



COLLEGE of AMERICAN PATHOLOGISTS

December 21, 2018

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

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-1693-IFC entitled “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program--Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions from the Medicare Shared Savings Program--Accountable Care Organizations--Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act”. 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.

In this comment letter, the CAP addresses the following issues:

- 1. Mandatory Licensing of Approved QCDR Measures**
- 2. Establishing Benchmarks for QCDR Measures**
- 3. Opt-In Policy to Participate in MIPS**
- 4. Non-Patient Facing Clinicians’ Inability to Fully Participate in QPP**
- 5. Facility-Based Scoring**
- 6. Clarification of the Eligible Measure Applicability (EMA) Process**
- 7. Refining of Cost Measures**
- 8. Changes to Direct PE Inputs for Specific Services - Market-Based Supply and Equipment Pricing Update**



Mandatory Licensing of Approved QCDR Measures

The CAP appreciates that CMS did not finalize its proposal that, as a condition of a Qualified Clinical Data Registry (QCDR) measure's approval for purposes of the Merit-Based Incentive Payment System (MIPS), QCDR measure owners be required to enter into a license agreement with the Centers for Medicare & Medicaid Services (CMS) permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS, beginning with the 2021 MIPS payment year.

The CAP notes that in the Final Rule, the CMS continues to assert that “we have experienced that this policy has created unintended financial burden for QCDRs requesting permission from other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures.” The CAP--and members of clinical registry coalitions—is unaware of instances of this, and requests that the CMS be transparent about the source of the complaints on this issue. In other words, we request CMS clarify the extent of this issue and whether it warrants this response. **Without there being evidence of a problem, the CAP urges the CMS to continue with the policy that was included in the 2018 Final Rule that requires QCDRs to make their measures available for a licensing or use fee.**

The CAP appreciates that CMS recognizes that QCDR measures constitute works of authorship that are subject to copyright protection because any move that would violate this would certainly be challenged legally and found to be unlawful. However, the CAP is disappointed that CMS asserts in its comments that it does not “believe this proposal would have violated intellectual property rights or law, as QCDRs would not have been required to submit QCDR measures for approval, and if a QCDR had refused to enter into such a license agreement, the QCDR measure would have been rejected and another QCDR measure of similar clinical concept or topic may have been approved in its place.” This assertion represents a radical reversal of CMS' existing policy, and this new policy direction that negates the time, effort, and tremendous resources that specialty society measure developers/ QCDRs have invested to assist CMS with implementing the Quality Payment Program. It is undeniable that physician-led measure development and ongoing stewardship, and the QCDR platforms that allow for reporting of these measures, was a foundation for the successful implementation of QPP. Abrupt reversal of policies that support physician-led professional society measure development and disincentivize physician-lead QCDR stewardship will erode the foundation of trust with CMS.

Without the contribution of physician-led specialty societies, the measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance. If CMS had finalized its proposal, it would have allowed third parties to routinely use these measures and, in the case of commercial QCDRs, profit at the societies' time and



expense, and prevented physician-led specialty societies from being able to dedicate resources to developing QCDR measures.

The CAP understands that CMS is seeking to reduce duplication, and the total number of measures in the program, to focus on a smaller number of more “meaningful measures.” In addition, we understand that having multiple QCDRs reporting the same QCDR measures allows CMS to collect a larger performance pool, which statistically helps establish more reliable benchmarks over a wider performance range.

The CAP is pleased that CMS has delayed considering this proposal. The CAP asks for fuller discussion of the concerns expressed here. There are much less intrusive options for ensuring that QCDR measures are widely available to all qualified QCDRs, especially as CMS has finalized its proposal to modify the QCDR criteria to ensure that all QCDRs have clinical expertise and experience in quality measures.

We urge CMS to continue its existing policy direction that recognizes the importance of physician-led specialty society QCDRs, and allows QCDRs to enforce their ownership rights in the QCDR measures they develop, and directly enter into licensing agreements with measures owners as outlined in the 2018 Final Rule. Meanwhile, to address the duplication and proliferation of measures in the QPP program, the CAP urges CMS to work with stakeholder organizations to develop a mutually beneficial approach. We would appreciate the opportunity to meet with CMS on this issue.

Establishing Benchmarks for QCDR Measures

As stated in the comment letter on the 2019 proposed rule submitted by the Physician Clinical Registry Coalition (PCRC) and co-signed by the CAP, it is critical that CMS create separate benchmarks for QCDR measures just as CMS does for Quality Payment Program (QPP) measures that are reported via different mechanisms. Many QCDRs offer two methods of reporting—web portal entry for users that do not have an Electronic Health Record (EHR) system such as a Laboratory Information System (LIS), and electronic data extraction and measure calculation for users that do have an EHR system. If a QCDR measure is reported both manually and electronically, two separate benchmarks should be established for the measure. This is done already for QPP measures that are reportable via multiple mechanisms, such as claims, qualified registry or eQCMs. **QCDRs are electronically specifying quality measures using the Measure Authoring Tool, and for QCDR measures that are collected, calculated and reported electronically, a separate benchmark should be established to ensure fair comparisons and to encourage electronic reporting.** If CMS does not do so, measures may appear to be prematurely topped out, as is apparent from QPP



measures for which manual measure benchmarks (QR and claims) are typically topped out before electronically reported measure benchmarks are (eCQMs).

In response, CMS stated in the final rule that “a QCDR measure for which data is abstracted through EHRs or manually (that is, paper records) would have to be approved as two separate measures. As a result, each measure would only be compared to its own benchmark.” The CAP does not agree with this as this would require QCDRs to submit two separate QCDR measures for the same measure concept in order to have two benchmarks created. It would effectively reduce our QCDR measure allowance in half from 30 to 15. In addition, this seems counter to CMS’ goal to reduce duplicative measures. **We hope to meet with CMS on this issue to ensure that QCDR benchmarks are established appropriately and without additional burden on QCDRs to submit two separate measures for the same measure concept.**

Opt-In Policy to Participate in MIPS

The CAP asks CMS to clarify several issues regarding the new opt-in policy for those clinicians or groups who meet or exceed at least one, but not all three, of the low-volume threshold criteria. The CAP agrees with CMS that an election to opt-in to MIPS must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. **The CAP asks CMS to clarify how a clinician or group would indicate their decision to opt-in to participate in MIPS for each submission type, direct, log in and upload, log in and attest, Medicare Part B claims, and the CMS Web Interface.**

In the Final Rule, CMS states that a clinician or group’s decision to opt-in to participate in MIPS should be deliverable through a third party intermediary (such as a QCDR), if a clinician or group is utilizing a third party intermediary for their data submission and the third party intermediary must be able to transmit that decision to CMS. Especially as CMS did not include this requirement in the Proposed Rule, and there was not an opportunity to comment on this requirement, **the CAP urges CMS to provide clarification on expectations for QCDRs on this functionality to collect clinicians’ decision to opt-in and submit to CMS.**

Lastly, the CAP asks that CMS clarify when a clinician or group would make an election to opt-in to MIPS either via a QCDR or otherwise. CMS has not provided a deadline, but the CAP believes that clinicians and groups should be able to until data submission to decide whether they want to opt-in to MIPS. This would allow them to make an informed decision based on their performance.



Non-Patient Facing Clinicians' Inability to Fully Participate in QPP

While the CAP appreciates the CMS decision to continue some flexibility for MIPS in 2019, we believe that further flexibility is needed to ensure that non-patient facing clinicians such as pathologists are able to participate successfully in the program. **A significant barrier to pathologists' ability to participate fully in the QPP is that pathologists practice in LISs, and most LISs cannot attain Certified Electronic Health Record Technology (CEHRT) status.** Thus, pathologists face unique challenges in meeting many of the typical EHR and health information technology requirements in both MIPS and the Alternative Payment Models (APM) CEHRT use thresholds.

One example where MIPS favors the use of CEHRT is that clinicians are eligible for a bonus point for each quality measure submitted via end-to-end electronic reporting using CEHRT. Pathologists who are using end-to-end reporting are not eligible to receive these bonus points because they do not practice in CEHRT. The CAP urges CMS to grant pathologists bonus points if they are using end-to-end electronic reporting via LISs in which there is no manual manipulation of data. They are accomplishing the goal of end-to-end electronic reporting but do not reap the rewards because they are not practicing in CEHRT.

With regards to APMs, pathologists are unable to contribute to CEHRT thresholds because they practice in LISs and thus unable to demonstrate this aspect of their value to APMs. The CAP appreciates CMS' goal to encourage continued EHR and CEHRT adoption but urges CMS to consider the contributions of diagnostic specialties in the exchange of electronic patient data, which is key in APMs' ability to effectively coordinate care.

The ONC and CMS both set minimum standards for EHRs to meet to be considered CEHRT. These standards do not permit diagnostic specialties, like pathology and radiology, to participate, because EHR standards were narrowly tailored for traditional clinical medical record systems and do not allow for laboratory and imaging information systems. In the end, this limits the diagnostic specialty physicians' participation in the Quality Payment Program and other federal "promoting interoperability" programs. **The CAP requests that CMS work with ONC and the CAP to adapt its CEHRT requirements to account for laboratory information systems.**

Facility-Based Scoring

The CAP was pleased that CMS finalized its proposal to allow facility-based measurement based on the Hospital Value Based Purchasing (VBP) program starting with the 2019 MIPS performance period. **Since CMS will apply the facility-based**



score automatically to those clinicians who meet the facility-based definition, the CAP asks that CMS provide as much information as possible to clinicians to allow them to decide if they should submit data for MIPS separately. This information should include notifying clinicians whether they meet the facility-based definition and their potential facility-based scores by the first quarter of 2019. CMS could accomplish this via its QPP participation look-up tool. This transparency would allow clinicians full control over their MIPS submission and score. It would allow them to choose to report MIPS measures and activities if they believe their facility-based score would be lower than their score if they separately submitted for MIPS. In order to make this decision, clinicians would need this essential information about their potential facility-based MIPS score.

The CAP supports the finalized definition of facility-based clinicians as those physicians who perform 75 percent or more of their services in inpatient (Place of Service or POS 21), on-campus outpatient (POS 22) or emergency room (POS 23) settings, and have at least one service billed with the POS code used for inpatient (POS 21) or emergency room (POS 23). For groups, 75 percent or more of the National Provider Identifiers (NPIs) billing under the group's Tax Identification Number (TIN) must be eligible for facility-based measurement as individuals. The CAP believes the modified definition that includes outpatient settings will appropriately capture significantly more pathologists as facility-based clinicians. In this rule, the CMS has presented an analysis of the number of anesthesiologists who would meet the previous definition of facility-based clinicians versus the number who would meet the finalized definition that includes POS 22. The CAP asks that the CMS conduct a similar analysis of pathologists so that we are able to educate our pathologist members on this new MIPS policy.

Clarification of the Eligible Measure Applicability (EMA) Process

The CAP appreciates that the CMS approved all 21 of the submitted CAP QCDR measures for the Pathologists Quality Registry. However, we are disappointed that the CMS removed three of the eight pathology QPP measures, leaving pathologists with only five QPP measures from which to choose. **Since CMS has maintained a minimum of six measures to be reported for the quality category, the CAP asks that CMS publish updated 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 or did not submit an outcome or high priority measure in the quality category of MIPS.** Specifically, the CAP would appreciate CMS publishing updated clinically related clusters for claims and Qualified Registry (QR) pathology measures.

The CAP also asks for clarification on the Minimum Threshold Test that is part of the EMA process. The CMS states in the EMA fact sheet:



The Minimum Threshold Test looks at the Medicare claims you submitted to see if there are at least 20 denominator eligible instances for any extra measures found in the Clinical Relation Test. This EMA step only applies to the claims data you submitted.

The CAP asks that CMS clarify whether the above statement means that if any additional measures found via the EMA Clinical Relation Test do not pass the minimum threshold test (i.e., do not have at least 20 denominator cases), then the additional measures would not count toward the quality category score.

Due to the complexities of EMA, the CAP asks that CMS not use the EMA process going forward and that it not require ECs to report on a minimum number of measures. This would not only reduce burden but would allow pathologists to report on measures that are most meaningful and appropriate to their practices.

Refining Cost Measures

The Value-Based Modifier (VBM) program, the predecessor the Cost category of MIPS, was designed for primary care specialties and generally did not measure the value that pathologists provide to their patients. For the Cost category, the CMS has acknowledged that many patient-facing and non-patient-facing MIPS ECs may not have sufficient measures and activities available to report and would not be scored on this category. Based on this, the CAP has generally believed that it would be difficult meaningfully to attribute the Total Per Capita Cost (TPCC) and the Medicare Spending Per Beneficiary (MSPB) cost measures to pathologists based on the CMS' attribution mechanisms. These measures were also part of the VBM, and the CAP is not aware of any pathologists that received Quality and Resource Use Reports (QRURs) that outlined attribution of clinicians to these measures.

However, based on 2017 MIPS performance feedback, the CAP has learned that at least one pathology group practice was attributed to the MSPB measure. The MSPB measure is calculated by CMS to assess costs during episodes of care initiated by acute inpatient hospital stays. It includes the cost of Medicare Part A and B services 3 days before and 30 days after an Inpatient Prospective Payment System (IPPS) hospital admission. The MSPB measure is calculated based on all Medicare Parts A and B final action claims during the performance period, including: inpatient hospital; outpatient; skilled nursing facility; home health; hospice; durable medical equipment, prosthetics, orthotics, and supplies; and Medicare Part B Carrier (non-institutional Physician/Supplier) claims. It's attributed to the provider who provides plurality (largest share of costs) of Medicare Part B services, as measured by Medicare standardized allowed amounts, during an MSPB episode's index admission (the period between



admission date and discharge date of the hospital stay, inclusive). The case minimum is 35.

Since the MSPB measure is attributed to the provider who provides plurality of Medicare Part B services, we are struggling to understand how a pathology group could have provided the plurality of services relative to other providers during the episode. Since CMS did not provide beneficiary level data for the cost measures in 2017, it is difficult to determine how the pathologists came to be attributed. **We ask that in 2018 performance feedback and in future years CMS make available beneficiary level data on cost measures that provide an opportunity for clinicians to improve their performance by learning how they were attributed to cost measures.**

In the meantime, the CAP appreciates that CMS recently revised the attribution methodology and conducted field testing on the revised TPCC and MSPB measures that would go into effect in the 2020 MIPS performance year. The CAP hopes that the revision of these measures results in more accurate assignment of costs for these episodes to clinicians accountable for patient outcomes within the scope implied by their clinical role. **While pathologists routinely contribute to team-based care, the CAP does not believe it is appropriate to attribute them to the TPCC or the MSPB measure under the current or revised methodology.**

Changes to Direct PE Inputs for Specific Services - Market-Based Supply and Equipment Pricing Update

For 2019, the CMS finalized an update to the direct practice expense (PE) input prices for supplies and equipment as recommended by StrategyGen. The CMS will transition the updated prices for a 4-year period beginning in CY 2019. The CAP agrees with the process of updating the prices of supplies and equipment. However, we continue to note errors in the updated prices published in the final rule.

In particular, for some pathology codes, prices are implemented that do not reflect the proper product, quantity and/or unit of measure associated with the service. Specifically, the final rule includes atypical prices and inaccurate calculations due to incorrect units of measure, and prices for items that are considered obsolete. These errors represent serious methodological flaws affecting direct costs of physician services.

In our comments on the proposed rule, we provided a list of supplies and equipment with pricing errors. In our review of the final ruling, we noticed similar errors. For example, we noticed:

- Supply SL484 Bluing reagent, measured in milliliters, appears to be quantified incorrectly by a number of tests.



COLLEGE of AMERICAN PATHOLOGISTS

- Equipment EP001 DNA/digital image analyzer (ACIS), is an obsolete equipment item which is inappropriately priced.

There are many other examples of the types of errors listed above. **Therefore, the CAP urges the CMS to accept these and other comments from the public on all practice expense supplies and equipment for throughout the entire four-year price transition period, so that all products are defined and priced appropriately, and reflect the typical price paid by stakeholders.**

The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions about the Physician Fee Schedule to Todd Klemp (202) 354-7105 / tklemp@cap.org, and questions about the Quality Payment Program to Loveleen Singh (202) 354-7133 / lsingh@cap.org.