COLLEGE of AMERICAN PATHOLOGISTS

December 19, 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". Final rule. CMS-5517-FC; 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 final rule CMS-5517-FC 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 over 17,000 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 appreciates the CMS decision to designate 2017 as a transition year for MIPS. ECs will need the flexibility that the CMS indicated in the Final Rule to submit a minimum amount of data in 2017 in order to avoid penalties in 2019. This will give eligible clinicians (ECs) an opportunity to familiarize themselves with the rules of the new Quality Payment Program (QPP) and get ready for future years of MIPS.

The CAP appreciates that the CMS has finalized inclusion of 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 appreciates the designation of three of the CAP measures as outcomes measures. These updates to the measure types accurately reflect 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. A correct diagnosis ends a patient's diagnostic odyssey:

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

The CMS did not designate the measures listed above as outcomes measures in the Pathology specific measure set. **We recommend the CMS designate these measures as outcomes measures in the Pathology specific measure set to be consistent and to avoid confusion among pathologists.**

In addition, there are 4 pathology measures that are similar in structure and intent as the lung and melanoma measures that we recommend 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

MIPS Eligible Clinicians

The CMS defines 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 definition of eligible clinicians. The CAP appreciates that the CMS addressed the eligibility of pathologists who work in independent laboratories in the Final Rule and considers them ECs**. However, we seek confirmation that the MIPS payment adjustments will only apply to the physician Part B services.**

Definition of Non-Patient-Facing MIPS Eligible Clinicians

While the CAP appreciates that the CMS has finalized a change to the definition of non-patient-facing ECs from 25 face-to-face encounters to 100, 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. **We request that pathologists (as identified in 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 send letters to tens of thousands of ECs every year. As noted above, 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 proposed definition of 100 or fewer face to face encounters is used for cases where the majority of the specialty is patient facing according to PECOS designation.

In the Final Rule, the CMS asked whether there is a better term for *non-patient facing*. The CAP prefers the term *clinician facing*.

In addition, the CMS decision not to finalize the requirement for reporting cross-cutting measures will be helpful to those pathologists who could be identified as patient-facing ECs since none of the cross-cutting measures apply to pathologists. We ask that CMS continue not to require the reporting of cross-cutting measures by pathologists until such time that applicable measures could be developed.

The CMS finalized identification of non-patient-facing ECs at the beginning of the performance year. The CAP asks for the specifics regarding when and how these ECs will be informed of their status. **We encourage the CMS to inform ECs as far in advance as possible before the beginning of each performance period as pathologists who are not identified as non-patient facing ECs will need to invest significant resources to be able to comply with the MIPS requirements.**

MIPS Category Measures and Reporting

a. 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 ECs, especially non-patient-facing ECs, may not have sufficient measures and activities available to report and that CMS is weighting this category at 0% for the 2017 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.

As we explain in more detail in our comments on the MIPS Final Score methodology, the CAP recommends that in future years of the MIPS program, 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 reweighting from a category (Resource Use) which is broadly assessed across specialties, to a category (Quality Performance) in which physicians are practically compared only within their own specialty, both 1) fails to incentivize wider performance improvement in that specialty and also 2) relatively disadvantages those specialists. In order to fairly assess the CPS of all ECs, the CAP suggests that the CMS provide non-patient facing ECs with a weighted median score for non-applicable categories instead of re-weighting them to zero and re-distributing the weight entirely to the Quality performance category.

b. 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 appreciate that the CMS lowered the burden on non-patient-facing ECs in this category by finalizing reporting on one medium-weighted activity for one-half of the credit for this performance category or two medium-weighted or one high-weighted activity for full credit for this performance category.

However, the CAP was disappointed to see that the CMS did not finalize any of the CPIA we had submitted in our response to the MACRA Proposed Rule. While there are some CPIA as published in the Final 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 Final Rule are not applicable to pathologists. The CAP re-submits the following examples of activities that could qualify for the 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

- 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.

- Category: **Expanded Practice Access**
  - 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. Providing consultation services regarding appropriate 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
  - 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 as Laboratory Director under CLIA for Point of Care Testing

Method of reporting- Attestation or QCDR

- Category: **Care Coordination**
  - 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: Presentation of 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

<u>MIPS Composite Performance Score Methodology</u>

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 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 resource use 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 the CMS finalized not to modify the methodology for scoring topped out measures in 2017. For future years, we encourage that the CMS not score topped out 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. 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.

b. Calculating the Final Score

- Redistributing Performance Category Weights

  The CMS has finalized that if the MIPS eligible clinician does not receive a resource use or advancing care information performance category score, to reassign the weights of the performance categories without a score to the quality performance category.

  Most would agree that a CPS weighted differently for certain specialties cannot be fairly compared with other specialties. Hence, ECs who cannot be scored for resource use or the advancing care information 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 a CPS that are weighted differently across specialties can be fairly compared.

Please direct questions on these comments to:

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