



COLLEGE of AMERICAN PATHOLOGISTS

September 13, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1715-P, RIN 0938-AT72

Subject: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1715-P entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B Policies." 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.

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

1. P. Payment for Evaluation and Management (E/M) Visits (page 1)
2. N. Valuation of Specific Codes for CY 2020; (52) Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001) (page 2), (practice expense, page 5)
3. E. Potentially Misvalued Services under the PFS (page 6)
4. B. Determinations of Practice Expense (PE) Relative Value Units (RVUs); (1) Market-Based Supply and Equipment Pricing Update, Table 9 (page 6)
5. O. Comment Solicitation on Opportunities for Bundled Payments under the PFS (page 6)
6. E. Medicare Shared Savings Program (page 6)
7. J. Advisory Opinions on the Application of the Physician Self-Referral Law (page 7)
8. K. CY 2020 Updates to the Quality Payment Program (page 7)

1) P. Payment for Evaluation and Management (E/M) Visits

Last year, CMS proposed to significantly restructure the current E/M office visit codes, purportedly to achieve administrative simplification, reduce, eliminate redundancy of data entry, improve payment accuracy, and decrease documentation burden and inefficiencies. The AMA provided a counter proposal, with similar goals, by developing new and revised coding, documentation guidelines, and a valuation alternative. We appreciate the efforts of the AMA CPT/RUC E/M Workgroup and their work to develop a more reasonable alternative to the CMS proposal. However, in the CY 2020 NPRM, the



CMS proposed to significantly increase the payment for the office/outpatient E/M office visit codes for CY2021 and to add a new add-on G-code to account for the inherent complexity.

For pathology, these cuts are significant. The proposed regulation predicts an 8% cut in pathology payments and a 4% cut for independent laboratories. According to the CMS' estimates, the decision to go beyond the AMA workgroup recommendations and propose a new add-on HCPCS code GPC1X accounts for an additional three percent cut to pathology payment, representing an additional \$2 billion redistribution of funds. The 2021 reductions in pathology would result from an unnecessary redistribution of \$7 billion to family medicine and away from specialties, like pathology, with low utilization of E/M services. Pathology and other specialties that do not generally bill office/outpatient E/M codes will see the greatest decrease in payment in 2021.

Medicare's physician payment dollars represent a fixed amount. In order to maintain budget neutrality, if spending is projected to increase by more than \$20 million, cuts are made across the board. As we discussed earlier, the proposed changes to the E/M codes are projected to redistribute \$7 billion to family medicine and away from other medical specialties such as pathology. The extent and nature of the changes CMS is proposing associated with E/M coding, documentation, and valuation are monumental, and represent regulatory change that necessitates additional Medicare funding to sustain and enhance patient care as described by its initial goals. We believe without additional funding severe disruption of patient care and access issues will result. **The CAP urges the agency to minimize the impact of these "burden reducing" E/M revaluations on to the medical community as follows:**

- **Do not implement budget neutrality reductions to the Physician Fee Schedule pool as the increased expenditures for E/M provisions represents new regulations, and therefore additional funding is appropriate and necessary; or if this action is not taken**
 - **Minimize unintended impacts by applying any budget neutrality adjustments uniformly across all services, not excluding any specialties, procedures, or service codes**
- **Make no adjustment to the physician work values for codes with a global period (10 and 90 day) to reflect the changes made to the values for office/outpatient E/M visits.**
- **Withdraw HCPCS code GPC1X as this service can be reported with existing codes and goes beyond the AMA CPT/RUC recommended revisions**
- **Providing a five-year phase-in of the final relative values so the medical community can adapt to these disruptive changes.**

This revaluation of E/M services will negatively affect the payments of all other non-E/M services and procedures through huge payment redistributions. These adjustments to the Physician Fee Schedule will cause industry disruptive reductions to sorely needed specialty care revenue that will seriously jeopardize patient care. The CAP urges the agency to be mindful of well-intentioned policy changes, particularly those that focus on specialty-specific interests, as such proposals often result in inappropriate redistributions of Medicare outlays that significantly impact the broader physician community and patients they care for. Modifications in payment and policy should be fair and balanced, ensuring no specialty favoritism over others, and directing Medicare revenues toward maintaining and enhancing a robust network of participating physicians.

2) N. Valuation of Specific Codes for CY 2020; (52) Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001)

CMS is proposing a work RVU of 0.26, and to accept the RUC recommended 10 minutes for intra-service time and total time for codes 88141, G0124 and G0141 and 12 minutes intra-service time and total time for code P3001. The crosswalk or methodology used in the original valuation of this



service is unknown and not resource-based, and it is therefore invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS/Other, indicating that this service has never been surveyed. The crosswalk or methodology used in the original valuation of this service is unknown and not resource based. Therefore, it is invalid to compare the any CMS/Other time and work to the surveyed time and work. The current time was most likely crosswalked to another code. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. A 38 percent decrease in work value based on CMS/Other as the data source is an arbitrary reduction. CMS continuously applies this erroneous methodology and if finalized would assign these services an inappropriately low work value, creating a rank order anomaly relative to other pathology services. Additionally, lowering the work value of code P3001, using CMS' 25 percent time ratio methodology, would equate to a work RVU of 0.32, not 0.26 as proposed. It is clear the CMS misinterpreted the RUC's recommendations. The CAP also urges the Agency to discontinue its arbitrary use of invalid time components, invalid methodologies using time ratios, and other irrational uses of data to value physician services.

The CAP opposes CMS' proposed physician work relative value unit (RVU) of 0.26 for CPT codes 88141, G0124 and G0141 and urges the agency to adopt the American Medical Association's (AMA) Relative Value Update Committee's (RUC) recommended work RVU of 0.42 for these services. In the CY2020 NPRM, CMS disagreed with the RUC stating that since CPT codes 88141, G0124 and G0141 incur a 38 percent reduction in the survey intra-service time from 16 minutes to 10 minutes and CPT code P3001 incurs a 25 percent reduction in the survey intra-service time from 16 minutes to 12 minutes, the RUC recommended work value is too high. CMS also referenced CPT code 93313 *Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only* (work RVU = 0.26 and 10-minutes total time) using the work value as a crosswalk. However, when moderate sedation was unbundled from this reference code, the time and work value were systematically reduced by 5 minutes and 0.25 work RVUs making this service (much more than the RUC recommended reduction of 0.09), cutting the work value in half and greatly reducing the services intra-service work per unit of time. Code 93313 separately describes only the work of placing a probe, while code 93314 *Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only* (work RVU = 1.85 and 50 minutes total time) separately describes the work of acquiring/interpreting images, interpreting the results, and creating a report. The RUC described the work of 93313 and 93314 as one physician placing the probe, while another acquires and interprets images, interprets the results, and creates a report. Therefore, CPT code 93313 is an inappropriate reference code and should not be used as a crosswalk for the review or valuation of any service.

When the RUC reviewed these codes, they compared the relativity of the physician work of the surveyed codes to CPT code 92134 *Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina* (work RVU = 0.45 and intra-service time of 10 minutes), noting that the codes both have similar intra-service time and intensity. The RUC also compared the survey code to MPC codes 92250 *Fundus photography with interpretation and report* (work RVU 0.40, intra-service time of 10 minutes) and 92083 *Visual field examination, unilateral or bilateral, with interpretation and report; extended examination (eg, Goldmann visual fields with at least 3 isopters plotted and static determination within the central 30 deg, or quantitative, automated threshold perimetry, Octopus program G-1, 32 or 42, Humphrey visual field analyzer full threshold programs 30-2, 24-2, or 30/60-2)* (work RVU 0.50, intra-service time 10 minutes), noting that the survey code is appropriately positioned between these codes. Furthermore, the RUC compared the survey code to CPT code 72084 *Radiologic examination, spine, entire thoracic and lumbar, including skull, cervical and sacral spine if performed (eg, scoliosis evaluation); minimum of 6 views* (work RVU = 0.41, intra-service time of 8 minutes, total time of 10



minutes, last reviewed January 2015); the comparator code has slightly less intra-service time, justifying the slightly lower work value. In addition, the RUC compared the survey code to 2nd key reference service, 88112 *Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal* (work RVU = 0.56, intra-service time of 15 minutes), noting that the reference code has 15 minutes of intra-service time justifying the higher work value, and CPT code 88388 *Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (eg, nucleic acid-based molecular studies); in conjunction with a touch imprint, intraoperative consultation, or frozen section, each tissue preparation (eg, a single lymph node)* (List separately in addition to code for primary procedure) (work RVU = 0.45 and 12 minutes intra-service time).

Codes 88141, G0124, and G0141

Based on a robust survey the RUC recommended a work RVU of 0.42 with 10 minutes of physician time, which is below the work survey 25th percentile, for codes 88141, G0124, and G0141. This value is supported by CPT codes; 92134, MPC code 92250, and 72084 as mentioned above. Codes 88141, G0124, and G0141 are not simple pap smear services. Most pap smears are performed by the cytotechnologist and paid through the clinical laboratory fee schedule. Only tests that are identified as abnormal are brought to the attention of the cytopathologist and utilize this service paid through the physician fee schedule.

The CMS proposed work value of 0.26 for 88141, G0124, and G0141 would create significant rank order anomalies within the array of pathology services. The value of 0.26 is based only on a 38 percent reduction in time, to compute the value. The CAP disagrees with this mathematical computation to establish the value of a physician service. The Pap Smear is a population-based screening test that is a critical link in the prevention of cervical cancer. It is imperative for pathologists to accurately analyze and report findings so that potential pre-cancerous conditions and/or cancer is detected early, affecting patient treatment and outcomes. Only tests that are identified as abnormal (10-12%) are brought to the attention of the cytopathologist, who utilizes these services paid through the physician fee schedule. Because these are the abnormal cases, with significant health and testing implications, as well as heavy regulation, the intensity and complexity of performing these services is high. The CAP urges CMS to review the full RUC recommendations including surveyed time, but also intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. **The CAP urges CMS to accept and implement a work RVU of 0.42 for CPT code 88141, and HCPCS codes G0124 and G0141.**

Code P3001

Based on a robust survey the RUC recommended a work RVU of 0.42, with 12 minutes of physician time, which is below the work survey 25th percentile, for HCPCS code P3001. This value is supported by CPT codes; 92134, MPC code 92250, and 72084 as mentioned above. CPT code P3001 is not a simple pap smear. Most pap smears are performed by the cytotechnologist and paid through the clinical laboratory fee schedule. Only tests that are identified as abnormal are brought to the attention of the cytopathologist and utilize this service paid through the physician fee schedule.

Within its proposed ruling, the CMS states that its proposed work value of 0.26 for P3001 is based on a 25 percent reduction in time, to compute the value. **This computation appears to be in error, as a 25 percent reduction of a work value of 0.42 equates to 0.32 RVUs and not 0.26 RVUs.** The physician time from our RUC survey and recommended by the RUC was 12 minutes of intra-service and total time, not 10 minutes. It is clear the CMS misinterpreted the RUC's recommendations. The Pap Smear is a population-based screening test that is a critical link in the prevention of cervical cancer. It is imperative for pathologists to accurately analyze and report findings so that potential pre-cancerous conditions and/or cancer is detected early, affecting patient treatment and outcomes. Only tests that are identified as abnormal (10-12%) are brought to the attention of the cytopathologist, who



utilizes these services paid through the physician fee schedule. Because these are the abnormal cases, with significant health and testing implications, as well as heavy regulation, the intensity and complexity of performing these services is high. The CAP urges CMS to review the full RUC recommendations including surveyed time (12 minutes for P3001), but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. **The CAP urges CMS to accept and implement a work RVU of 0.42, with 12 minutes of physician time for HCPCS code P3001.**

Practice Expense Refinements proposed for codes 88141, G0141, G0124, and P3001

The CAP opposes CMS' proposed changes to the RUC recommended practice expense inputs for codes 88141, G0141, G0124, and P3001. Specifically, the CMS is proposing to:

- *Reduce the clinical labor time for "Perform regulatory mandated quality assurance activities" from seven minutes to five minutes similar to time allotted for codes 78012-78014.*
- *Remove the one-minute of clinical labor time for "File specimen, supplies, and other materials" under the rationale that this task is a form of indirect practice expense.*
- *Reduce the equipment time for the compound microscope (EP024) to 10 minutes for all four codes in the family to match the work time of the procedures.*

Reduce the clinical labor time for "Perform regulatory mandated quality assurance activities" from seven minutes to five minutes similar to time allotted for codes 78012-78014.

The CAP disagrees with CMS' proposal to decrease the time for these regulatory mandated quality assurance tasks and urge the Agency to accept the RUC recommended seven minutes for codes 88141, G0141, G0141, and P3001.

The cytotechnologist is involved in one or more CLIA mandated regulatory quality assurance and compliance activities including prospective rescreen of at least 10% negative Pap smears, review of all negative cytologies for a newly diagnosed High grade squamous intraepithelial lesion (HSIL), cytologic histologic correlations of discordant diagnoses. The above requires review of slides and hence access to microscope, documentation and archiving of data. In addition, the cytotechnologists are required to record the number of slides examined, type of preparation, the amount of time spent in slide examination etc. Suffice it to say that gynecologic cytology practice is the most regulated per the CLIA 88 mandates, hence we urge the CMS to accept the RUC PE recommendations

Remove the one-minute of clinical labor time for "File specimen, supplies, and other materials" under the rationale that this task is a form of indirect practice expense.

The CAP disagrees with the Agency that "File specimen, supplies, and other materials" can be categorized as an indirect expense. These tasks must be performed for each individual patient case. The results are manually entered in most facilities, as there is typically no interface capable to perform this function. The laboratory technician carefully reviews, double checks the information, and enters the reporting results into the LIS. One minute for this task very typical and appropriate for this service. It is a direct cost that is dependent upon the volume of this service.

Reduce the equipment time for the compound microscope (EP024) to 10 minutes for all four codes in the family to match the work time of the procedures.

The CAP disagrees with CMS' proposal to decrease the microscope time for code all of these codes to 10 minutes. The microscope is utilized by the pathologist for the entire physician time of 10 minutes for 88141, 10 minutes for G0124, 10 minutes for G0141, and **12 minutes for P3001.** In addition, the RUC agreed that the cytotechnologist uses a different microscope (in a common area) for at least four minutes, to assist in the performance of regulatory mandated quality assurance



activities. The equipment time for the compound microscope (EP024) should be; 14 minutes for 88141, 14 minutes for G0124, 14 minutes for G0141, and 16 minutes for P3001.

3) E. Potentially Misvalued Services under the PFS

The CMS received public nominations for two codes as potentially misvalued, including fine needle aspiration biopsy services CPT codes 10005, 10021. The CAP disagrees with CMS' proposal to classify codes 10005 and 10021 as potentially misvalued. In June 2017, specialties refined the code set within CPT by revising 10021, deleting 10022, and creating nine new codes to describe the services with and without imaging. The CAP, in conjunction with other stakeholders, provided physician work and practice expense recommendations to the AMA RUC in 2018. Last year, the CMS proposed new values for the codes, which the agency finalized in its 2019 final rule. In our comments to the CMS, the CAP disagreed with the agency's proposed revisions and urged the CMS to adopt the RUC approved values. Specifically, the CMS appears to have misunderstood the RUC recommendations and subsequent comments provided to the Agency regarding both 10005 and 10021. The CAP urges the CMS to thoroughly reexamine the RUC recommendations and public comments provided during the 2019 proposed rule comment period and accept the physician work RVUs approved by the RUC. **The CAP urges that the Agency take CPT codes 10005 and 10021 off its potentially misvalued code list and instead implement the RUC recommendations from its most current valuation.**

4) B. Determinations of Practice Expense (PE) Relative Value Units (RVUs); (1) Market-Based Supply and Equipment Pricing Update, Table 9

In an ongoing effort to correct errors affecting Medicare reimbursements for physician services, last year, the CMS finalized its proposals associated with a market research study to update the physician fee schedule direct practice expense inputs for supply and equipment pricing. The CAP subsequently submitted direct practice expense supplies and equipment prices to correct errors prices included in the 2019 final rule. For CY 2020, the CMS proposes to act on the CAP's specific recommendations and update 36 direct practice expense supplies or equipment prices. **The CAP urges the Agency to finalize the proposed update to the direct practice expense supplies and equipment prices listed on Table 9.** The CAP will provide additional pricing corrections and updates in the future.

5) O. Comment Solicitation on Opportunities for Bundled Payments under the PFS

While we support CMS's goal of "achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system," we have concerns with the agency's belief that there is "considerable flexibility for developing payments," including developing bundled payments ("such as establishing per-beneficiary payments for multiple services or condition-specific episodes of care"), under the existing statutory framework of the PFS. As CMS notes, the mechanism through which the agency currently tests payment and service delivery models is CMS' Center for Medicare and Medicaid Innovation (Innovation Center). While the CAP continues to have serious concerns with operations of the Innovation Center, we do not believe this process should be bypassed for development of alternative payment models, and we continue to only support those Innovation Center models that are voluntary for physicians. Further, as CMS explains, Section 1848 of the Social Security Act requires CMS to establish payment for physicians' services based on the relative resources involved in furnishing the service. While this may allow for the bundling of multiple services into a single CPT code as has been done recently, the CAP believes this does not allow for the kind of bundling the agency describes in this proposed rule.



6) E. Medicare Shared Savings Program

CMS solicits comment on “aligning the Shared Savings Program quality score with the MIPS quality performance category score” and “aligning the Shared Savings Program quality measure set with proposed changes to the Web Interface measure set under MIPS per previously finalized policy.” As we have commented previously, pathologists participate in Accountable Care Organizations (ACOs), including under the Shared Savings Program, but still face challenges to ensure greater access to and meaningful participation in these models. We continue to believe that aligning the quality reporting requirements under the Shared Savings Program with the reporting requirements under other Medicare initiatives and those used by other payers will help “minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting.” Valid and less burdensome measurement of the quality of care provided through ACOs is essential to ensure the ACO’s success and that the promotion of higher quality of care and cost savings are not the result of limiting necessary care. With extensive experience as a quality standards-setting organization, the CAP looks forward to continuing our conversation with CMS to establish appropriate measures for pathologists as non-patient-facing clinicians.

7) J. Advisory Opinions on the Application of the Physician Self-Referral Law

In this proposed rule, CMS notes that the agency reviewed its physician self-referral advisory opinion regulations “in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.” The CAP applauds CMS for taking seriously the recommendations provided in response to the Request for Information Regarding the Physician Self-Referral Law (83 FR 29524) (June 2018 CMS RFI) and we further support CMS’ efforts to improve the self-referral advisory opinion process. Making this process more user-friendly, including with a shortened deadline and expedited review option, will help ensure a more “accessible process that produces meaningful opinions on the applicability” of the self-referral law. However, we would emphasize that CMS must ensure any changes to the self-referral law do not further develop or create additional abusive self-referring arrangements that over-utilize services. As we commented in our response to the June 2018 CMS RFI¹, we urge CMS to move cautiously in updating any aspect of the self-referral law to avoid unintended consequences on physician self-referrals in the future. Related, CMS has stated that other comments in response to the RFI “are expected to be addressed in separate rulemaking,”² and the CAP looks forward to evaluating these proposals. In particular, the CAP has strongly encouraged action that closes the in-office ancillary services (IOAS) exception for anatomic pathology (AP) services and we will continue to urge CMS to include this necessary change in any efforts related to the self-referral law.

8) K. CY 2020 Updates to the Quality Payment Program

The CAP is looking forward to continuing our engagement with the CMS on elucidating the challenges of the Merit-Based Incentive Payment System (MIPS) in order to determine how to appropriately measure providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. Through the years, the CAP has advocated to increase flexibility for pathologists in a way that recognizes and accounts for the value pathologists play in patient care as non-patient-facing clinicians in an inherently patient-facing program. The CAP continues to believe considerable accommodations or alternate measures are necessary to meet this

¹ <https://documents.cap.org/documents/CAP-2018-stark-RFI-comments.pdf>

² <https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-2>



clause³ in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments on the Quality Payment Program (QPP), specifically on MIPS and the MIPS Value Pathways RFI.

The CAP highlights the following comments for CMS' reference:

1. **The CAP appreciates CMS verbal indication in listening sessions that there will be an additional time period to provide more detail responses to the specific questions raised in the RFI.** The CAP will submit additional detailed comments. The MIPS Value Pathways (MVP) Request for Information (RFI) is an extremely significant and important transition for the MIPS program from the current formulation of reporting on four different categories to the new framework where measures and activities across the four performance categories will be aligned. The CAP wants to provide a thoughtful response and the time given to respond within the QPP proposed rule is insufficient. The CAP asks that in addition to gathering feedback from this proposed rule, CMS further engage stakeholders in development of MVPs by issuing a separate RFI with adequate time for consideration, expanding the time period for receipt of comments on this component, and extending the implementation timeline to ensure thoughtful implementation. While the CAP agrees that the MIPS program must move to a more cohesive and simplified state, the CAP is concerned that CMS is moving at an accelerated pace on a significant programmatic change that would put increased burden on specialty societies to develop MVPs in a short timeframe while they are still attempting to ensure their members are well positioned in reporting for MIPS and QPP. In addition, the CAP strongly encourages CMS to ensure that all providers be able to continue participating in MIPS in its current form for several years—without penalty for not participating in MVPs—due to the limited comment period and rapid implementation timeframes CMS is proposing. **The CAP strongly urges CMS to delay the implementation of MVPs, ensure providers can continue to participate in MIPS in its current form for several years without penalty, and ensure MVPs align with the MACRA legislative mandate to encourage QCDR use.**
2. CMS should maintain the current pathology specialty measure set and add Measure 440: Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC) Biopsy Reporting Time so that the 2020 pathology specialty measure set consists of 6 measures:

Measure 249: Barrett's Esophagus

Measure 250: Radical Prostatectomy Pathology Reporting

Measure 395: Lung Cancer Reporting (Biopsy/Cytology Specimens)

Measure 396: Lung Cancer Reporting (Resection Specimens)

Measure 397: Melanoma Reporting

Measure 440: Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician

The CAP strongly opposes removal of 4 pathology measures as proposed. This would limit

³ In carrying out this paragraph, with respect to measures and activities specified in subparagraph (B) for performance categories described in subparagraph (A), the Secretary—

“(I) shall give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient; and

“(II) may, to the extent feasible and appropriate, take into account such circumstances and apply under this subsection with respect to MIPS eligible professionals of such professional types or subcategories, alternative measures or activities that fulfill the goals of the applicable performance category.

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



the pathology specialty set to 2 measures both of which are skin cancer measures and thus would not be applicable to more than 50% of pathologists.

3. By increasing requirements for Qualified Clinical Data Registries (QCDRs) and QCDR measures, CMS continues to shift costs and burden of administering the MIPS programs onto physicians, via their specialty societies that create measures and have QCDRs. This is a hidden cost of the program that is ultimately being borne by physicians. **CMS should not require QCDRs to do the significant pre-submission audits of all categories without some remuneration for providing this service on behalf of CMS.** Specialty societies responded to CMS when the QPP was initiated by investing heavily in QCDRs and in measure development. These investments to support our physicians in MIPS continue to increase, without recognition of the costs of administering the program. The positive payment adjustment to physicians is already incredibly low, and when the costs of QCDR investment and infrastructure are added in, this makes MIPS a significant cost to physicians that is not accounted for.
4. QCDR measures require more clinical data than MIPS Clinical Quality Measures (CQMs), but non-patient facing, hospital-based physicians do not have easy access to this additional data for reporting purposes. Non-patient facing and hospital-based physicians are increasingly disadvantaged in the MIPS program because it is difficult or impossible to access data from hospitals' Electronic Health Records (EHRs) and Laboratory Information Systems (LIS). These physicians need hospital-owned data to support their ongoing participation in MIPS. As physicians working in and supporting hospitals, we should have access to all our patient's data from the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult, and is resource-intensive under any circumstances. Although hospitals claim that they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital has its own legal framework for potentially accessing data, so this becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since multiple specialties presumably approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for non-patient facing and hospital-based physicians. **CMS should develop ways to incentivize hospitals to make data available to hospital-based physicians, who need this data for MIPS reporting. Alternatively, we will need to work with CMS on measures that do not rely on data from hospitals.**

Following are the CAP's more extensive comments on the proposed rule:

Transforming MIPS: MIPS Value Pathways Request for Information

MVP Implementation

The MIPS Value Pathways (MVP) Request for Information (RFI) is an extremely significant and important transition for the MIPS program from the current formulation of reporting on four separate categories to the new framework where measures and activities across the four performance categories will be aligned. The CAP wants to provide a thoughtful response and the time to respond given within the QPP proposed rule is insufficient. The CAP asks that in addition to gathering feedback from this proposed rule, CMS further engage stakeholders in development of MVPs by issuing a separate RFI with adequate time for consideration, expanding the time period for receipt of comments on this component, and extending the implementation timeline to ensure thoughtful implementation. In addition, while the CAP agrees that the MIPS program must move to a more coherent and simplified state, the CAP is concerned that CMS is moving at an accelerated pace that would put increased burden on specialty societies essentially to develop MVPs in a few months while



they are still attempting to ensure their members are well positioned in reporting for MIPS and QPP. **Further, the CAP asks CMS to ensure that participation in an MVP is VOLUNTARY and focus on measures that are meaningful to physicians.**

MVPs for Non-Patient Facing Clinicians

The CAP believes that there are several aspects of the proposed MVP framework that do not take non-patient facing, diagnostic specialties such as pathology into account. CAP appreciates that CMS has indicated that existing “exemptions” in the program (ie, for non patient facing clinicians) would remain in place, but it remains quite unclear how this would translate to new MVPs. For example, CMS envisions that Promoting Interoperability category as a foundational element and thus would generally apply to all clinicians, regardless of the specific MVP. However, pathologists as non-patient facing clinicians are automatically reweighted for the PI category since the category requires the use of Certified Electronic Health Record Technology (CEHRT) and pathologists practice in Laboratory Information Systems (LIS) which are not CEHRT. In addition, the current PI measures are patient-facing and not applicable to pathologists. The CAP asks CMS how it envisions an MVP where a foundation of PI measures is not possible.

The CAP urges CMS to consider the implications of the types of measures that will be needed for pathologists in MVPs and MIPS. We ask whether CMS is envisioning quality measures that measure the quality of care provided by the pathologist or by the laboratory. Depending on the answer, significant concerns will need to be addressed regarding measure development, data availability, and attribution for both MVPs and MIPS.

The CAP is concerned that CMS wants to increase the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of specialty specific measures. This would put pathologists at a significant disadvantage since administrative claims-based quality measures are not applicable or relevant to pathologists. Trying to apply the same measure across different specialties would result in intrinsically inequitable performance comparisons between clinicians, which is especially important in a program that is budget neutral like MIPS.

CMS is also intending to incorporate more patient reported outcomes and care experience measures into MVPs. Since pathologists are non-patient facing, these measures do not apply to them. Most patients do not select their pathologist, and thus patient reported feedback is not an appropriate measure of the quality of health care delivery of pathologists.

The CAP urges CMS to maintain the current and necessary special statuses for MIPS as it moves to the MVP framework. These will be important for clinicians who are non-patient facing, facility-based, in small practices, or hospital-based etc. so that they can continue participating in the program. While these special status clinicians are unable to participate in some measures and activities for MIPS such as PI and cost, they can continue to demonstrate their value to patient care within the afforded special statuses.

Selection of Measures and Activities for MVPs

CMS states that its goal in using MVPs is to standardize which measures and activities are reported, both to reduce clinician burden and better measure performance. The CAP fears that in its pursuit of simplifying the program, CMS is losing sight of the flexibility required for different physician specialties. **In particular, pathologists practice in various different settings and subspecialties where a single specific list of measures and activities would NOT be appropriate or feasible for all pathologists to report.** The CAP believes that CMS should NOT require all clinicians of the



same specialty to report on the same list of quality measures and improvement activities. Clinicians should have the flexibility of reporting on measures and activities that are most meaningful to their practice. The CAP also encourages CMS to maintain all the current collection types for quality measures, including MIPS Clinical Quality Measures (MIPS CQMs), CMS Web Interface, and QCDR measures in order to allow clinicians to have flexibility in choosing the collection type most appropriate and feasible for them and their practices. Specialty societies have invested significant resources in QCDRs, and the CAP encourages CMS to integrate QCDR measures into MVPs along with MIPS measures. Being able to choose the most appropriate measures from within an MVP will allow clinicians to demonstrate quality measurement and improvement in areas that are most meaningful to their practices.

Regarding Improvement Activities (IAs), instead of a physician having to attest to IAs, the developer of each MVP should be able to note to CMS which IAs are inherent in a particular MVP, and IA credit should be automatic. This is similar to how MIPS APMs are currently scored in the IA performance category. In addition, the CAP strongly supports CMS in leveraging participation in specialty accreditation programs. Most pathologists practice in accredited laboratories as specified by Clinical Laboratory Improvement Amendments (CLIA). As such, through participating in the CAP's accreditation program, pathologists promote the evaluation and improvement of clinical processes and care. The CAP believes that it is appropriate to incorporate attestation to participation in the CAP's accreditation program as an approach to satisfy the requirements of the Improvement Activities category.

MVP Assignment for Clinicians and Groups

The CAP encourages CMS to carefully consider how to assign clinicians and groups to an MVP. **In order to maintain flexibility, CMS should adopt an opt-in policy to provide clinicians and groups with the MVP(s) that would be most appropriate for them and allow them to select the MVP from those identified or to continue to report on MIPS through the traditional pathway.** CMS should base its suggested MVP for each clinician or group practice on a combination of past MIPS reporting data, physician specialty designation, and claims history. CMS should provide its suggested MVP to each clinician through multiple avenues, including the QPP Participation Status Tool, QPP submission portal, and the performance feedback report provided to clinicians regarding their previous years' data.

For multispecialty groups, the CAP believes that CMS should allow clinicians within the group to decide on which MVP they should report while maintaining the Web Interface reporting option for multispecialty practices. Some clinicians may not have the resources within a multispecialty group to report on a separate MVP and may prefer to report on the multispecialty group measures instead. Trying to establish sub-group reporting within multispecialty groups will increase clinician burden of reporting and cause unnecessary complications in identifying which clinicians within a group should report on which MVP.

MVP RFI Summary Comments

The CAP appreciates CMS verbal indication in listening sessions that there will be an additional time period to provide more detail responses to the specific questions raised in the RFI. The CAP will submit additional detailed comments. Overall, the CAP is very concerned with CMS' accelerated implementation of such an important change to the MIPS program. While the CAP supports simplification and burden reduction of MIPS, we encourage CMS to maintain the current flexibilities including those for special status clinicians. It is essential to maintain options and considerations for specialties such as pathologists who are non-patient facing. While MVPs could be appropriate for certain specialties, they might not be feasible for others. **The CAP supports CMS'**



intention to promote specialty reporting at large group practices (eg, hospital and academic medical centers), and looks to CMS to promote use of specialty QCDRs for this purpose. The CAP hopes that CMS does not stipulate a one-size-fits-all approach for MVPs and allows specialties sufficient time to consider whether they can operationalize MVPs within their already limited resources. The CAP further requests that CMS address the hidden costs of the QPP program being borne by physicians (via their specialty societies) in MVP development by offsetting costs to those societies.

MIPS Performance Category Measure and Activities

Pathology Specialty Measures Set

As the CAP noted in previous communications with CMS staff, as it relates to pathology measures and measure sets, the content of the text of the proposed rule is inconsistent with the tables in the proposed rule.

In the text of the proposed rule, CMS includes the following language on Page 780⁴:

Four of the five quality measures within the pathology specialty set have been identified as extremely topped out in the 2019 benchmarking file. However, we believe that it is important to retain these pathology specific measures in the MIPS quality measure set to ensure that pathologists have a sufficient number of quality measures to report.

Page 775:

The following specialty measure sets have been excluded from this proposed rule because we did not propose any changes to these specialty measure sets: Pathology... Therefore, for the finalized Pathology specialty measure set, we refer readers to the CY 2019 PFS final rule corrections notice (84 FR 566).

However, when we reviewed the specialty sets, the proposed pathology specialty set which is included in the appendix indicated the following:

Previously Finalized Measures in the Pathology Set for 2020

- Measure 397: Melanoma Reporting

Measures Proposed for Addition to the Pathology Set for 2020

- Measure 440: Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician

Previously Finalized Measures Proposed For Removal From the Pathology Set for 2020

- Measure 249: Barrett's Esophagus
- Measure 250: Radical Prostatectomy Pathology Reporting
- Measure 395: Lung Cancer Reporting (Biopsy/Cytology Specimens)
- Measure 396: Lung Cancer Reporting (Resection Specimens)

When we asked CMS for clarification, it stated that the preamble text language (on page 775) is not

⁴ Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40,482. Pages 775, 780 (Aug. 14, 2019). <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16041.pdf>. Accessed September 5, 2019.



accurate, and that CMS was confirming the proposals for the removal of 4 pathology measures, and the addition of *Measure 440: BCC/SCC Biopsy Reporting Time* measure to the previously finalized *Measure 397: Melanoma Reporting* measure for only 2 measures proposed for the Pathology Measure Set in 2020.

As the CAP indicated in follow-up conversations with CMS, we strongly oppose CMS’ removal of the 4 pathology measures based on our scoring analysis. First, our scoring analysis depends on the point values available for Measures 397 and 440; the scores and benchmarks for 2020 MIPS will not be available until after the Final Rule is released. Second, the scoring analysis depends on whether Measures 397 and 440 apply to the practice, i.e., whether the individual/practice meet the 20 case minimum for Melanoma Reporting (Measure 397) and BCC/SCC Biopsy Reporting Time (Measure 440). Extrapolating from the CAP’s QCDR, the Pathologists Quality Registry’s 2018 submissions to CMS for Melanoma Reporting (Measure 397), half of the practices who reported as a group did not meet the 20 case minimum and 92% of individuals who reported did not meet the 20 case minimum. Thus, our limited data suggests that most pathology practices who are single specialty will not be able to report on one or, most likely, either of the 2 proposed measures. These practices would have no available measures for MIPS Quality reporting. These practices and individuals who cannot report on the 2 measures would likely receive a neutral payment adjustment with no positive payment adjustment. If a practice or individual *can* report the two measures, both smaller and larger practices would score better with this smaller measure set.

As the CAP also indicated to CMS in our conversations, even with the removal of the QPP measures, there is still not a scoring advantage to report QCDR measures to practices that can report the 2 QPP measures. Practices that cannot report the 2 QPP measures (and thus only have a neutral payment adjustment) could potentially achieve a very small positive payment adjustment by reporting 6-7 QCDR measures. However 1) this increases administrative burden, 2) these practices will not be able to achieve the 80-point exceptional performance threshold, and 3) most practices do not own the data needed for reporting QCDR measures and thus there is a burden to access and report the data from the hospital-owned LIS.

Further, if a practice is able to report on only one of the two proposed MIPS CQMs (either Measure 397 or 440) via a Qualified Registry or on only Measure 397 via Medicare Part B Claims, CMS will subject it to the Eligible Measure Applicability (EMA) process since the practice will be unable to report on a minimum of 6 measures and on the complete Pathology Specialty Measure Set. The CAP has discovered that CMS is not applying the EMA process automatically to practices who are unable to report on a minimum of 6 measures. **The CAP urges CMS to apply the EMA process automatically to these practices. Otherwise, the practices are subject to erroneous scoring and are unable to achieve the maximum MIPS final score.** This is especially important as the recently released pathology clusters for the 2019 EMA process are not necessarily clinically related measures.

We identified two pathology clinical clusters for Medicare Part B Claims collection type:

Quality ID	Outcome/ High Priority	Quality Measure Title
249	N/A	Barrett’s Esophagus
250	N/A	Radical Prostatectomy Pathology Reporting

AND



395	High Priority	Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396	High Priority	Lung Cancer Reporting (Resection Specimens)

We also identified one pathology clusters for MIPS CQMs:

Quality ID	Outcome/ High Priority	Quality Measure Title
395	High Priority	Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396	High Priority	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 NOT include these clusters as part of the EMA process, especially if CMS is not automatically applying the EMA process.

- Case Example: If a pathologist is performing measure 249 (Barrett’s Esophagus) in the claims data submission, it does not mean that he/she could also report on measure 250 (Radical Prostatectomy 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.

For these reasons stated above, the CAP asks that CMS maintain the previous Pathology Specialty Measure Set consisting of 5 measures and add Measure 440: BCC/SCC Biopsy Reporting Time even if CMS finalizes its proposal to increase data completeness to 70%. This would allow pathologists to report on measures that represent the specialty as a whole instead of just the 2 proposed skin cancer measures.

The CAP also urges CMS to consider the implications of the types of measures that will be needed for pathologists in MVPs and MIPS. We ask whether CMS is envisioning quality measures that measure the quality of care provided by the pathologist or by the laboratory. Depending on the answer, significant concerns will need to be addressed regarding measure development, data availability, and attribution for both MVPs and MIPS.

Cost Performance Category

Pathologists continue to familiarize themselves with the cost measures but have only received detailed feedback for one year – 2018. Based on 2018 MIPS performance feedback, the CAP has



learned that there were some pathology group practices to which the Medicare Spending Per Beneficiary (MSPB) measure was attributed. 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 compared to other providers during the episode. Since CMS has not provided transparent and clearly defined data for the cost measures in 2018, it is difficult to determine how exactly the pathology practices were attributed. We ask that CMS make available easy to understand and detailed data on cost measures that can provide an opportunity for clinicians to improve and learn exactly how cost measures were attributed to them. Furthermore, this feedback would be based on the MSPB measure methodology that CMS is proposing to substantially revise in 2020 and, pathologists have received no information about any of the episode-based cost measures, the first wave of which went into effect in 2019.

While pathologists routinely contribute to team-based care, the CAP does not believe it is appropriate to attribute to them measure under the current MSPB methodology. The CAP feels that until appropriate measures are developed, pathologists as non-patient facing clinicians should be excluded from this category.

Improvement Activities

The CAP appreciates our ongoing and productive collaboration with the CMS regarding the Improvement Activities (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. **However, the CAP does not agree with the CMS proposal to increase the attestation threshold for groups to at least 50% of MIPS eligible clinicians in a group participating in or performing the activity for the same continuous 90 days in the performance period to which the group is attesting.** This is a steep proposed increase from the previous policy of requiring one clinician in a group to perform the activity in order for the group to attest to the activity. Even though several clinicians in a group might be performing the activity, not all clinicians are necessarily performing it for the same continuous 90 days.

In addition, there are several Improvement Activities where it is not appropriate for more than one clinician in a group to perform or participate in the activity. For example, it would be appropriate for the leadership of a pathology group to attend laboratory management meetings, surgical case review committee, or infectious control committee etc. in order for the group to attest to IA_PSPA_20 (Implementation of formal quality improvement methods, practice changes or other practice improvement processes) but it would not be reasonable or appropriate for 50% of the group's clinicians to attend such meetings; in short, while some IA activities might reasonably be enhanced by broad participation within a practice, there are others for which broad participation would actually compromise effectiveness. Despite this, the CAP urges CMS not to increase the complexity of complying with this category with multiple reporting options, depending on the IA.

Finally, CMS has indicated that it will be requiring QCDRs to provide details in the data validation plan for the IA performance category in addition to the Quality category. This will put a huge additional burden on practices and QCDRs especially with a 50% attestation threshold for practices. Practices and QCDRs will need to track and retain documentation for at least 50% of the clinicians in the group for each activity, instead of the current requirement of retaining documentation for at least one clinician in the group who is performing the activity. Such a requirement would be exceedingly difficult with respect to auditing improvement activities, as CMS has failed to fully define what constitutes as sufficient documentation for performing or participating in certain improvement activities, which creates operational challenges in auditing such activities. It is also unclear what, if any, documentation would be required to demonstrate that such audit activity occurred.



For the reasons listed above, the CAP strongly urges CMS to keep the current policy of one clinician in a group having performed each activity for the group to attest. This would not only reduce burden on groups and QCDRs regarding documentation retention but also encourage best practices as clinicians focus on quality improvement per the goal of this category of MIPS.

Promoting Interoperability

The CAP appreciates the CMS' recognition that many of the measures under the Promoting Interoperability (PI) performance category require face-to-face interaction with patients and that sufficient measures are not applicable to non-patient-facing MIPS clinicians. Most pathologists can currently only participate in two of the four categories of MIPS. This means that 85% of the MIPS final score for pathologists is based on quality measures which places a disproportionate amount of weight on that category for these clinicians. While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists that recognize their efforts in promoting the electronic exchange of health information, while ensuring their participation in the PI category is not administratively burdensome.

Third Party Intermediaries

QCDR Proposals

CMS is proposing several requirements for QCDRs for both the 2020 and the 2021 MIPS performance years. For example, beginning with the 2021 performance period, QCDRs would be required to support the reporting of measures and activities in the Quality, Improvement Activities (IA), and Promoting Interoperability (PI) performance categories of MIPS. In addition to these proposed increased requirements, CMS has been asking QCDRs during the self-nomination period regarding details of how the QCDRs will audit PI and IA data. If QCDRs are indeed required to provide details in the data validation plan for the PI and IA performance categories in addition to the Quality category, it will put a huge additional burden on QCDRs. Such a requirement would be exceedingly difficult with respect to auditing improvement activities as CMS has failed to fully define what constitutes as sufficient documentation for performing or participating in certain improvement activities, which creates operational challenges in auditing such activities. It is also unclear what, if any, documentation would be required to demonstrate that such audit activity occurred. **Therefore, we urge CMS to refrain from requiring QCDRs to perform pre-submission audits of all three MIPS performance categories without additional guidance on documentation requirements, plus remuneration for providing this service on behalf of CMS. The burden and cost of administering this program is being placed on physicians, via their societies with registries.**

CMS is also proposing that beginning with the 2020 performance period, CMS will place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive performance periods. Those that do not, may not continue to be approved. The CAP performed a detailed scoring analysis for pathologists, and identified that in almost all circumstances, pathologists can score higher by reporting MIPS CQMs over QCDR measures. This is mostly because of the fact that the majority of our QCDR measures have needed to be new each year (since 2017), and thus do not have benchmarks and are limited to three points. Bonus points for high priority measures do not seem to create significant incentive for this purpose. With MIPS CQMs able to score higher, there is no scoring incentive for pathologists to report on QCDR measures. The CAP appreciates that CMS recognizes the challenges of non-patient facing clinicians, and has appropriately modified MIPS scoring to reweight the Promoting Interoperability and (most often) Cost categories. In this reweighting, pathologists have significantly more weight on the Quality category compared to other specialties; this has the effect of focusing our providers on maximizing points in the Quality category. Thus, the scoring



incentives/disincentives are proportionally more important to pathologists than most specialties. **The CAP would like to work with CMS on ways to incentivize reporting QCDR measures and assessing scoring for QCDR measures.**

There are additional proposed measure requirements for the 2021 performance year, including that QCDR measures would be required to be fully developed with complete testing results at the clinician level and must be ready for implementation at the time of self-nomination. The CAP strongly opposes this proposal as it would be very burdensome on QCDRs. Currently QCDRs review performance data after implementing it in the registry which allows QCDRs to access how feasible it is for providers to report the measure. Full measure testing would require QCDRs to reach out to practices and participating providers to ask for volunteers for measure testing and chart reviews to test the validity of measures. It would require QCDRs to invest significantly more resources in terms of time and finances. We believe that this proposal is ultimately contrary to MACRA's requirement to encourage the use of QCDRs for reporting measures.

The CAP urges CMS to finalize its proposal that beginning with the 2021 performance period, CMS will allow 2-year QCDR measure approvals (at CMS discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements. The CAP has long advocated for CMS to increase the length of QCDR approval from one to two years and is very pleased that CMS has proposed 2-year QCDR measure approvals. This will allow practices the necessary time to put in the substantial work required to implement measures, especially with the increasing complexity of measures and the movement toward automated data integration for reporting. Specifically, practices will have additional time to learn the new measures and specifications and the data elements that must be mapped from their LIS. Very little data in pathology reports is in discrete data fields; thus, mapping of measures relies on pathologist-specific keyword searches and pathologist-specific location in the pathology report. This is a highly resource-intensive process that takes months in order to ensure measures are being captured and calculated accurately; pathologists will now have this necessary time if CMS finalizes its proposal of 2-year measure approvals. Finally, practices generally focus on mapping the current year measures once they have submitted those from the previous year—which is in February or March for most practices. Thus, if a practice chooses to report QCDR measures (and very few do for the reasons noted above), then data generally begins accurately populating a dashboard midway through the year at the earliest. CMS' finalization of 2-year approvals will allow sufficient time for measure implementation, data collection for the next year's self nomination, and improvement opportunities for practices.

While the CAP is pleased by the 2-year QCDR measure approval proposal, we are still disappointed by the numerous CMS proposals to increase requirements for QCDRs and QCDR measures. CMS continues to shift costs and burden of administering the MIPS program onto physicians, via their specialty societies that create measures and have QCDRs. This is a hidden cost of the program that is ultimately being borne by physicians. **Specialty societies responded to CMS when the QPP was initiated by investing heavily in QCDRs and in measure development. These investments to support our physicians in MIPS continue to increase, without recognition of the costs of administering the program.** The positive payment adjustment to physicians is already incredibly low, and when the costs of QCDR investment and infrastructure are added in, this makes MIPS a significant cost to physicians that is not accounted for.

Clinical Data Availability for QCDR Measures

QCDR measures require more clinical data than MIPS CQMs, but non-patient facing, hospital-based physicians do not have easy access to this additional data for reporting purposes. Non-patient facing and hospital-based physicians are increasingly disadvantaged in the MIPS program because it is



difficult or impossible to access data from hospitals' EHRs and Laboratory Information Systems (LIS). These physicians need hospital-owned data to support their ongoing participation in MIPS. As physicians working in and supporting hospitals, we should have access to all our patient's data from the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult, and is resource-intensive under any circumstances. Although hospitals claim that they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital has its own legal framework for potentially accessing data, so this becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since multiple specialties presumably approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for non-patient facing and hospital-based physicians. **CMS should develop ways to incentivize hospitals to make data available to hospital-based physicians, who need this data for MIPS reporting. Alternatively, we will need to work with CMS on measures that do not rely on data from hospitals.**

Performance Feedback

While data included in CMS' 2017 QPP Experience Report provided useful information (i.e., overall participation rates by specialty), the reports lack key details about specialists' specific engagement in the MIPS and A-APM tracks of the QPP. For example, specialty-specific MIPS data on scoring and payment adjustments (including exceptional performance), reporting mechanisms used, measures most often reported, and breakdowns of group vs. individual reporting, as well as detailed A-APM participation by model, is essential to our overall understanding of specialty participation in QPP and how we can best tailor educational materials for specialty physicians.

In addition, because CMS will take the highest score if a clinician has multiple MIPS submissions for 2019, in the 2019 performance feedback the CAP would also like CMS to publish on which submission clinicians were scored, i.e. individual, group, facility-based score etc. The CAP also encourages CMS to publish timely updates for facility-based score previews on the CMS QPP participation lookup tool. This is especially important for clinicians as their facility-based scores may change based on changes in the attributed facility's Value Based Purchasing score as well as the MIPS program scores for the quality and cost categories.

To address these concerns and in the spirit of transparency, we ask that **as part of the QPP Experience Reports and/or annual notice-and-comment rulemaking for the QPP, CMS provide detailed specialty-specific data and information on:**

- **MIPS scoring and payment adjustments (including exceptional performance);**
- **MIPS reporting mechanisms;**
 - **quality measures reported;**
- **group vs. individual reporting**
- **on which submission the clinician received his/her final score (i.e. individual, group, facility-based etc.)**

Public Reporting on Physician Compare

As the CAP has stated in prior comments to the CMS, we believe that all physicians 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. The CAP encourages the CMS to develop educational tools for patients viewing the Physician Compare website, especially with MIPS and as it moves to MVPs. 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. Cost or PI 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.

Advanced APMs and the All-Payer Combination Option

As CMS explains in this proposed rule, an Advanced Alternative Payment Model (APM) is an APM that requires its participants to use certified EHR technology (CEHRT), provides for payment based on quality measures comparable to measures under the quality performance category under MIPS, and meets the financial risk criterion. For Qualifying APM Participants (QPs) who achieve threshold levels of participation in Advanced APMs for the 2022 payment year, an eligible clinician “is excluded from the MIPS reporting requirements and payment adjustment and qualifies for a lump sum APM Incentive Payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year.” CMS estimates that the total lump sum APM incentive payments will be approximately \$500-600 million for the 2022 Quality Payment Program (QPP) payment year.

The CAP acknowledges CMS’ work to encourage meaningful participation in the Advanced APM track, to reduce reporting burden, and respond to stakeholder feedback. As we have previously emphasized, pathologists are integral in any care coordination initiatives – including Advanced APMs – as they apply their expertise to the diagnosis and management of a wide variety of medical conditions and undertake efforts targeted at increasing integration to improve patient care. However, while CMS notes the increasing number of clinicians participating in Advanced APMs, the number of Advanced APMs in which pathologists are able to participate remains limited. Even with the All-Payer Combination Option, physicians are not able to attain QP status without some participation in an Advanced APM within the Medicare program. More innovative health care payment and delivery models must be developed in an open and transparent fashion with the input of those specialties impacted by the models. The CAP believes it is only with physician input and buy-in that we can ensure effective delivery system reform that will benefit Medicare patients and achieve the value-based goals of this Administration.

At the same time, changes that would make participation in existing models more difficult, such as potential adjustments to the definition of “expected expenditures,” should be avoided. Rather, the CAP has consistently supported those changes that facilitate more APMs achieving Advanced APM status and that provide additional opportunities for appropriately-developed physician focused payment models. Currently, it is important to focus on increasing opportunity and incentives for specialty physician involvement in Advanced APMs. For example, the CAP supports AMA efforts to urge Congress to extend the Advanced APM incentive payments for an additional six years.

Most significantly, the CAP reiterates our concern that models are being submitted to the PTAC without input of those specialties impacted by the model. Model submitters should be required to provide evidence of consultation and concurrence from specialties participating in their models prior to their submission so that PTAC is making recommendations on models that are truly physician-focused and enable meaningful contribution by their participants to enhance the care of patients. The CAP is supportive of pursuing innovative models but seeks to ensure that physicians, especially the societies that represent physicians participating in and affected by new payment models, have input into their development.



COLLEGE of AMERICAN PATHOLOGISTS

* * * * *

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 related to items 1-4 of these comments to: Maurine Dennis (202) 354-7136 / mdennis@cap.org, or Todd Klemp (202) 354-7105 / tklemp@cap.org; items 5-7 to Elizabeth Fassbender (202)354-7125 / efassbe@cap.org, and for item 8, contact Loveleen Singh (202) 354-7133 / lsingh@cap.org.