

August 21, 2017

Ms. Seema Verma Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Subject: Medicare Program; "CY 2018 Updates to the Quality Payment Program". Proposed rule. CMS-5522-P; RIN 0938-AT13

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

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-5522-P entitled "CY 2018 Updates to the Quality Payment Program". As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians whose diagnoses drive care decisions made by patients, primary care physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value is recognized throughout the care continuum and many patient encounters.

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 continue to be necessary to meet this clause¹ in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments on the Quality

"(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.

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—

In carrying out the previous sentence, the Secretary shall consult with professionals of such professional types or subcategories.



Payment Program (QPP), specifically on the Merit-Based Incentive Payment System (MIPS) and on Alternative Payment Models (APMs).

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. Low Volume Threshold
- 4. Virtual Groups
- 5. MIPS Category Measures and Reporting
- 6. MIPS Final Score Methodology
- 7. Review and Correction of MIPS Composite Performance Score
- 8. Third Party Data Submission
- 9. Public Reporting on Physician Compare
- 10. Alternative Payment Models

MIPS Program Details

The CAP appreciates that the CMS is proposing to retain the eight current MIPS 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 appreciates the continued designation of three of the CAP measures as outcomes measures. This accurately reflects that the diagnosis is a patient outcome with respect to pathology services. As a diagnostic specialty, pathology contributes to understanding the patient's condition; thereby allowing for appropriate medical care decisions. Diagnosis is an important initial outcome, providing a basis for other important clinical outcomes:

- Measure #395 Lung cancer reporting (biopsy/cytology specimens)
- Measure #396 Lung cancer reporting (resection specimens)
- Measure #397 Melanoma reporting

However, there are 4 pathology measures that are similar in structure and intent as the lung and melanoma measures that we recommend also be designated as outcomes measures:

- 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



II.C.1.a Definition of a MIPS Eligible Clinician

The CMS proposes to continue to define MIPS eligible clinicians ("ECs") 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 in section 1861(bb)(2) of the Act), and a group that includes such clinicians. 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 (ILs). Previously, CMS has indicated that MIPS applies to Medicare Part B services furnished by a MIPS eligible clinician at the TIN/NPI level. Since facilities are not eligible to participate, services billed under an IL are not eligible for MIPS. However, Medicare Part B services billed outside of an IL by eligible clinicians (using a TIN/NPI combination) are eligible for MIPS. In regard to ILs, they are not included in the definition of a MIPS eligible clinician and are not required to participate, but CMS has stated that there may be circumstances in which a MIPS eligible clinician would furnish the professional component of a Part B covered service that is billed by an IL. In the Physician Quality Reporting System (PQRS), ILs were specifically excluded because they were considered suppliers; however their status with regard to MIPS is unclear. The CAP is awaiting publication of CMS guidance and asks that CMS make it available as soon as possible to provide clarification to pathologists working at ILs.

II.C.1.e Non-Patient-Facing MIPS Eligible Clinicians

While the CAP appreciates that in the CY 2017 QPP final rule, the CMS changed the definition of individual non-patient facing ECs from those who bill 25 or fewer patient-facing encounters to those who bill 100 or fewer patient-facing encounters, the definition of non-patient facing ECs still does not seem adequate.

The CAP requests that pathologists (as identified in the Provider Enrollment, Chain and Ownership System or PECOS) be automatically identified as nonpatient-facing ECs at the beginning of each year. The agency has previously used PECOS to identify ECs that are exempt from Meaningful Use; therefore it seems reasonable to use PECOS to identify non-patient-facing specialties. In addition, the use of PECOS is more efficient and will not require CMS to calculate the patient-facing or non-patient facing status for tens of thousands of ECs every year. Pathologists may occasionally provide face-to-face service but these are not typically in an office setting. We understand that use of PECOS may not cover all non-patient facing ECs and in that case, we recommend a hybrid approach where PECOS is used to identify specialists that are rarely patient facing and the definition of 100 or fewer patient-facing encounters



is used for cases where the majority of the specialty is patient facing according to PECOS designation. This will also facilitate ECs decision to join virtual groups as we explain below.

Further, the CAP asks that CMS release all patient-facing codes via formal noticeand-comment rulemaking, rather than regulatory guidance. CMS made available the list of patient-facing encounter codes in December 2016, shortly prior to the beginning of the 2017 MIPS performance year. The actual list of patient-facing codes was released via regulatory guidance and not through a formal notice and comment rulemaking, thereby preventing public stakeholders from adequately vetting and commenting on the specific codes prior to finalization. If CMS continues to publicize this information only through guidance, the code list can continue to be revised by the agency in the future without public transparency or appropriate stakeholder input. This coupled with the release of the list shortly before the performance period, does not provide enough time for ECs to prepare for compliance with the program.

II.C.2.c Low-Volume Threshold

The CMS is proposing to increase the low-volume threshold to exclude individual ECs or groups that have Medicare Part B allowed charges less than or equal to \$90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries. The CAP encourages CMS to finalize this proposal as it will reduce burden and will help mitigate adverse effects on small practices.

II.C.4. Virtual Groups

The CMS is proposing to establish requirements for MIPS participation at the virtual group level for 2018. The CMS is proposing to define a virtual group as a combination of two or more TINs composed of a solo practitioner (a MIPS EC who bills under a TIN with no other NPIs billing under such TIN), or a group with 10 or fewer ECs under the TIN that elects to form a virtual group with at least one other such solo practitioner or group for a performance period. The CMS is also proposing to modify the definition of non-patient facing MIPS ECs to include clinicians in a virtual group provided that more than 75 percent of the NPIs billing under the virtual group's TINs meet the definition of a non-patient facing individual MIPS EC. The CAP encourages CMS to finalize these proposals, including the definition of a non-patient facing virtual group.

The CAP has concerns with the CMS proposed election process for virtual groups. CMS proposes that beginning with the 2018 performance period ECs electing to be in a virtual group must make their election by December 1 and cannot change their election during the performance period. Further, CMS is proposing that each virtual group member would be required to execute formal written agreements with each other. While the CAP



agrees that there should be an election process and written agreements in place, the timeframe for the election is relatively short, particularly from the date that CMS issues the final rule toward the end of 2017. In addition, if CMS follows the same timeframe and policies for publication of patient-facing encounter codes as it did for 2017, ECs will not know their patient-facing status for 2018 before electing to be part of a virtual group. This information will affect their decision process to be part of a virtual group since the reporting requirements for patient-facing vs. non-patient facing virtual groups will be different and ECs will not be able to change their decision to be part of a virtual group during the performance period. This further supports our position as explained above to use PECOS to define non-patient facing ECs. It will reduce confusion and facilitate non-patient facing and patient-facing eligible clinicians' decision on whether they should be part of a virtual group. Finally, the CAP asks that in addition to providing resources and technical assistance for virtual groups to assist them in preparation of health IT systems and to train staff, CMS also publish an agreement template as soon as possible. The CAP believes that in order for virtual groups to be a successful participation option, it will be imperative for ECs who choose to join a virtual group to have as much information as possible before they make this decision, including knowing their patient-facing status and where they can find resources and technical assistance.

II.C.6. MIPS Performance Category Measures and Activities

a. Performance Category Measures and Reporting

The CMS is proposing to allow individual MIPS eligible clinicians and groups to submit data on measures and activities via multiple data submission mechanisms for a single performance category. While the CAP supports this proposal, we do not believe that those individual ECs and groups that have fewer than the required number of measures applicable and available under one mechanism should be required to identify and submit data on additional measures via additional submission mechanisms. The CMS should recognize an EC's choice to report measures across multiple reporting mechanisms, but should not penalize those ECs who might not have the resources to do so and will face undue cost and burden if CMS imposes this requirement. If the CMS goal is to provide flexibility without undue complexity, we believe that an EC should be able to choose but not required to report independent measures through multiple mechanisms. Furthermore, we believe that an EC should only be required to report on all applicable measures from one reporting mechanism, even if additional measures may be available on another reporting mechanism.



b. Quality Performance Criteria

The CAP is pleased 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.

While the CAP appreciates that the CMS has lowered the previous 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 and recommend that CMS not require a minimum number of measures that an EC should 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.

The CAP also encourages CMS to publish guidance on the Eligible Measure Applicability (EMA) process that determines the number of measures a physician should have reported on when a physician reported on less than the required six quality measures in the quality category of MIPS. The CAP previously provided feedback on the pathology clinical clusters that CMS had drafted for the EMA process. We identified two pathology clinical clusters for claims data submission mechanism:

Quality ID	Outcome/ High Prior	ity Quality Measure Title
99	N/A	Breast Cancer Resection Pathology
		Reporting: pT Category (Primary Tumor)
		and pN Category (Regional Lymph
		Nodes) with Histologic Grade
100	N/A	Colorectal Cancer Resection Pathology
		Reporting: pT Category (Primary Tumor)
		and pN Category (Regional Lymph
		Nodes) with Histologic Grade
249	N/A	Barrett's Esophagus
250	N/A	Padical Prostatactomy Pathology
250	N/A	Radical Prostatectomy Pathology Reporting



251	N/A	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients
AND		
395	Outcome	Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396	Outcome	Lung Cancer Reporting (Resection Specimens)

We also identified two pathology clusters for registry data submission mechanism:

Quality ID	Outcome/ High Priori	ty Quality Measure Title
99	N/A	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
251	N/A	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients
AND		
395		Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396		Lung Cancer Reporting (Resection Specimens)

While these clusters may appear related in scope, due to diverse practice settings and case mixes the proposed clusters would likely negatively impact many pathologists and/or practices that simply do not examine specimens that pertain to all the clustered measures and therefore would be 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 indicate he/she can report on the others. The CAP asks that CMS SHOULD NOT include these clusters as part of the EMA process.

• Case Example: If a pathologist is performing measure 99 (Breast Cancer Resection Pathology Reporting) in the claims data submission, it does not mean that he/she could also report on measure 100 (Colorectal Cancer Resection Pathology Reporting) which is in the same cluster. This



pathologist would be unfairly penalized under the EMA methodology using this cluster.

 Case Example: A practice may primarily receive biopsy type specimens and no cancer resections. In this example, the group could possibly report on measure 395 but would be unable to report on measure 396 because they do not handle lung cancer resection cases. This group would then be unfairly penalized under EMA methodology using these clusters.

The CAP asks that CMS clarify the process and logic used for the EMA methodology.

The CAP appreciates that CMS has proposed to maintain the data completeness criteria of 50% of Medicare Part B patients seen during the performance period for claims submission and 50% of both Medicare and non-Medicare patients for submissions via QCDRs, qualified registries, or EHR. The CAP would also encourage CMS to set an absolute threshold for data completeness so that if ECs hit that threshold even if it is not 50% of their patients, they receive credit for meeting data completeness criteria. The 50% threshold disadvantages those who have to report on a larger number of patients. For example, an EC who reports on 2999 out of 6000 patients would receive 1 point in the quality category whereas an EC who reported on 50 out of 100 patients would be eligible to receive more points. We also believe it is inappropriate for the CMS to increase this data completeness threshold to 60% as CMS proposes for future years of MIPS. We believe this will put undue pressure on ECs as they get used to a still new program and new requirements. We ask that CMS keep the data completeness criteria to the existing reporting requirement of 50% for at least through the 2019 MIPS program.

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

We appreciate the inclusion of the 8 existing pathology quality measures in the MIPS proposed rule and encourage the CMS to finalize those measures. We also would encourage the CMS to work with the CAP to continue to develop additional measures for pathologists for future years of MIPS, especially for the CAP developed Qualified Clinical Data Registry (QCDR) known as the Pathologists Quality Registry (PQR). 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.



The CAP appreciates that CMS is not proposing to remove any topped out measures for the 2018 performance period and encourages CMS to finalize this proposal. There are currently a large number of topped out measures and removing them would impact the ability of many MIPS ECs, including pathologists, to be able to successfully participate in the program. Instead CMS has proposed a three year timeline for identifying and proposing to remove topped out measures. After CMS identifies a measure as topped out for three consecutive years, CMS may propose to remove the measure through comment and rulemaking for the fourth year. In the fourth year, if finalized through rulemaking, CMS would remove the measure and it would no longer be available for reporting. The CAP supports the CMS proposal that if a measure benchmark is topped out for only one submission mechanism, then CMS would remove that measure from the submission mechanism, but would not remove the measure from other submission mechanisms available for submitting that measure. While the CAP appreciates the clarity that CMS has proposed for identification and removal of topped out measures, we believe that pathology measures with high performance rates are still useful to demonstrate performance improvement and patient safety and encourage CMS to keep them in the MIPS program for future years.

d. Cost Performance Category

The Value-Based Modifier (VBM) program was designed for primary care specialties and generally did not measure the value that pathologists provide to their patients. For example, none of the cost measures or outcomes measures applied to pathologists and the attribution mechanism was 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 patientfacing and non-patient-facing MIPS ECs may not have sufficient measures and activities available to report and would not be scored on this category. We encourage CMS to finalize its proposal to keep the weight of the cost category at 0% for 2018 and look forward to working with the CMS to develop alternative resource use measures for use in MIPS in future years and ask that CMS continue not to score non-patient facing ECs in this category.

Additionally, the CAP recommends that in future years the CMS not 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 final score 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. Therefore, in future, the CAP asks that the CMS provide pathologists with a weighted median score for this category instead of re-weighting the category and redistributing the weight to the Quality performance category.

e. Improvement Activity Criteria

The CAP appreciates our ongoing conversations with the CMS regarding the Clinical Practice Improvement Activities (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. While there are some existing and proposed CPIA that pathologists could report on, we believe that additional CPIA will be needed to accommodate the differences between specialties and recognize the value they provide to Medicare beneficiaries. Most of the activities listed in the Proposed Rule are not applicable to pathologists. The CAP submitted several CPIA during CMS' Call for Measures in February 2017. CMS did not accept any of our submitted CPIA and did not provide a reason as to why they were rejected. We ask that CMS respond with specifics as to why CAP submitted CPIA were not accepted for the 2018 MIPS proposals. Further, we ask that CMS clarify whether any of our suggested CPIA below would already be covered under the CMS existing/proposed CPIA given the vague nature of CPIA descriptions.

The CAP is including its previously submitted list of improvement activities below and strongly encourages CMS to reconsider them for inclusion in the 2018 MIPS program:

o 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
- o 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.

 Activity: Participation in a departmental or institutional quality assurance effort

Criteria for Success: Meeting activities might include transfusion services, infection control, patient safety, or general departmental quality meetings.

o 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
- o 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.

o Activity: Hospital Antimicrobial Susceptibility Report

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

• Category: Expanded Practice Access



o Medical Direction of a Point of Care testing program

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, transport the specimen 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.

• Category: Care Coordination

 Activity: Participation in multidisciplinary patient management conferences

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. Examples would include specialty and general tumor boards; medical liver conference; medical renal conference; pediatric gastrointestinal conference; coagulation conference; transplant conference and molecular board.

We appreciate CMS' continued 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 requests clarification on the CMS proposal to require a minimum of 90 days as the amount of time for performing a CPIA. The CMS requirement of a minimum of 90 days is contrary to several already approved improvement activities. Further, 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. Another example is an EC who is part of a committee for a continuous 90 days or more but the committee meets sporadically within that time period. 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.

The CAP asks that CMS not establish a minimum threshold of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (TIN) to receive credit in this performance category. This would unnecessarily increase cost and burden on groups still trying to acclimate to a new program and new performance category of improvement activities. The group would be enabling and providing individual clinicians the time and resources to participate in improvement activities and should be recognized for those efforts in an indirect manner.

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.

Previous 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 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 the ACI 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.

For this reason, 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 final score based on fewer than three or 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 is pleased that CMS acknowledges the unfairness of putting all of the ACI points in the quality category as shown by the CMS alternate proposal of redistributing the weight of the ACI category to both the quality and CPIA categories. This redistribution would result in a weight of 75% for the quality category and a weight of 25% for the CPIA category and would minimize the impact of the quality category on the final score. While the CAP prefers the median score for the ACI category as explained above, we believe that in the absence of a weighted median, we support the alternative proposed by CMS that would split the ACI score between Quality and improvement activities categories (i.e. 75:25 split).

The CAP believes that a weighted median score or reweighting 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 current definition of a non-patient-facing specialist may potentially 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.

II.C.7. MIPS Final 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

(c) Identifying and Assigning Measure Achievement Points for Topped Out Measures

The CAP opposes the CMS proposal to cap the score of topped out measures at 6 points in the second year that the measures are identified as topped out. The CAP prefers the alternative proposed by the CMS where ECs are scored on their percentage of their performance rate. The CAP believes that using flat percentages also helps ensure those with high performance on a measure are not unfairly penalized as low performers. The CAP encourages the CMS to keep high performing measures in the program when they are indicators of high quality. The program should reward quality improvement <u>and</u> also provide incentives for maintenance of high quality care.

(d) Case Minimum Requirements and Measure Reliability and Validity

The CAP also opposes scoring of measures that do not meet the minimum case number criteria at 3 points and the change in scoring of measures that do not meet the data completeness criteria of 50%. CMS is proposing to score measures that do not meet the data completeness criteria at 1 point instead of the 3 points that were awarded in 2017 performance year. This proposed lowering of the points will unfairly penalize ECs as they learn the rules of the still new MIPS program. The CAP encourages CMS to retain the current 3 point floor for measures that do not meet the data completeness criteria and to raise the points available for measures that do not meet the minimum case number criteria. ECs should not be penalized if they successfully meet the quality requirements of a measure just because they may have fewer than the minimum case number required.

(i) Scoring Improvement for the MIPS Quality Performance Category

The agency is presenting a new proposal to include improvement in the quality score. While the CAP generally supports the idea of rewarding clinicians for improving their performance, we believe the CMS methodology unfairly disadvantages those clinicians who are already performing well in the program. To achieve even an increase of 1 percentage point in the quality score, clinicians would have to greatly improve upon their performance from the previous year. This will be easier for those clinicians who are low performers. While this encourages low performers to improve, it does not provide a similar incentive for those clinicians who are already participating and performing well in the program.



The CAP proposes that the agency use the alternative approach for improvement scoring where CMS 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. 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.

(4) Facility-Based Measures Scoring Option

The CAP supports the CMS proposal to allow facility-based measurement based on the Hospital Value Based Purchasing (VBP) program. We encourage CMS to finalize this proposal given that this would be a voluntary option for facilitybased clinicians who furnish 75% or more of their services in the inpatient hospital setting. The CAP urges CMS to inform those MIPS ECs who would be eligible for facility-based measurement prior to the submission period as some pathologists but not all will meet the definition of a facility-based clinician and would be able to utilize this new proposed option to participate in MIPS.

The CAP believes that ECs who are eligible to utilize facility-based measures should be able to opt into the program via attestation instead of opting out. As such, we encourage CMS to provide as much information as possible to ECs opting into this option, including their potential facility-based scores before the data submission period. This ensures transparency and reduces burden on ECs.

b. Calculating the Final Score

(c) Small Practice Bonus for the 2020 MIPS payment year

The CAP supports the CMS proposal to add a small practice bonus of five points to the final score for MIPS ECs who are in small practices with 15 or fewer ECs. The CAP believes that this bonus will mitigate the disproportionate negative impact on solo and small practices in which many pathologists practice. The finalization of this proposal will go a long way in encouraging small practices to participate in MIPS and to do so successfully. At the same time, the CAP urges CMS to provide resources to solo and small practices to assist in staffing and technology required for MIPS participation.

(d) Redistributing Performance Category Weights



The CMS has proposed that if a MIPS EC does not receive an ACI category score, to reassign the weight of the ACI category to the quality performance category or to both the quality and IA performance categories.

Most would agree that a final score weighted differently for certain specialties cannot be fairly compared with other specialties. Hence, ECs who cannot be scored for the ACI performance category as currently formulated should receive only a weighted median score in that category, which maintains a more even playing field while the CAP helps to develop equivalent alternatives that permit pathologists to participate equally across the full complement of categories. We look forward to working with the CMS to develop alternative methods for pathologists to comply with all MIPS performance categories in future years, but until such time, the CAP does not believe that a final score that is weighted differently across specialties can be fairly compared.

Absent a weighted median, we ask that CMS finalize its alternate proposal to redistribute the weight of the ACI category to both the quality and IA categories such that the quality category is weighted at 75% and the IA category is weighted at 25%. This would help in mitigating the impact of the quality category on the final score.

II.C.9. Review and Correction of MIPS Final Score

a. Feedback and Information to Improve Performance

The CAP encourages CMS to provide real time feedback to ECs as they submit MIPS data. At the very least, the CAP requests that feedback be made available at least quarterly on all four MIPS categories, but that more frequent feedback would contribute the most to performance improvement and allow ECs to adjust their practice. The CAP notes that previous feedback reports for PQRS and VBM had few if any data points relevant to pathology practice and that these reports were 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.C.10. Third Party Data Submission

The CAP strongly urges CMS to finalize its proposal to move to a more simplified process for QCDR self-nomination. The current process is resource intensive and cumbersome. It is understandable to have a vetting process for QCDRs applying as such for the first time. However, if an existing previously approved QCDR in good standing wishes to continue participation in MIPS and has minimal changes from the



previous year, it should be approved without having to complete the long self-nomination process again. The PCPI's National Quality Registry Network (NQRN) also supports a move toward a simplified QCDR approval process.

II.C.11. 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.

Alternative Payment Models (APMs)

The CAP appreciates the QPP strategic objective to increase availability and adoption of Advanced APMs (AAPMs) and looks forward to the addition of new AAPMs particularly where they afford an opportunity for participation for specialists who have not been able to do so meaningfully under existing models such as pathologists. Of the AAPMs available for performance year 2017, pathologists are only conceivably able to participate in three models.

a. Other Payer Advanced APMs



The CAP appreciates the additional information on Other Payer Advanced Payment Models and the agency's efforts to factor Other Payer Advanced APMs into achievement of Advanced APM threshold for incentive purposes beginning in the 2019 Qualifying Participant (QP) performance year. In particular, the CAP is supportive of the proposed voluntary payer-initiated process that would allow payers to report payment arrangements and request CMS determine whether they qualify as Other Payer Advanced APMs. Acknowledging the complexity of that process and the determination by CMS, we were disappointed the payer-initiated process would be available only for Medicaid, Medicare Advantage, and Centers for Medicare and Medicaid Innovation multi-payer models for performance year 2019. While CMS indicates it intends to add remaining payer types in future years, this intent does not provide sufficient comfort or incentive for those actively participating in commercial and other payer AAPMs. We encourage CMS to implement the payer-initiated process for <u>all</u> other payers in the 2019 QP performance year.

We look forward to guidance and submission forms for both payers and clinicians for each other payer type as soon as possible. Provision of this information early in the calendar year prior to each All-Payer QP performance period does not provide sufficient lead-time particularly where QP status hinges on the inclusion of an Other Payer Advanced APM.

b. Physician-Focused Payment Models (PFPMs)

Broadening the PFPM Definition - The CAP is supportive of the strategic objective under the Quality Payment Program to increase the availability and adoption of Advanced APMs (AAPMs). Broadening the definition to include payment arrangements that involve Medicaid or the Children's Health Insurance Programs (CHIP) even if Medicare is not a payer should indeed serve to increase the adoption of Advanced APMs particularly for those specialties that do not have opportunities for meaningful participation under existing models. As such, we support the inclusion of models that involve Medicaid and/or CHIP without Medicare. At this point, though, whether including models that encompass just Medicaid and/or CHIP will broaden AAPM options is unknown in that the PTAC has made recommendations on its initial models reviewed, but the Secretary's responses and any adoption based upon those recommendations is not yet available. In addition, data and other information necessary to assess the viability of proposed Medicaid and CHIP models could be less accessible. To encourage the development of additional options, though, this should not prevent the submission and assessment of models applicable solely to Medicaid and/or CHIP populations that seek to effectively manage costs and care for these patients. The CAP recognizes the PTAC's resources are not without limit, and would suggest prioritizing models that include Medicare for PTAC review and assessment, given the potential impact on QPP participation.



Secretary's PFPM Criteria – The CAP commends the diligence with which the PTAC has adhered to application of the existing PFPM Criteria and thorough vetting and assessment of models prior to recommendation to the Secretary. The CAP's review of each of the models submitted to the PTAC for their impact on pathology along with the PTAC assessments, recommendations and our attendance at PTAC meetings has led us to identify the need for the following refinements and establishment of high-level principles for PFPMs that impact pathology and other specialties.

1. Most importantly, while supportive of pursuing innovative health care payment and delivery models, the CAP seeks to ensure physicians, especially the societies that represent physicians participating in and affected by new payment models have input into their development through PFPM process.

The CAP suggests model submitters be required to consult participating and affected specialties prior to submission to the PTAC. The CAP finds merit in the PTAC's role in the review and recommendation of models developed by physicians, particularly specialists and those who have not had the opportunity to participate in existing models to the HHS Secretary. Under the current process, though, model submitters are <u>not</u> required to consult specialties affected by their proposed models. At least four of the initial models submitted to the PTAC to date included pathology services. The CAP is the largest organization representing board-certified pathologists yet submitters did not consult the CAP prior to proposing their models. The CAP learned that the models encompassed pathology services upon their posting for public comment. Model submitters should be required to reach out to the specialties their model affects prior to submission and to attest to such outreach.

Physician input and buy-in is critical to effective delivery system reform. For PFPMs to ensure meaningful collaboration and to preserve and ideally improve the care of patients, submitters must contact impacted specialties prior to transmitting their proposals to the PTAC. When physicians are included in models submitted to the PTAC, but unaware of them, they cannot optimize care coordination for patients or meaningful physician participation.

2. In addition, as the CAP has gained experience with review of the public submission of PFPM proposals to the PTAC, we would like to provide comments on the following Secretary's criteria for PFPMs:

• <u>Flexibility</u>: Provide the flexibility needed for practitioners to deliver high quality health care.



Given the inherent complexity associated with PFPM development and participation, the CAP suggests the organization operating the PFPM encourage and enhance flexibility by providing clear and concise information about the options for participating in the model to maximize the understanding of model participants. The organization operating the model should be transparent to affected providers and most importantly participants, about the details of the model and the expected results. This information should transparently walk participants through the model including its impact on them, case examples, retrospective data, and/or other examples as needed on a case-to-case basis. Including this information will allow providers to base their decisions on whether to participate in the PFPM with the benefit of full information. If they choose to participate, they will be able to optimally engage and contribute to the efficient operation of the PFPM and enhance the quality of care received by patients. Therefore, the CAP recommends that, under this flexibility criterion, the CMS should provide more language regarding the kind of information that the organization operating the PFPM should provide to the participants to maximize physician engagement.

• <u>Payment methodology</u>: Pay APM Entities under a payment methodology designed to achieve the goals of the PFPM criteria; Address in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

The CAP is deeply concerned that this criterion does not clearly require that any payments <u>not</u> made directly from the payer to the PFPM participants be calculated and distributed by a party that does not directly benefit from such determinations (e.g. does not have financial stake in the model that could influence to the detriment of other participants). The CAP recommends the Secretary's criteria require a neutral party determine and disseminate the aforementioned payments to participants to avoid financial conflict of interest, particularly in models involving multiple specialties. This neutral and unbiased party should supervise the flow of payment through the PFPM and should distribute payments to participants, as applicable to reduce financial self-interest. Therefore, the CAP encourages that the CMS be more explicit in this criterion about how payments are determined and disbursed to participants.

 <u>Ability to be evaluated</u>: Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

The CAP is concerned that this criterion does not provide enough detail about the extent of evaluable goals and their division among the participants. The PFPM goals should afford opportunities to all practitioners that could be involved in the model to



participate in both quality and cost measurement that offer commensurate risks and rewards. Especially in multispecialty models, the evaluable goals for quality of care, cost and any other goals of the PFPM need to be shared by participating specialties corresponding to their individual ability to meaningfully participate in the model. This sharing of responsibility would prevent one participant or specialty from absorbing all the financial and quality risks but receiving no equal rewards while another party could be at no risk but could gain substantial benefits. Therefore, the CAP recommends that the CMS provide additional clarity on its expectations for evaluable goals to avoid any untoward effects of imbalances in the opportunities for participation between the parties and focus on coordination of care in the best interest of patients.

• Patient Safety: Aim to maintain or improve standards of patient safety.

In some of the PFPMs proposed to date, reduction of costs has taken such precedence over patient safety that they could jeopardize patient safety. In in the interest of protecting patient safety and appropriateness of care, any PFPM should not dictate restrictions on a given specialty's services particularly without consultation and concurrence with that specialty. The impacted specialty is in the best position in concert with the PFPM to determine which services within their scope are most appropriate for the patient. If a model were to attempt to restrict pathology services, for example, as an avenue for cost reduction, the patient might not receive those services needed for a complete, timely, and thorough diagnosis. Therefore, the CAP recommends that the CMS should put a high priority on this criterion to ensure access to necessary services is not compromised for the sake of establishing new models.

Summary

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

<u>MIPS</u>

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 100 or fewer patient-facing encounters during the performance year.

• Re-Weighting of Performance Categories



The CMS has proposed to re-weight the Advancing Care Information (ACI) performance category to 0 for non-patient-facing clinicians and to re-distribute the weight of this category 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 the advancing care information performance category receive a median score in that category 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 final scores that are weighted differently across specialties can be fairly compared. Absent a weighted median, we ask that CMS finalize its alternate proposal to redistribute the weight of the ACI category to both the quality and IA categories such that the quality category is weighted at 75% and the IA category is weighted at 25%. This would help in mitigating the impact of the quality category on the final score.

• 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 CMS proposal to cap the score of topped out measures at 6 points. The CAP prefers the alternative approach 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.

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 existing and 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 submitted several CPIA during CMS' Call for Measures in February 2017. CMS did not accept any of our submitted CPIA and did not provide a reason as to why they were rejected. If CMS believes that our suggested CPIA are already contained in the CMS' existing/proposed CPIA inventory, we ask the agency to provide that clarification. We ask that CMS



respond with specifics as to why CAP submitted CPIA were not accepted for the 2018 MIPS proposals and hope that CMS considers them for the future.

<u>APMs</u>

- Facilitate inclusion of all eligible other payer AAPMs in performance year 2019
- Broaden the PFPM Definition to encompass models that do not include Medicare
- Enhance Secretary's PFPM Criteria to:
 - Ensure physicians, especially the societies that represent physicians participating in and affected by new payment models have input into their development through PFPM process by requiring model submitters to consult them prior to submission to the PTAC.
 - Address patterns observed in initial submissions and provide clarification in the interest of more consistent submission of models that enhance the quality of care and cost reduction.

Please direct questions on these comments to:

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