarification.**

II.E.1.b Definition of Non-Patient-Facing MIPS Eligible Clinicians

While the CAP appreciates that the CMS has proposed to change the definition of non-patient-facing ECs from one face-to-face encounter to 25, the definition of non-patient-facing ECs still does not seem adequate. The definition is dependent on the codes that define patient-facing encounters which are not yet available. For example, previously the CMS has included CPT codes for Fine-Needle Aspiration (10021 and 10022) as a face-to-face encounter. While this service does indeed require a face-to-face interaction with the patient, none of the cross-cutting measures are applicable to this service (nor are these codes included in the denominators of those measures. We request that pathologists (as identified in PECOS) be automatically identified as non-patient-facing ECs at the beginning of each year. The agency plans to use PECOS to identify ECs that are exempt from the Advancing Care Information category; therefore it seems reasonable to use PECOS to identify non-patient-facing specialties. As noted above, pathologists may occasionally provide face-to-face service but these are not typically in and office setting and cross-cutting measures would still not apply.

In the Proposed Rule the CMS provided examples of pathologists and other specialists within the non-patient-facing spectrum. While almost all pathologists should be in this spectrum, the CMS used an illustrative example that represents less than 1% of pathologists –

- Pathologists who may be primarily dedicated to working with local hospitals to identify early indicators related to evolving infectious diseases.

In addition, the definition non-patient-facing ECs appears to be the same for individuals and groups which could force groups of non-patient-facing ECs to be required to report



on non-applicable outcomes and cross-cutting measures if several individuals' rare face-to-face patient encounters are summed as a group (e.g. a group of 10 physicians with 2-3 face to face patient encounters per year per EC). The CAP requests that number of face-to-face encounters that define patient-facing be proportional to the group size to avoid the above scenario.

Regardless of the threshold for non-patient-facing ECs, the CAP believes that those ECs who are in this category should be identified at the beginning of the reporting year. If an EC's status changes during a reporting year by crossing an arbitrary threshold on patient-facing encounters, it will be difficult for the EC to meet the reporting requirements of a patient-facing EC. For example, an EC using claims reporting would not be able to retrospectively report a cross-cutting measure or outcome measure (were one applicable.)

II.E.2.b. MIPS Eligible Clinician Identifier

The CAP supports the CMS proposal to have each unique TIN/NPI combination considered a different MIPS eligible clinician and to use the TIN to identify group practices.

II.E.5. MIPS Category Measures and Reporting

a. Performance Category Measures and Reporting

The CMS asks for comment regarding feasibility of incorporating measures from other systems into MIPS. The CAP believes that system level and population based measures should be applicable to eligible clinicians (ECs), such as pathologists, who typically furnish services that do not involve face-to-face interaction with patients. Activities such as blood utilization, infection control, and test utilization activities, including committee participation, should be credited to the whole group as pathology practices typically function as one unit with different members of the group having different roles. We urge the CMS to be flexible and not to focus exclusively on measures and activities that involve face-to-face encounters, as these would have an unfair and negative impact on the MIPS composite performance scores of pathologists and other non-patient facing specialties.

The CMS is proposing several data submission mechanism for MIPS ECs reporting individually and as group practices but is not proposing to allow two or more submission mechanisms for a single MIPS category. While we recognize that the CMS' goal is to provide flexibility without undue complexity, we believe



limiting the number of submission mechanisms for a category is too restrictive. There may be a need for a physician to report independent measures through multiple mechanisms and for those measures, in total, to count toward satisfying the quality measure reporting requirement. For example, an EC might identify a handful of clinically relevant electronically specified (e-specified) measures that can be reported through an electronic health record (EHR), but also might identify a few other relevant measures that are not yet e-specified and can only be reported through a registry. The CMS should recognize the reporting of measures across multiple reporting mechanisms in order to promote meaningful engagement and to encourage ECs to experiment with different options.

b. Quality Performance Category

The CAP is pleased that the CMS has proposed to maintain the current mechanisms available to report data to CMS as an individual EC and as a group practice participating in the Group Practice Reporting Option (GPRO). We are also appreciative that the CMS has proposed to maintain the claims-based reporting option as that is the most viable option for pathologists to report quality measures. We would also urge the CMS to continue exclusion of pathologists from selection as focal providers about whom the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey asks. Since pathologists do not have an appointment-based practice and are generally non-patient-facing providers, it is appropriate that they not be included in the CAHPS requirement.

The CAP appreciates that the CMS has eliminated many of the existing criteria, including reporting on outcomes and cross-cutting measures for non-patient-facing clinicians and reporting on three National Quality Domains. These and other criteria had unnecessarily complicated the Physician Quality Reporting System (PQRS) program and did not provide any additional assurance of quality.

While the CAP appreciates that the CMS has lowered the current PQRS requirement of reporting on 9 quality measures to reporting on 6 quality measures for MIPS, we are disappointed that the CMS has maintained an absolute minimum number of measures that ECs have to report. The current measures list is insufficient to cover all practice types, and the challenge of participating will only be exacerbated by imposition of a minimum number of measures. We do appreciate that ECs who are unable to report on the minimum will not be penalized if they do not have applicable measures. The measure development process is difficult and requires numerous resources that many specialties do not have readily available. In addition, the turnover of measures due to changing guidelines adds to the challenge of maintaining a selection of



appropriate measures that may be used by the many specialties and sub-specialties.

Currently, in the PQRS program, ECs are required to report on a minimum of 50% of their Medicare Part B patients seen during the performance period. However, we believe it is inappropriate for the CMS to increase this requirement for the MIPS quality category. The CMS is proposing that individual MIPS ECs using claims submission submit data on at least 80% of the Medicare Part B patients seen during the performance period to which the measure applies. For those ECs submitting using QCDRs, qualified registries, or via EHR, the data completeness criteria is at least 90% of both Medicare and non-Medicare patients. We believe this will put undue pressure on ECs as they get used to a new program and new requirements. We ask that the CMS lower the data completeness criteria to at least the existing PQRS reporting requirement of 50% of Medicare patients.

The CAP appreciates inclusion of 8 existing pathology measures for the MIPS quality category in the proposed rule and encourages the CMS to finalize those measures. These measures will go a long way towards allowing pathologists to participate in this category of MIPS.

c. Selection of Quality Measures for Individual MIPS Eligible Clinicians and Groups

We appreciate the inclusion of the 8 existing PQRS pathology quality measures in the MIPS proposed rule. We would encourage the CMS to work with the CAP to continue to develop additional measures for pathologists for future years of MIPS. Even with the 8 proposed pathology measures, we do not believe that all pathologists have measures available to report. Measure development and maintenance are onerous and costly processes for specialty societies with limited resources, and the CAP would appreciate any assistance and funds the CMS could provide for these activities.

d. Resource Use Performance Category

The current Value-Based Modifier (VBM) program is designed for primary care specialties and generally does not measure the value that pathologists provide to their patients. For example, none of the cost measures or outcomes measures applies to pathologists and the attribution mechanism has been designed for primary care specialties. While pathologists routinely contribute to team-based care, it is difficult to account for their resource use under the current system.



As such, the CAP appreciates the CMS' acknowledgement that many non-patient-facing MIPS ECs may not have sufficient measures and activities available to report and would not be scored on this category. We look forward to working with the CMS to develop alternative resource use measures for use in MIPS in future years.

As we explain in more detail in our comments on the MIPS Composite Performance Score (CPS) methodology, the CAP recommends that the CMS not finalize its proposal to re-weight the Resource Use performance category for non-patient-facing ECs who do not have sufficient measures to report in this category. While we appreciate CMS' recognition of the non-applicability of this category to pathologists, we believe that a MIPS CPS based on fewer than four categories would not be comparable to scores based on four categories. The CAP is continuing to explore alternatives for Resource Use for pathologists and ask for further discussions between the CMS and the CAP to assure that appropriate measures in this category are available for future years of MIPS. In the meantime, the CAP asks that the CMS provide pathologists with a weighted median score for this category instead of re-weighting the category and re-distributing the weight to the Quality performance category.

e. Clinical Practice Improvement Activity (CPIA) Category

The CAP appreciates our ongoing conversations with the CMS regarding the CPIA category and the CMS' recognition that non-patient-facing MIPS ECs and groups will have a limited number of measures and activities to report in this category. We urge the CMS to finalize its proposal to allow non-patient-facing ECs 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 CPIA submission criteria.

The CAP opposes the CMS proposal to require a minimum of 90 days as the amount of time for performing a CPIA. While performance of an activity for a minimum of 90 days may be appropriate for some CPIA, we believe it is not appropriate for others. For example, if a pathologist attends several departmental or institutional quality assurance meetings per year, his/her participation in such meetings should qualify as a CPIA as these meetings are an integral part of population management, even though it would not be possible to perform this activity for 90 days. However, each individual meeting may cover events which occurred over a given period of time such as 90 days. The CAP asks the CMS to clarify the definition of performing an activity for 90 days. For example, a procedural review may cover activities over the course of 90 days,



but the review itself does not take 90 days. In addition, many important patient safety courses will not take 90 days, but should be included as CPIA. Thus, we encourage CMS to be flexible and not set a minimum amount of time that a CPIA must be performed. We believe these activities will be varied from specialty to specialty and a one-size-fits all approach would be inappropriate.

While there are some proposed CPIA as published in the proposed rule that pathologists could report on, we believe that additional CPIA will be needed to accommodate the differences in practices between specialties and the sub-specialties. Most of the activities listed in the Proposed Rule are not applicable to pathologists. The CAP offers the following examples of activities that could qualify for the proposed CPIA subcategories and proposes that these be measured at the group (TIN) level instead of at the level of the individual physician:

- Category: **Population Management**
 - Activity: Population management, such as monitoring health conditions of individuals to provide timely health care or participation in a qualified clinical data registry;
 - *Blood Product Utilization management*
 - *Clinical laboratory services utilization management workgroup*
 - Detailed Example -
 - Participation in clinical laboratory services utilization management workgroup or efforts

Criteria for successful participation: Participation in the effort of a hospital, health care network, ACO, or insurance company that monitors laboratory test utilization and promotes optimal utilization of laboratory resources to the practitioners within the organization. The activities of the workgroup or committee are documented and available for an annual audit.

Acceptable documentation: Any of the following: Minutes from meetings, written communications from the committee to health care professionals in the organization promoting recommendations of the committee, or implementation of notifications in the laboratory order system to encourage appropriate ordering such as avoiding duplicative testing.

Method of reporting: Attestation



- Activity: Participation in a departmental or institutional quality assurance effort

Criteria for Success: Attendance in four or more departmental or institutional quality assurance meetings per year. The meeting activities might be of various types and might include transfusion services, infection control, patient safety, or general departmental quality meetings.

Acceptable documentation: Minutes of the meeting would serve as documentation of attendance and the meeting contents.

Method of reporting: Attestation

- Category: **Patient Safety and Practice Assessment**
 - Activity: Patient safety and practice assessment, such as use of clinical or surgical checklists and practice assessments related to maintaining certification;
 - *Proficiency Testing (PT) on unregulated analytes*
 - *Practice level assessments*
 - *Patient Safety checklist*
 - *Interim CLIA inspection*
 - Detailed Example -
 - Activity: Participation in an activity to improve quality of patient care that involves reviewing data beyond one's own principal institution.

Criteria for successful participation: Participating as an inspector for a laboratory accreditation inspection or Participation in a national or local quality project where standard practices or procedures are compared amongst participants such as the CAP Q probes. Documentation for such activity must include confirmation of the attester's participation.

Method of reporting: Attestation

- Activity: Hospital Antimicrobial Susceptibility Report

Definition of participation: The creation and distribution of annual antimicrobial susceptibility testing report for the hospital.



Acceptable documentation: Records of the annual reports.

Method of reporting: Attestation

- o Activity: Assessments related to Maintenance of Certification (MOC)

Definition of participation: Participation in an American Board of Pathology approved educational course related to Patient Safety.

Acceptable documentation: Certificate of completion.

Method of reporting: Attestation.

- o Category: **Expanded Practice Access**

- o Activity: After hours service and clinical advice.

Criteria for successful participation: Processing and/or interpretation of either anatomic or clinical pathology specimens after normal business hours in instances where the clinician has indicated the results will urgently impact therapy. Consultation regarding laboratory test utilization or result interpretation after normal business hours. Examples include, but are not limited to proper blood product utilization, appropriate ordering of laboratory tests, proper specimen collection techniques and interpretation of laboratory test results. Appropriate documentation could include a redacted anatomic pathology or clinical pathology report, a note documenting the date and nature of the blood bank consultation or other clinical pathology consultation or notes made in the patient chart.

Method of reporting: Attestation

- o Medical Direction of a Point of Care testing program

Examples: clinical laboratory testing performed at the site of service with real time results

Definition of participation: Management/Director of a program which enables the patient to obtain tests and/or procedures with real time results, eliminating the need to leave the site of service or make another appointment. For example, participation or oversight in any health fair



that provides laboratory testing results directly to patients at the time of the fair.

Acceptable documentation: Minutes from meetings of a point of care testing workgroup/committee or documentation of Laboratory Director under CLIA for Point of Care Testing

Method of reporting- Attestation or QCDR

o **Category: Care Coordination**

- o Activity: Participation in multidisciplinary patient management conferences

Examples include: Specialty and general tumor boards; medical liver conference; medical renal conference; pediatric gastrointestinal conference; coagulation conference; transplant conference and molecular board

Definition of participation: Present surgical, cytopathology or other relevant clinical pathology results during a multidisciplinary meeting for the purpose of developing a patient care management plan. Frequency – minimum of four times per year by the group in aggregate or an individual representative of the group.

Acceptable Documentation: Activities are documented and are available for annual audit. Examples include secured records of conference date, physicians in attendance and list of patients discussed.

Method of reporting: Attestation

f. Advancing Care Information (ACI) Performance Category

The CAP appreciates the CMS' recognition that many of the measures proposed under the ACI performance category require face-to-face interaction with patients and that sufficient measures are not applicable to non-patient-facing MIPS ECs. Pathologists typically, as medical directors have significant and extensive responsibility and involvement in EHR's through laboratory and anatomic pathology information systems and would urge that the CMS consider inclusion of these activities in the future as pathologist participation in this performance category.



As we explain in more detail in our comments on the MIPS CPS methodology, the CAP recommends that the CMS not finalize its proposal to re-weight the ACI performance category for non-patient-facing ECs who do not have sufficient measures to report in this category. While we appreciate the CMS' recognition of the non-applicability of this category to pathologists, we believe that a MIPS CPS based on fewer than four categories would not be comparable to scores based on four categories. The CAP is continuing to explore alternatives for ACI for pathologists and ask for further discussions between the CMS and the CAP to assure that appropriate measures in this category are available for future years of MIPS. In the meantime, the CAP asks that the CMS provide pathologists with a weighted median score for this category instead of re-weighting the category and re-distributing the weight to the Quality performance category.

The CAP believes that a weighted median score for this category should be granted automatically, without an EC having to submit an application, based on the ECs Provider Enrollment, Chain and Ownership System (PECOS) specialty code and not based on the number of patient-facing encounters billed during a performance period. The former has precedence in the Meaningful Use (MU) program. The CMS currently grants automatic relief from MU penalties under a hardship exception to pathologists based on their PECOS specialty code. We believe this is more appropriate since the definition of a non-patient-facing specialist may not be applicable to all pathologists. However, all pathologists would not be able to participate in the ACI category and using a PECOS specialty code would ensure that they are not subject to reporting on measures that do not apply to them. If the CMS finalizes its proposal to re-weight this category for pathologists, the CAP urges the CMS to use the same methodology described above.

The CAP also requests that CMS clarify whether ECs will need to submit an annual application to be excluded from the ACI category or if this will occur automatically. The Proposed Rule seems to indicate both scenarios. The CAP requests that once an EC is excluded that the status be maintained and that the EC should not have to reapply annually.

II.E.6. MIPS Composite Performance Score Methodology

The CAP appreciates the consideration the CMS gave to non-patient-facing specialties in all of the categories but in particular to the CPIA requirements of only two activities. The CAP encourages the CMS to keep the requirements minimal for non-patient-facing specialties until they can ensure there are enough activities applicable to these



specialties, especially since pathologists are not able to participate in resource use and ACI categories at this time.

a. Converting Measures and Activities into Performance Category Scores

(2) Scoring the Quality Performance Category

The CAP opposes the way the CMS has proposed to score topped out (high performing) measures by identifying clusters within topped out measures and assigning all MIPS eligible clinicians within the cluster the same value, which would be the number of points available at the midpoint of the cluster. The CAP prefers the alternative proposed by the CMS where ECs are scored on their percentage of their performance rate. The CAP agrees that using flat percentages also helps ensure those with high performance on a measure are not penalized as low performers.

(c) Case Minimum Requirements and Measure Reliability and Validity

The CAP also opposes limiting the number of high performing measures as this would reduce the already low number of measures that pathologists have to report. For this reason, the CAP also opposes limiting the use by MIPS eligible clinicians of measures that are not able to be scored due to not meeting the required case minimum. If CMS requires these MIPS eligible clinicians to submit different measures with sufficient cases for the next performance period, many pathologists may not have sufficient measures to report as there are already few measures that are applicable and available to them.

(d) Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria

The CAP supports the CMS proposal to allow MIPS eligible clinicians to receive credit for any measures that they report, regardless of whether or not the MIPS eligible clinician meets the quality performance category submission criteria.

(e) Incentives to Report High Priority Measures

While the CAP does not oppose the CMS proposal to give bonus points for the reporting of high priority measures, the CAP asks that CMS ensure that all ECs have applicable high priority measures so as to not give any particular ECs an advantage in this budget neutral system.



(h) Measuring Improvement

The agency offered several alternative ways to include improvement in the quality score. In Option 1 the agency would assign from 1-10 points for achievement and from 1-9 points for improvement for each measure and then compare the achievement and improvement points for each measure in the quality performance category and score whichever is greater.

The CAP prefers Option 1 for incorporating performance improvement in the Composite Performance Score (CPS). With this option the CMS would compare the achievement and improvement scores for each measure and only use whichever is greater, but only those eligible clinicians with the top achievement would be able to receive the maximum number of points.

b. Calculating the Composite Performance Score (CPS)

(c) Redistributing Performance Category Weights

The CMS has proposed that if the MIPS eligible clinician does not receive a resource use or advancing care information performance category score, and has at least three scored measures (either submitted measures or those calculated from administrative claims) in the quality performance category, to reassign the weights of the performance categories without a score to the quality performance category. The CAP prefers that ECs who cannot be scored for resource use or the advancing care information performance category receive a median score in those categories until such time that the CAP can develop viable alternatives for pathologists to be able to participate in these categories. The CAP does not believe that CPS that are weighted differently across specialties can be fairly compared.

II.E.8. Review and Correction of MIPS Composite Performance Score

a. Feedback and Information to Improve Performance

The CMS has requested information on how often the feedback should be made available to ECs on their performance in the MIPS categories. The CAP requests that feedback be made available at least quarterly, but that more frequent feedback would contribute the most to quality improvement and allow ECs to adjust their practice. The CAP notes that current QRUR feedback reports have few if any data points relevant to pathology practice and that these reports are very difficult to access. The CAP encourages the CMS to make the reports easier to access and more relevant for non-patient-facing specialties.



II.E.10. Public Reporting on Physician Compare

As the CAP has stated in prior comments to the CMS, we believe that all ECs 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 improving health care quality. As the CMS moves forward with implementation of MIPS, we ask that the current 30-day preview period be extended to 60 days to give physicians adequate time to review any potential inaccuracies they may find during the review process and that the CMS provide a specific methodology through which physicians can correct any inaccuracies prior to the CMS publicly posting the information. Anecdotally, we found many entries for the CAP members were inaccurate. For example, some entries failed to note participation in the PQRS when the member had participated and received an incentive payment, and the opposite was also true, physicians who had not participated were noted as having done so. Accuracy of information should be the first and highest priority before any additional information is considered for the site.

The CAP reiterates its comments from previous years that encourage the CMS to develop educational tools for patients viewing the Physician Compare website, especially with implementation of MIPS. 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. Resource Use or ACI 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 actually lack of applicability of the program to that physician. The CAP reiterates the need to indicate clearly on the website when a program does not apply to a particular physician.

MIPS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY PRACTICE SIZE* (Table 64)

In Table 64 in the Proposed Rule, the CMS has provided estimates of the impact of MIPS on practices based on the size. The CAP is concerned that the disproportionate negative impact on solo and small practices demonstrates a bias in the programs implementation. While the CMS has proposed a few mechanisms such as limiting the CPIA reporting requirement to two activities, it is not clear at this time whether these accommodations will be sufficient to allow solo and small practices to be successful in the program. The CAP suggests that the CMS not penalize these practices until there is sufficient experience and data showing that the mechanisms put in place remove the inherent bias in the program. The CAP thinks that the CMS should demonstrate in 2019 that the program is not biased against small practices and non-patient-facing specialties and delay for one year the imposition of penalties on those practices.



In addition, analysis by the American Society of Anesthesiologists has identified additional bias against ECs who cannot report on the ACI category. The CMS's proposal to load Advancing Care Information (ACI) weights onto the Quality component of MIPS means that the quality metrics (values and distribution) have a disproportionate impact on specialties that are unlikely to participate in this category. The distribution of Quality scores is not likely to mirror the distribution of scores for the ACI component of MIPS. Because ACI has a "base score" of 50%, re-weighting this category to Quality will disadvantage clinicians unable to report under ACI (including all non-patient-facing physicians). In particular, the Quality score can range from 0% to 100% of the denominator for the Quality component. By contrast, assuming the physician meets the minimum reporting and data protection thresholds, the ACI score has a more constricted range from 50% to 100%. Since the CMS has proposed a single overall MIPS performance threshold, physicians without the ability to be scored under the ACI component will be at a significant disadvantage relative to other physicians.

Low-Volume Threshold

The CAP also recommends that the low-volume threshold be raised significantly in the final rule. This additional change will help mitigate adverse effects on small practices. The CMS has proposed a low-volume threshold that would exempt physicians with less than \$10,000 in Medicare allowed charges and fewer than 100 unique Medicare patients per year from MIPS. The proposed threshold, however, would help very few physicians and other clinicians. An AMA analysis of the 2014 "Medicare Provider Utilization and Payment Data: Physician and Other Supplier" file found that just 10% of physicians and 16% of all MIPS eligible clinicians would be exempt under the \$10,000/100 beneficiary proposal, and that these clinicians account for less than one percent of total Medicare allowed charges for Physician Fee Schedule services. **Instead, the recommendation is that clinicians with less than \$30,000 in Medicare allowed charges per year OR fewer than 100 unique Medicare patients be exempt from MIPS.** The less than \$30,000 OR fewer than 100 patients threshold should apply to claims for each eligible clinician identified with a National Provider Identifier (NPI) and not be applied at the group level. In addition, physicians in small practices who are providing care to patients in rural areas and HPSAs should be provided opportunities to be exempt from MIPS. By raising the threshold to \$30,000 in Medicare allowed charges, the CMS would provide a better safety net for small providers. This would exclude approximately a quarter of physicians while still subjecting more than 95% of allowed spending to MIPS.



II. F. Incentive Payments for Participating in Advanced APMs

Physician-Focused Payment Models (PFPMs)

With MACRA's establishment of a new process for stakeholder submission of proposed PFPMs to an ad hoc committee, the PFPM Technical Advisory Committee (PTAC), for consideration and the express inclusion of specialist physicians amongst such models, we eagerly awaited a proposed PFPM definition and criteria. The CAP was pleased the proposed rule recognized that these models were to provide openings for those whose opportunities to participate in other PFPMs with the CMS have been limited to date (e.g. those who have not been able to apply for any other PFPM because one has not been designed that would include physicians of their specialty). Pathologists fall into this category.

Based on our review of the proposed rule, the CAP is challenged to reconcile the CMS' intention to broaden its APM portfolio to include new specialties with what in practicality as proposed seems not to fully accomplish this objective. As such, we seek areas of clarification and offer comments as follows:

PFPM Definition

The CAP was hopeful the definition as proposed would be cast so as to truly include an opportunity for model development by all specialists. On its face, the proposed definition targeting physician services encompassing individual eligible clinicians, physician group practices or other entities, and possibly including facilities or other practitioner types seems broad enough to encompass all specialties and afford flexibility in model development.

The definition coupled with the criteria and information considered essential to evaluating new models, though, serves to narrow the field of potential PFPMs and disfavor certain specialties including pathology. Amongst the information characterized in the proposed rule as fundamental to evaluating new models is the defined period of performance or clinical episode. Pathology and other hospital-based specialties are less episodic in nature. Similarly the aspects of the second category of PFPM criteria focused on patient choice and how the model affects disparities among Medicare beneficiaries and health-related preferences are not meaningfully applicable to non-patient-facing specialties such as pathology. We expound on the limiting effect of the criteria and supplemental information below and underscore the challenges they present to specialties the CMS intended to afford opportunities under PFPMs, particularly if all proposed criteria are to be exhaustively fulfilled for PFPM consideration by the PTAC.



PFPs as Advanced APMs

By definition, a PFP is not an Advanced Alternative Payment Model nor does the proposed rule define PFPs “solely as Advanced APMs.” The proposed rule instead acknowledges that stakeholders may propose either Advanced APMs or other PFPs that might lead to better care for our patients, better health for our communities, and lower health care spending. While developing an “other PFP” for these purposes is a laudable goal, clarity around the practical implications of this statement in terms of APM Incentive Payment is needed before stakeholders begin PFP development. Such clarification is foundational to determining both whether and the extent to which stakeholders invest in pursuing PFP development for PTAC submission. **The CAP concurs with the CMS’ statement in the proposed rule that the “statutory requirements for Advanced APMs can or should be waived for proposed PFPs.”**

In response to CMS’ suggestion in the proposed rule that stakeholders may want to discuss in their comment whether a proposed PFP would be an Advanced APM, the CAP urges that PFPs not be required to fulfill Advanced APM requirements for consideration by the PTAC. To require such a high bar will only dissuade stakeholders, particularly those who do not currently have an opportunity to participate meaningfully in existing PFPs, from investing in development of such models. The more appropriate set of requirements for qualification as a PFP and eligibility for APM Incentive Payment is for PFPs to be assessed based on the definition, criteria, and process we suggest are refined in the final rule rather than fulfillment of the Advanced APM requirements. Requiring Advanced APM financial risk requirements for a specialist PFP seems inapplicable and even misplaced given their objectives. **Qualifying Participant thresholds at the level of an Advanced APM are also inapplicable and particularly problematic in pathology where a model or even several models are not likely to encompass a broad swath of pathologists who specialize in many areas including, but not limited to hematopathology, dermatopathology, cytopathology, and infectious disease.** To require PFPs to fulfill Advanced APM criteria for PFP participants to qualify for an APM Incentive Payment will result in the development of very few models, leaving the physician community to wonder whether the intent under the proposed rule really was to broaden opportunities for participation through this new and more transparent process.

Criteria

While the PFP definition on its face seems sufficiently broad, depending on how extensively and precisely the proposed criteria are to be applied for each model, the PFP criteria may lack the necessary breadth to encourage the development of specialist models particularly for those who do have sufficient opportunity currently. **The CMS belief stated in the proposed rule that it has designed the criteria so that they**



are broad enough to encompass all physician specialties and provide stakeholders with flexibility in designing PFPMs may not be true if each and every category and sub-category of criteria is to be precisely fulfilled by all submitters.

The CAP understands that the criteria would be used by the PTAC, the Secretary, and CMS to evaluate PFPM proposal and that the CMS believes proposed PFPMs that meet all of the proposed criteria may need less time to go through the development process.

What remains unclear is the status and handling of PFPMs that fulfill a substantial amount, but not all of the specified criteria including sub-categories. **Particularly as certain elements of the criteria are more applicable to certain specialties than others and no one set of criteria can fit all possible models, the CAP urges the criteria guide submission and review, but not serve as a threshold for serious consideration and priority review of PFPMs. To adhere so rigidly to criteria especially where inapplicable will disqualify PFPMs for certain underrepresented specialties and discourage their very development.**

In addition to the criteria, the proposed rule includes numerous items “the PTAC may request or stakeholders may wish to provide.” These items include, but are not limited to information about specific incentives; how they incentivize; how feasible it would be for APM Entities in the PFPM to deliver high-quality care; how the PFPM can adapt to accommodate clinical differences in patient subgroups; how the payment model would affect access to care for Medicare beneficiaries; how the payment model would affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography; and what measures may be used to measure the provision of necessary care and monitor for any potential stinting of care; and how patient choice is preserved by accommodating individual differences in patient characteristics. **While some of this information could indeed be provided for a pathology PFPM, the CAP urges the agency to specify this information is not essential and will not result in any negative consequences in the PTAC consideration process** (i.e. the PFPM be considered with the same priority and processed on the same schedule as other PFPMs particularly where the information may be inapplicable to the specialty and to the model).

a. Category 1

In the first category of criteria regarding incentivizing value over volume, **the CAP questions the inclusion of the requirement that the PFPM payment methodology cannot be tested under current payment methodologies and aims to solve an issue in payment policy not addressed in the CMS APM portfolio at the time proposed.** While there are variations on models and methodologies, they are finite and distinction over current designs largely one of degree. To encourage participation, the focus should be on whether the PFPM includes in its design APM Entities that have had limited opportunities to participate in APMs as the CMS offers in the alternative or describes how it can



be distinguished from current models and methodologies if even by a matter of degree. With no clarification in the final rule, these requirements will limit flexibility and discourage PPFM development contrary to what appears to be the CMS' objective.

Substantively within the first category of criteria, the CAP concurs PPFMs should have evaluable goals and that the submitter can identify evaluable goals for quality of care, cost, and other applicable goals. While identified as items the submitter may "wish to provide," the CMS as evaluator of the models having operated and analyzed large scale models is likely in a better position than the submitter to provide information on, for example, evaluation study design and the level of precision the evaluation may reach.

b. Category 2

The second category of criteria, care delivery improvements, represents another area where one size does not fit all. Given this, the CAP would suggest each sub-category may not be an absolute requirement particularly where not applicable to the specialty PPFM. In this category, a pathology PPFM could very much promote better care coordination and protect patient safety. As a non-patient-facing specialty, though, encouragement of patient engagement and the preferences of individual patients will be far less direct.

c. Category 3

The CAP supports a category of criteria as proposed in category three that addresses information enhancements that improve the availability of information to guide decision-making. While daily medical decisions made by pathologists and the laboratories they direct produce critical diagnostic information driving an estimated 70% of decision making and serving as a key influence on health care and the coordination of care, they have long utilized computerized laboratory information systems (LIS) to support their work of analyzing patient specimens and generating test results. Through these LIS, electronic health records or enterprise-wide clinical information systems exchange laboratory and pathology data. The proposed rule's suggestion that to address this category of criteria, the PTAC may request or stakeholders may wish to provide information about how the payment model could incorporate certified EHR technology would therefore be problematic for a pathology PPFM. If taken literally, a pathology PPFM would likely not meet this criteria despite its having fulfilled the objective of this category of criteria by improving the availability of information that guided decision-making.



Supplemental Information

The CAP appreciates that only three items have been identified as fundamental to evaluating new models with deference afforded the PTAC on how it may approach requesting any supplemental information required to meet the PFFM criteria. We are also encouraged that estimates seem to be acceptable for most of the required items. **The CAP finds it difficult, though, to reconcile this seemingly more minimal list with the statement in the proposed rule that to the extent stakeholders develop PFFM proposals that address the factors the CMS uses in evaluating payment model designs, they “would increase the probability that PTAC recommendations would be positive” and might lead the CMS to test the proposed PFFM. As with the exhaustiveness of the criteria when all descriptors and subcategories are included, the bar for PFFM submission and acceptance is less clear, higher than expected, and inconsistent with the stated objective of broadening opportunities for participation.**

As with the criteria, one size will not fit all specialty PFFMs regarding the three items identified as fundamental to evaluating new models. While the third piece of information regarding an assessment of the financial opportunity including why it would be attractive to participants and feasible to implement could be provided for a pathology PFFM, some of the information in the first and second requirements including the “clinical episode of care,” target population, and any criteria for including or excluding patients from the model, burden in terms of morbidity, and mortality on a population, cannot be provided. These items are more applicable in patient-facing specialties and those that are less facility-based and lend less to episodes of care by their very nature.

We are perplexed by the recommendation that PFFMs submitted to the PTAC include information about whether the submitter believes the PFFM would meet Advanced APM criteria to evaluate “whether the proposed PFFM would provide eligible clinicians with an opportunity to become QPs for purposes of the incentives for participation in Advanced APMs.” This two-tier PFFM classification is not only confusing, but also impractical from a development and implementation perspective. We urge that fulfillment of PFFM criteria and favorable recommendation by the PTAC renders eligible clinicians QPs for purposes of APM Incentive Payment.

PTAC Recommended Models

We recognize (a) statutorily the CMS is not required to test models recommended by the PTAC and (b) additional considerations including competing priorities and available resources will be factors in what models are selected by the CMS for testing. **Greater and clearer commitment from the agency on proceeding with PTAC-recommended models including at a minimum, time frames and parameters for the CMS testing**



is needed to encourage PFFM development. Submitters also have competing priorities and available resources, and will invest significant time and resources should they develop models and prepare them for submission. We do not discount the CMS' need for flexibility and ability to make final decisions on which models to test and when, but urge greater commitment and specificity. These are essential factors for submitters including specialty societies to consider in determining whether to pursue development and submission of models they believe will be seriously entertained and not deprioritized upon receipt at the CMS despite PTAC recommendation.

In addition, as part of the CMS' review of the proposal submitted by the PTAC along with the PTAC's comments "and any other resources" the CMS believes is useful, **we suggest the CMS interact with the submitter to ensure determinations are made timely based on complete and accurate, information with the benefit of full clinical and operational context received directly from the original source.**

Similarly, while we appreciate the CMS may consider testing at a later time those models not immediately tested, a reasonable time frame for later testing should be specified. Without this the submitter may invest additional efforts needlessly pursuing development of another model when its initial or previous submission was a solid prospect for deferred testing. A feedback loop to the submitter from the agency is needed after PTAC recommendations have been made public.

Finally, the CAP disagrees that setting a deadline through rulemaking for the Secretary's review of the PTAC's comments and recommendations, publication of a response to them and potential testing is inappropriate. Establishment of a time frame should be standard practice. Not committing to deliver such creates inefficiencies, duplication and falls far short of offering an opportunity for those who previously have not had one to participate in APMs to which the CMS aspires. The CMS' suggestion in the proposed rule that setting a deadline "would be difficult" does not obviate the need for one if the changes intended under MACRA and principles espoused in the proposed rule are to be accomplished. Given the level of commitment by those who have invested in PFFM development, the level of commitment on timing simply cannot be when the CMS "believes it is the right time to do so" as proposed.



APMs

We found the seven goals that drove much of the framework for making APM incentive payments to QPs and for approaching interactions between MIPS and APMS set forth in the proposed rule a very appropriate foundation for the APM pathway under MACRA. Even acknowledging the CMS intends to design the program so that the APM Incentive Payment is attainable for increasing numbers of practitioners over time by those organizations truly engaged in care transformation, two of the seven goals strike us as largely unattainable. **The bar for participation in Advanced APMs is too high to effectively achieve continuing to build a portfolio of APMs that collectively allows for participation of a broad range of physicians and other practitioners. Likewise, maximizing participation in both Advanced APMs and other APMs is not likely to happen as particularly Advanced APMs will be out of reach based on QP thresholds and financial risk requirements.**

With regard specifically to financial risk, the bar remains too high to be attainable by a broad range of physicians even taking into account the CMS' stated belief its proposal will enable more and more APMs to meet the financial risk bar over time. In addition the methodology as proposed for determining what it means for an APM Entity to bear financial risk for monetary losses under an APM and what levels of risk the CMS would consider to be in excess of a nominal amount are not straightforward enough for physicians to determine whether the APM Entity through which they participate will fulfill the requirements. The objective the CMS seeks to achieve is therefore not met without an approach that is less complex and retrospective, and more easily understood and applied.

In response to the agency's inquiry regarding whether a lower average adoption of certified HIT is needed for those APMs targeting eligible clinician populations such as specialty-focused APMs, a different threshold should apply to pathology PFPMs. As indicated in our comments above regarding the proposed rule's PFPM provisions, pathologists rely heavily on and extensively use health information technology. They have long utilized computerized laboratory information systems (LIS) to support their work of analyzing patient specimens and generating and communicating test results. Through these LIS, electronic health records or enterprise-wide clinical information systems exchange laboratory and pathology data. These LIS, however, are not considered certified HIT or EHR. This distinction gives rise to the need for a different and lower threshold.

With respect to pathology specifically, the CAP seeks to clarify that when the CMS proposes to define a participant for purposes of participation in an APM as an entity participating in an APM under an agreement with the CMS or statute or regulation that may either include eligible clinicians or be an eligible clinician and that is directly tied to



beneficiary attribution, quality measurement or cost measurement under the APM, beneficiary attribution to a participant is not required. Our reading of the requirement is that beneficiary attribution is an option as is quality or cost measurement under the APM. **While attribution mechanisms designed for primary care providers and some specialists certainly exist, we have yet to encounter a mechanism to attribute patients to pathologists despite their routine and ongoing contributions to team-based care.** The very nature of their services does not lend itself to patient attribution.

The CAP offers the following in response to its request for comment on whether the specified point in time for each QP Performance Period used to identify the eligible clinician group for each Advanced APM Entity should be earlier than December 31. To appropriately incentivize APM participation and avoid gaming the incentive payment system, the CMS should revisit its proposal that an eligible clinician would have to be listed on December 31 of the QP Performance Period to attain QP status. While such an approach will typically work for multi-year APM participants, it does not take into account contributions such participants make should they relocate for example to an area where Advanced APM participation is an option and suddenly find themselves subject retrospectively to MIPS. Conversely, it affords full credit to those who may have very recently become APM participants. While the CMS views the snapshot in time as providing the best opportunity to comprehensively assess the eligible clinicians' active participation throughout an entire QP Performance Period, the most accurate approach would be to calculate the percentage of the APM Incentive Payment to which the QP is entitled based on actual months of participation. Recognizing the CMS is looking for administrative purposes at a snapshot in time for an APM participation list, should it retain the snapshot approach, a more appropriate specified point in time would be at the start of the third quarter of the year such that QPs as of that date receive full credit and those who have not joined the APM by that point assume APM Incentive Payment eligibility in the subsequent performance period.

Regarding another timing issue, a shorter and more defined time period is needed for the CMS' proposal that the APM Incentive Payment would be made no later than one year from the end of the incentive payment base period. The Advanced APM Entity should receive its incentive payment in a more timely fashion and the CMS should obligate itself to a more precise time frame to truly encourage Advanced APM participation.

In the All-Payer space, the CAP does not disagree that information submitted to determine whether an eligible clinician is a QP under the All-Payer Combination Option should be retained by eligible clinicians and Advanced APM Entities. This time period, though, cannot be without limit. The CAP recommends the agency specify a reasonable retention period not to exceed three years.



The CAP appreciates the CMS' attempt at minimizing reporting burden for APM Entities and eligible clinicians by entertaining the possibility of receiving information on Other Payer APMs and their participants directly from other payers. Despite its conceptual appeal, in practical terms, ensuring information delivery in this fashion is not likely to be effective. Such an approach would also include additional steps in that eligible clinicians would want to validate the information submitted by the other payers and dispute as needed. Required administrative resources aside, the degree of confidence, timeliness and completeness will be higher when not placed on the other payer who lacks any vested interest in the All-Payer Combination Option under MACRA.

Summary

The CAP appreciates the opportunity to comment on this Proposed Rule. We look forward to working with CMS to establish appropriate pathways for pathologists to participate in MIPS and APMs. In summary, the CAP offers the following recommendations:

MIPS

- **Definition of Non-Patient-Facing Clinicians**

The CAP recommends that pathologists (as identified in PECOS) be automatically identified as non-patient-facing ECs at the beginning of each year instead of the current proposed the CMS definition of non-patient-facing clinicians as those who bill less than 25 patient-facing encounters during the performance year.

- **Re-Weighting of Performance Categories**

The CMS has proposed to re-weight the Resource Use and Advancing Care Information (ACI) performance categories to 0 for non-patient-facing clinicians and to re-distribute the weight of these categories either entirely to the Quality performance category or between the Quality and CPIA performance categories. The CAP prefers that ECs who cannot be scored for resource use or the advancing care information performance category receive a median score in those categories until such time that the CAP can develop viable alternatives for pathologists to be able to participate in these categories. The CAP does not believe that CPS that are weighted differently across specialties can be fairly compared.

- **Quality Performance Category**

- The CAP appreciates inclusion of 8 existing pathology measures for the MIPS quality category in the proposed rule and encourages the CMS to finalize those measures. These measures will go a long way towards allowing pathologists to participate in this category of MIPS. The CAP encourages the CMS to work with the CAP to continue to develop additional measures for pathologists for future years of MIPS.
- The CAP opposes the way the CMS has proposed to score topped out (high performing) measures by identifying clusters within topped out measures and



assigning all MIPS eligible clinicians within the cluster the same value, which would be the number of points available at the midpoint of the cluster. The CAP prefers the alternative proposed by the CMS that ECs are scored on their percentage of their performance rate. The CAP agrees that using flat percentages also helps ensure those with high performance on a measure are not penalized as low performers.

- **CPIA Category**

- The CAP appreciates the consideration the CMS gave to non-patient-facing specialties in all of the categories but in particular to the CPIA requirements of only two activities. The CAP encourages the CMS to keep the requirements minimal for non-patient-facing specialties until they can ensure there are enough activities applicable to these specialties, especially since pathologists are not able to participate in resource use and ACI categories at this time.
- While there are some proposed CPIA as published in the proposed rule that pathologists could report on, we believe that additional CPIA will be needed to accommodate the differences in practices between specialties and the sub-specialties. Most of the activities listed in the Proposed Rule are not applicable to pathologists. The CAP offers several examples of activities that could qualify for the proposed CPIA subcategories and proposes that these be measured at the group (TIN) level instead of at the level of the individual physician

APMs/PFPMs

- The CAP does not object to the PFFPM definition, but believes if all the underlying criteria and subcategories are required in total including those that are not terribly applicable to pathology, the CMS will not achieve its goal of providing openings for those whose opportunities to participate in other PFPMs with the CMS have been limited to date.
- Similarly, the CMS requires only three fundamental pieces of information for PFFPM submission to the reviewing body, the PTAC. The CAP's comments seeks clarity and objects to any negative impact on consideration of PFPMs of the many additional items CMMI currently uses to assess models that "would increase the probability that PTAC recommendations would be positive" and might lead the CMS to test a proposed PFFPM.
- The CAP recommends an increased commitment to test PFPMs where the CMS is under no obligation to test models the PTAC endorses.
- The CAP fully concurs with the CMS' statement that statutory requirements for Advanced APMs can or should be waived for proposed PFPMs. The CMS seems to be leaning toward requiring all Advanced APM requirements (financial risk, etc.) for PFPMs which will only serve to discourage their development if participants are not eligible for the 5% Advanced APM incentive payment.
- Regarding APMs that are not PFPMs, the CAP believes the bar is too high and certain requirements not straightforward enough to encourage participation. We also point out pathology-specific issues regarding EHR/LIS and patient attribution and comment on



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some peculiarities of the program, as proposed (e.g. securing information from health plans on the non-Medicare panel, determining qualifying participation status based on participation on December 31 of the performance year, etc.)

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