



COLLEGE of AMERICAN PATHOLOGISTS

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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. Final rule. CMS-5522-FC; 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 final rule CMS-5522-FC 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 services patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.

While the CAP appreciates the CMS decision to continue some flexibility for MIPS in 2018, we believe that further flexibility is needed to ensure that eligible clinicians (ECs) are able to participate successfully in the program. As 2018 is only the second year of this new paradigm, we strongly urge CMS to give ECs an opportunity to familiarize themselves with the rules of the Quality Payment Program (QPP) and get ready for future years of MIPS.

Defining Outcomes Measures for Non Patient Facing Diagnostic Specialties

The CAP appreciates that the CMS has finalized inclusion of the eight current QPP pathology measures developed by the CAP for the Quality category of MIPS. 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. Non patient facing diagnostic specialties like pathology require a nuanced consideration of the definition of outcomes measures; the three measures CMS already classified as outcomes reflect that the diagnosis is a patient outcome with respect to pathology services. As a diagnostic specialty, pathology contributes to the understanding of the patient’s condition; thereby allowing for appropriate medical care decisions. Diagnosis is an important initial outcome, which



defines the health state of a patient resulting from a pathologist's care, providing a basis for other important clinical outcomes. **There are 4 additional pathology measures that are similar in structure and intent as the already-classified lung and melanoma outcomes measures, and thus we recommend they 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

Definition of 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 non-patient-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 services 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 notice-and-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.



Low Volume Threshold

The CAP supports the CMS decision 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. This will reduce burden and mitigate adverse effects on small practices.

However, we believe that those ECs who are excluded because they do not exceed the low-volume threshold should be allowed to voluntarily opt-in to the MIPS program as soon as possible. This is particularly true for those ECs who exceeded the low-volume threshold for 2017, but not for 2018. Many clinicians have invested significant resources towards being able to comply with MIPS; they should have the opportunity to benefit from upward MIPS adjustments if they are high performers, even if they fall below the new low-volume threshold. The CAP believes that CMS should provide as much support as possible for these ECs and not discourage them from participating in the program. This includes providing technical assistance as well as informing ECs of their exclusion status due to the low-volume threshold. The CAP also asks CMS to clarify if the agency will increase, decrease, or keep the low-volume threshold at the current level for future years of MIPS. Especially if CMS plans to gradually decrease the low-volume threshold in the future, the voluntary opt-in policy will help ECs prepare for MIPS participation in the coming years.

Group Reporting

Currently, within MIPS CMS defines a group, for the purposes of group reporting, as those individual ECs who are part of a single TIN associated with two or more National Provider Identifiers (NPIs). While the CAP is in strong support of the group reporting option, we urge CMS to explore establishing group-related policies that would permit participation in MIPS at a subgroup level, such as redefining a group to allow for specialties within a TIN to create a group. This would allow specialists in large multi-specialty groups the option of forming a sub-group in order to report on specialty specific measures that are most applicable to their practice. We ask that CMS implement sub-group reporting on a voluntary basis to allow as much flexibility as possible and for ECs to have options in how they choose to report.

Virtual Groups

The CMS has finalized requirements for MIPS participation at the virtual group level for 2018. **While the CAP is pleased with this additional option for ECs to participate in MIPS, we have concerns with the CMS proposed election process for virtual groups.** CMS finalized that beginning with the 2018 performance period ECs electing to be in a virtual group must make their election by December 31 and cannot change their election during the performance period. Further, CMS is requiring 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. 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 on whether 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.**

MIPS Category Measures and Reporting

a. Quality Performance Category

The CAP is disappointed that CMS has raised the data completeness criteria from 50% to 60% of Medicare Part B patients seen during the performance period for claims submission and 60% of both Medicare and non-Medicare patients for submissions via QCDRs, qualified registries, or EHR. The CAP believes this will put undue pressure on ECs as they get used to a still new program and new requirements. We encourage CMS to lower the data completeness criteria to the existing reporting requirement of 50% for at least through the 2019 MIPS program.

CMS sought comment on whether to remove non-outcomes and outcomes measures that cannot be reliably scored against a benchmark for 3 years. **Given the repeated delayed recognition of diagnosis-related measures as outcomes measures as discussed above, and the fact that CMS has not defined several current pathology measures as outcomes measures, the CAP strongly urges CMS not to remove measures from the program.** Pathologists need the current complement of measures to be able to participate fully in the quality category of MIPS. This is especially important as they are currently unable to participate in the ACI and Cost categories of MIPS and must rely on the score of the quality category for 85% of their final score in MIPS.

CMS is also seeking comment on applying different scoring for measures where clinical guideline changes occur during the performance period that may significantly impact a measure so that it is not comparable to the historical benchmark. For these measures, CMS would use 9 months of data instead of 12 months of data. The CAP urges CMS not to apply this scoring as the shorter reporting period could result in unsuccessful reporting and could also affect the measure logic. It would put undue burden on ECs as they try to meet the requirements of a fairly new program.

b. Cost Performance Category



CMS finalized the weight of the Cost category at 10% in Year 2 of the QPP for patient-facing ECs. The current Cost measures are designed for primary care specialties and generally do not measure the value that pathologists provide to their patients. For example, the attribution mechanism for the Cost measures has been designed for primary care specialties. While pathologists routinely contribute to team-based care, it is difficult to account for their contribution and resource use under the current system.

The CAP does appreciate the CMS' acknowledgement that many ECs, especially non-patient-facing ECs, may not have any measures and activities available and that in such cases CMS would reweight this category to 0% for the 2018 performance period. **We look forward to working with the CMS to develop alternative methods for pathologists to comply with all MIPS performance categories in future years.**

c. Improvement Activity (IA) Category

The CAP appreciates our ongoing conversations with the CMS regarding the IA 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 appreciate that the CMS will continue to lower the burden on non-patient-facing ECs in this category by allowing them to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit (regardless of the weight of the activities) to meet the IA submission criteria.

CMS previously requested comment for future consideration on whether a minimum threshold of clinicians (NPIs) in a group should be established that must complete an IA in order for the entire group (TIN) to receive credit for an IA in future years. As explained in our comments on the proposed rule, the CAP does not believe this would be an appropriate policy and encourages CMS not to establish a threshold in future years. It would create undue burden for ECs, especially for pathologists who are only able to report on the quality and IA categories of MIPS.

While there are some existing and proposed IA that pathologists could report on, we believe that additional IAs 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 Final Rule are not applicable to pathologists. The CAP submitted several IA during CMS' Call for Measures in February 2017. **CMS did not accept any of our submitted IA and did not provide a reason as to why they were rejected. We ask that CMS respond with specifics as to why the CAP submitted IAs were not accepted for the 2018 MIPS. Further, we ask that CMS clarify whether any of our previously suggested IAs would already be covered under the CMS existing and newly finalized IAs given the equivocal nature of many of the IA descriptions. The CAP also requests that CMS allow Qualified Clinical Data Registries (QCDRs)**



to develop and incorporate specialty-specific IAs into specialty society developed QCDRs. This will further expand the menu of IAs available to specialty society ECs.

d. Advancing Care Information (ACI) Category

The CAP appreciates the CMS' recognition that many of the measures 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. However, the CAP was disappointed that CMS did not finalize its alternate proposal to redistribute the weight of the ACI category to both the quality and IA categories. This redistribution would have resulted in a weight of 75% for the quality category and a weight of 25% for the IA category. It would have minimized the impact of the quality category on the final score and would have acknowledged the unfairness of putting all of the ACI points in the quality category. Instead CMS will continue to redistribute the weight of the ACI category to the quality category. **We ask that CMS clarify why it did not finalize either the 75:25 split between the quality and IA categories or awarding the weighted median for the ACI category as requested by the CAP and will instead continue to reweight the ACI category to the quality category.**

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 IA requirements of only one high-weighted activity to achieve full credit. 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 cost and advancing care information categories at this time.

a. Converting Measures and Activities into Performance Category Scores

- Scoring the Quality Performance Category

The CAP appreciates that CMS has raised the capped score of topped out measures to 7 points from the proposed 6 points to be applied in the second year that the measures are identified as topped out. However, the CAP would still prefer the alternative previously 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 and also provide incentives for maintenance of high quality care.



- Scoring Improvement for the MIPS Quality Performance Category

The agency has finalized its 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.

- Facility-Based Measures Scoring Option

The CAP supports the delay of facility-based measurement until the 2019 performance period as a voluntary option for facility-based clinicians who furnish 75% or more of their services in the inpatient hospital setting. The CAP asks that CMS release aggregate information of 2018 facility-based score distribution. Additionally, 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 option to participate in MIPS in 2019. Even though CMS did not finalize facility-based measurement in 2018, we encourage CMS to reach out to ECs to inform them whether they would have been eligible for facility-based measurement and to inform them of what their score would have been in 2018 based on their attributed hospital. The CAP also encourages CMS to provide additional information, such as scoring and attribution methodology to ECs opting into this option. This ensures transparency and reduces burden on ECs.

b. Calculating the Final Score

- Redistributing Performance Category Weights



The CMS has finalized that if the MIPS EC does not receive a cost or ACI performance category score, to reassign the weights of the performance categories without a score to the quality performance category.

While we appreciate CMS' recognition of the non-applicability of these categories to pathologists, most would agree that final scores weighted differently for certain specialties cannot be fairly compared with other specialties. **Hence, ECs who cannot be scored for cost or the ACI performance category as currently formulated should receive only a weighted median score in those categories, 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 final scores that are weighted differently across specialties can be fairly compared.

Third Party Data Submission

The CAP appreciates CMS's finalization of a more simplified process for Qualified Clinical Data Registry (QCDR) self-nomination. While this will ease the current resource intensive process, additional streamlining is needed. One such change the CAP suggests is the timeline for approval of QCDR measures. The current deadline for QCDR measure implementation is January 1, but this is unrealistic given that QCDRs do not receive CMS notification of approval until late November/early December. We urge CMS to instead implement multi-year approval of QCDR measures for QCDRs in good standing. This will not only give QCDRs more data to assess whether they should maintain a measure, but it will also minimize changes to a measure from year to year. When CMS requires QCDRs to tweak measures from year to year, it interferes with the ability of QCDRs to calculate benchmarks and to consistently track performance over time in addition to increasing confusion and burden for ECs.

Additionally, the CAP recognizes interest in the CMS QR and QCDR programs has increased significantly over the past year, and we understand the CMS challenges to support such a large volume of vendors. However, as a CMS client, working in our second year with CMS in the QR and QCDR programs, we are seeing the deadlines provided to CAP by CMS and its contractors to be more and more unreasonable. Many of these deadlines are related to review/approval/decline of the CAP QCDR measures included in our 2018 QCDR Self Nomination Application. CAP, like most of the other QR and QCDR vendors, work closely with our expert clinicians to develop measures and it is extremely important for us to engage them in any proposed modifications to measures. To provide such limited turn-around-times for responses risks our inability to engage the



experts. We recommend CMS evaluate and update the timeline of the MIPS QR and QCDR Self Nomination Program to ensure CMS, the CMS contractors and CMS clients all have sufficient time to review and respond to inquiries within a reasonable timeframe.

Finally, there are many organizations with QCDR status (such as EHR vendors) through which ECs can report, but the CAP does not believe that these organizations are able to contribute to quality improvement in a way that specialty society QCDRs are able. Much of the data in non-specialty society QCDRs remains in silos without the capabilities of data aggregation offered by specialty society QCDRs. In addition, non-specialty society entities do not necessarily have the relevant clinical experts to develop measures. Therefore, the CAP urges CMS to offer incentives for use of QCDRs that are able to foster quality improvement through data aggregation across sources.

Physician-Focused Payment Models (PFPMs)

The CAP was pleased to provide comment in response to the proposed rule on the previously finalized PTAC criteria. While we note that the final rule made no changes to the criteria, the CAP continues to urge the CMS to engage stakeholders at all phases of model development. 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 the PFPM process.

Specifically, the CAP suggests model submitters be required to consult participating and affected specialties prior to submission to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). Meaningful engagement of stakeholders at all phases of model development will result in a more transparent process. Non-patient-facing clinicians such as pathologists, and the services they provide, are essential to determining a patient's diagnosis, treatment decisions, and ongoing management of a broad array of acute and chronic diseases. Robust pathologist integration in alternative payment and delivery models will assist with appropriate utilization of laboratory testing (e.g., addressing over- and under- utilization of laboratory tests, duplicate tests and proper reference laboratory testing practices), not to mention advancing medical science in the origins and treatment of disease through personalized medicine delivered through genetic testing innovations and targeted treatment adoptions.

Under the current process, though, model submitters are not required to consult specialties affected by their proposed models. At least four of the initial models submitted to the PTAC and reviewed by the CAP 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



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submitters should be required to reach out to the specialties their model affects prior to submission and to attest to such outreach.

Physician input, analysis and buy-in is critical to effective delivery system reform. For PFPs to preserve and ideally improve patient care, collaboration, including requiring submitters to contact impacted specialties prior to transmitting their proposals to the PTAC, is essential. 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.

Pathologists are poised to address a great number of quality and cost challenges that persist in the Medicare program and beyond. While models focused exclusively on pathology services may take time to develop (based on our attempts at developing episode-based cost measures) our value in many other models, particularly those focused on specialty care, may be more evident.

While laboratory spending alone is unlikely to represent a large portion of a model or episode spend, the active engagement of pathologists can possibly lead to lower total spend and delivery of more efficient and effective patient care. The extensive influence of laboratory testing on clinical decision making uniquely positions pathologists to assist clinicians in achieving their objectives, particularly in eliminating waste and inefficiencies in innovative evidence-based ways. These factors make pathologists integral to the clinical team involved in managing an episode of care and achieving quality outcomes.

Please direct questions on these comments to:

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