



# COLLEGE of AMERICAN PATHOLOGISTS

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September 13, 2021

The Honorable Chiquita Brooks-LaSure, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
CMS-1751-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Attention: CMS-1751-P, RIN 0938-AU42

**Subject: CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements**

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1751-P entitled “Medicare Program; CY 2022, Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment 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. Proposed Valuation of Specific Codes for CY 2022 (section II.H.); Pathology Clinical Consultation Codes (CPT codes CPT codes 80XX0, 80XX1, 80XX2, and 80XX3)
  - A. Pathology Clinical Consultation Codes (CPT codes 80XX0, 80XX1, 80XX2, and 80XX3)
  - B. Proposed Changes to Recommended Direct Practice Expense Inputs CPT codes 80XX0, 80XX1, 80XX2, and 80XX3
  - C. Role of Independent Historian in Pathology Clinical Consult Codes
2. Changes to Direct PE Inputs for Specific Services/Clinical Labor Costs
3. Solicitation of Public Comment to Better Understand the Resource Costs for Services Involving the Use of Innovative Technologies, Including but Not Limited to Software Algorithms and AI
4. General Comments on Evaluation and Management Services Valuation
5. Medicare Shared Savings Program
6. Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs
7. Physician Self-Referral Updates
8. CY 2022 Updates to the Quality Payment Program
  - A. Merit-based Incentive Payment System (MIPS)
  - B. APM Incentive and Advanced APMs

**1. Proposed Valuation of Specific Codes for CY 2021 (FR section II.E.);**



### **A. Pathology Clinical Consultation Codes (CPT Codes 80XX0, 80XX1, 80XX2, and 80XX3)**

As the CMS noted, the RUC relativity assessment workgroup (RAW) identified CPT code 80500 family via the “CMS/Other source codes with Medicare utilization over 20,000 claims” screen. At the time, the CAP reviewed the ICD-10 data for both 80500 and 80502 to better understand the typical patient services. The CAP found that there was no clear typical patient or service connected with the then current clinical pathology consultation codes. A review from the CAP’s members and its Economic Affairs Committee concluded that 80500 and 80502 could not be accurately surveyed as the development of vignettes based on current ICD-10 data would misrepresent the typical patient and provide flawed survey results. It was specifically believed at the time that miscoding was occurring and that pathologists were unaware of how the services, as then described, should be used. Additionally, there was clear evidence through the historical ICD-10 data that the services were not understood. The CAP and the RUC agreed in October 2019 that a more accurate understanding of the appropriate usage of these services could result from a CPT review.

In October 2019, the RUC referred this issue to the CPT Editorial Panel to better define these services and create more specific descriptors. In October 2020, the CPT Editorial Panel replaced the CPT code family of 80500 and 80502 with four new codes, 80XX0, 80XX1, 80XX2, and 80XX3, to report pathology clinical consultations. In addition, separate guidelines were created to document the appropriate level of service for reporting of these codes. The distinction among the new code family involves degree of complexity and/or time of service, broken down by 20-minute increments each for codes 80XX0, 80XX1 and 80XX2, along with an add-on code 80XX3 reflecting additional 15–30-minutes above that spent on CPT 80XX2.

During our presentation to the RUC, the CAP noted the following reasons for the creation and appropriate valuation of these services: 1) There is evidence that incorrect assumptions were made in the previous valuation of this service. This service was valued through an unknown CMS crosswalk method about 25 years ago. This represents a flawed valuation assumption mechanism or methodology. This code is a CMS/Other source code and has never been RUC surveyed or reviewed by the RUC; and 2) it has been over 25 years since CPT code 80500 and 80502 were created by CPT and then valued by CMS. Since that time there has been an explosion in the number and complexity of laboratory tests, development of new drugs, and the increased numbers of patients living with chronic diseases and the services (80500 and 80502) as described in CPT had become essentially obsolete.

From the consulting pathologist’s viewpoint, the number of tests of utility in the investigation and explanation of these issues has similarly grown. The aging population is frequently more complex with several chronic conditions for which they are taking multiple drugs. Disease classification systems are now more complex requiring integration of several patient and laboratory parameters including molecular studies. The quantity of data that needs to be assessed and incorporated into a comprehensive meaningful report is extensive. Additionally, transplant and pre-transplant consultations are more complex. With this growth, the spectrum of complex interpretations and consultations has also widened. As a result of all of these trends and others, there is greater demand for a written order and written report by the pathologist.

From the clinician’s viewpoint, the explosive growth of laboratory tests and changes in population coupled with the fact that molecular diagnostic testing has dramatically increased, has made it difficult for physicians to keep pace with the indications for and understanding of the results of all of these different diagnostic tests, in the care and management of their patients. Furthermore, the number and complexity of laboratory tests has increased. As a result, there is tremendous variability in the naming and abbreviations for test names, which can make selecting the appropriate test even more difficult.



With so many test options available, there is an increased risk of a physician selecting the wrong or unnecessary test that may delay the determination of a diagnosis, impose risks on the patient, and impose other costs. To avoid this scenario, the necessity to consult a pathologist before choosing which laboratory tests to order has increased.

The CAP appreciates the fact that the agency agreed with most of the RUC recommendations for these codes. We offer the following comments for your consideration.

### **80XX0**

In the proposed rule, CMS notes that the RUC recommended a work RVU of 0.50 for CPT code 80XX0 based on the 25<sup>th</sup> percentile of the survey. The RUC recommended 15 minutes of intraservice and total times for CPT code 80XX0 are 2 minutes above the current intraservice and total times for CPT code 80500. This represents a 15 percent increase in the respective times. However, the RUC recommended work RVU of 0.50 is 35 percent higher than the current work RVU of 0.37 for CPT code 80500. The CMS believes that an increase or decrease in times should be commensurate with the increase or decrease in the work RVU. Therefore, the CMS is proposing a work RVU of 0.43. This value CMS proposed represents the ratio of total time between the current total time of CPT code 80500 and the proposed total time of CPT code 80XX0, (0.15) applied to the current value of CPT code 80500 ( $0.37 \times 0.15 = 0.43$ ).

The CAP respectfully disagrees with the CMS' assessment that the increase or decrease in time be commensurate with the increase or decrease in work RVU. The code set 80XX0 – 80XX3 represents services that are unique and distinct from those identified by 80500 and 80502. 80500 and 80502 are almost 25 years old and represented different services and should not be used for comparison. The CAP believes that CMS's proposed method of arriving at the value for 80XX0 is flawed for multiple reasons:

*CMS is not making an appropriate comparison.* CPT code 80500 was deleted and split out into three base codes and one add-on code with different reporting requirements. CMS should not compare the time of 80XX0 to the deleted code 80500 because the code descriptor for 80XX0, in contrast to 80500, includes “for a clinical problem with limited review of patient’s history and medical records and straightforward medical decision making”. Code 80500 expressly states that the service provided is “without review of patient’s history or medical records.” **Therefore, these distinct and different services are not equivalent and any changes in work and time should not be calculated commensurately.** The current valuation and time for 80500 is “CMS/Other”, therefore, how the times and values were established is unknown or potentially flawed. Additionally, there is no description of work for the old 80500 code to make any clinical assertions or comparisons. The CAP questions why a time ratio calculation is being proposed. In this case the increase in time is not an actual increase because CMS is not comparing it to a service that is the same, but instead to a differently described service in which the value and time source is unknown, rendering it a flawed rationale.

*CMS is not considering magnitude estimation.* CMS is ignoring survey data from pathologists who perform these services and their judgment related to not only the mental effort, technical skill and psychological stress that comprises the physician work and time, but also the relativity for the different levels of pathology clinical consultations. The RUC recommendations all relied on the survey 25<sup>th</sup> percentile work RVUs. CMS's disregard for survey data and magnitude estimation skews the relationship between the services in this family.



*CMS disregards compelling evidence.* CMS did not address the compelling evidence provided. CMS has a long history of reviewing potentially misvalued codes, first through the five-year review processes and more recently annual reviews. Statute requires CMS to modify relative values to account for changes in medical practice, coding changes and new data on relative values. CMS has worked with the RUC during the first five-year process and subsequent years to develop the compelling evidence criteria to demonstrate a change in physician services. Since the inception of the RBRVS, CMS has discussed compelling evidence in rulemaking as the Agency reviewed RUC recommendations. Although the pathology clinical consultations code family was work neutral, the RUC provided elaborate compelling evidence that these services were previously valued based on a flawed methodology, the physician work has changed due to technology advances and the patient population has changed. CMS does not address these changes and continues to compare to a flawed code.

The CAP believes the CMS should embrace the RUC processes with input from practicing physicians as we conducted valid surveys, rigorously reviewed by the RUC specialty society, and a review of magnitude estimation and cross-specialty comparison was conducted. **The CAP urges the agency to accept and implement the RUC recommended physician work value of 0.50 for CPT code 80XX0 for CY 2022.**

#### **80XX1**

In the CY 2022 proposed rule, the agency proposed to accept the RUC recommended work RVU of 0.91 without refinements for CPT code 80XX1. **The CAP agrees with CMS' proposal and urges the agency to finalize and implement the RUC recommended physician work value of 0.91 for CPT code 80XX1 for CY 2022.**

#### **80XX2**

In the proposed rule, CMS notes that the RUC recommended a work RVU of 1.80 for CPT code 80XX2 based on the 25<sup>th</sup> percentile of the survey. The current intraservice and total times for CPT code 80502 are 42 minutes. The RUC recommended times for CPT code 80XX2 are 54 minutes. Similar to the scenario described above for CPT code 80XX0, the intraservice and total times for CPT code 80XX2 increased 28.6 percent while the work RVU increased 35 percent. As stated above, the CMS believes an increase or decrease in time should be commensurate with the increase or decrease in the work RVU. Therefore, for CPT code 80XX2 CMS is proposing a work RVU of 1.71, which is the current total time ratio of CPT code 80502 compared to the RUC recommended total time for CPT code 80XX2.

The CAP believes that CMS's proposed method of arriving at the value for 80XX2 is flawed for multiple reasons:

*CMS is not making an appropriate comparison.* CPT codes 80500 and 80502 were deleted and split out into three base codes and one add-on code with different reporting requirements. CMS should not compare the time of 80XX2 to the deleted code 80502 because the code descriptor for 80502 described a clinical pathology consultation for a “complex diagnostic problem” without differentiating and accounting for increasing levels of complexity of the service and intensity of physician work related to medical decision making. In contrast, the new code 80XX1 describes a pathology clinical consultation for a “moderately complex clinical problem, with review of patient’s history and medical records and moderate level of medical decision making”. whereas 80XX2 is for a “highly complex clinical problem with comprehensive review of patient’s history and medical records and high level of medical decision making”. Therefore, **these distinct and different services are not equivalent, and any changes in work and time should not be calculated commensurately.** The current



valuation and time for 80502 is “CMS/Other”, therefore, how the times and values were established is unknown or potentially flawed. Additionally, there is no description of work for the old 80502 code to make any clinical assertions or comparisons. The CAP questions why a time ratio calculation is being proposed. In this case the increase in time is not an actual increase because CMS is not comparing it to a service that is the same, but instead to a differently described service in which the value and time source is unknown, rendering it a flawed rationale.

*CMS is not considering magnitude estimation.* CMS is ignoring survey data from pathologists who perform these services and their judgment related to not only the mental effort, technical skill and psychological stress that comprises the physician work and time, but also the relativity for the different levels of pathology clinical consultations. The RUC recommendations all relied on the survey 25<sup>th</sup> percentile work RVUs. CMS’s disregard for survey data and magnitude estimation skews the relationship between the services in this family.

*CMS disregards compelling evidence.* CMS did not address the compelling evidence provided. CMS has a long history of reviewing potentially misvalued codes, first through the five-year review processes and more recently annual reviews. Statute requires CMS to modify relative values to account for changes in medical practice, coding changes and new data on relative values. CMS has worked with the RUC during the first five-year process and subsequent years to develop the compelling evidence criteria to demonstrate a change in physician services. Since the inception of the RBRVS, CMS has discussed compelling evidence in rulemaking as the Agency reviewed RUC recommendations. Although the pathology clinical consultations code family was work neutral, the RUC provided elaborate compelling evidence that these services were previously valued based on a flawed methodology, the physician work has changed due to technology advances and the patient population has changed. CMS does not address these changes and continues to compare to a flawed code.

The CAP believes the CMS should embrace the RUC processes with input from practicing physicians as we conducted valid surveys, rigorously reviewed by the RUC specialty society, and a review of magnitude estimation and cross-specialty comparison was conducted. **The CAP urges the agency to accept and implement the RUC recommended physician work value of 1.80 for CPT code 80XX2 for CY 2022.**

### **80XX3**

In the CY 2022 proposed rule, the agency proposed to accept the RUC recommended work RVU of 0.80 without refinements for CPT code 80XX3. **The CAP agrees with CMS’ proposal and urges the agency to finalize and implement the RUC recommended physician work value of 0.80 for CPT code 80XX3 for CY 2022.**

## **B. Proposed Changes to Recommended Direct Practice Expense Inputs CPT codes 80XX0, 80XX1, 80XX2, and 80XX3 (FR section II.B.)**

For the direct practice expense inputs of CPT codes 80XX0, 80XX1, and 80XX2, the CMS has proposed to refine the time associated with the clinical labor activity PA001 (Accession and enter information) from the RUC-recommended time of 4 minutes to 0 minutes as the agency believes the time is duplicative with clinical labor activity PA008 (File specimen, supplies, and other materials). The CAP maintains that the time is not duplicative.





For these services, accessioning and entering information on the patient case is a preservice clinical labor task that is not duplicative with the post service work of filing specimen slides, filing reports and all relevant patient information retrieved for the pathologist to review, nor is this preservice clinical labor task captured within other laboratory or pathology services to be reviewed by the pathologist. This distinct preservice clinical labor work involves the careful documentation of the connection between the requesting physician and the pathologist onto a worksheet accession form or direct entry by staff into the laboratory/pathology information system or other reporting system. It is used to transcribe the request for consult, the primary complaint, patient encounter, and other related information so that it becomes part of the consultation report in the patient's electronic health record. This is an essential first step to create and initiate the complete service. **The CAP urges the CMS to understand the need to accept and implement the RUC recommended time of 4 minutes for clinical labor activity PA001 for CPT codes 80XX0, 80XX1, and 80XX2.**

The RUC recommended 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80XX0, 80XX1, 80XX2, and 80XX3, respectively. The agency believes that there is no indication from the code descriptors that the pathologist is reviewing physical slides. They maintain that the code descriptor and description of work indicate that the pathologist is reviewing paper records and/or EHR and therefore they propose to remove the equipment time associated with EP024 (microscope, compound) from CPT codes 80XX0, 80XX1, 80XX2, and 80XX3. The CAP believes there may be a misunderstanding of the RUC's recommendations.

When the pathologist is consulted on a patient case, as described in the physician work description on the RUC's summary of recommendation form, the pathologist reviews all relevant information about the patient that is available. Typically, a physical component of the patient material contained within the pathologist's patient case review is the patient's specimen slides. The physician work descriptions in the RUC's summary of recommendations contain the word "slides" within the sentence "All applicable diagnostic material, slides, primary analytical data are retrieved/unarchived for the pathologist's examination and review." These slides are typically reviewed on a high-grade professional microscope at the pathologist's workstation. During the service, the microscope itself is not available for other personnel to use on other patients, as the pathologist may review the slides multiple times during the service. The RUC understood that pathologists require a microscope to perform this and numerous other pathology related professional services. The retrieval of specimen slides for the pathologist to review is also mentioned in the RUC's NF practice expense summary of recommendation form: "Such data includes but is not limited to patient medical history records, retrieval of patient specimen slides, laboratory data, images, and printed/copied material. Electronic Health Records (EHR) and Laboratory Information Systems (LIS) are referenced as well." Specimen slide review on a compound microscope is typically performed and a key component of this pathology consultation. **The CAP urges the CMS to understand the need to accept and implement the RUC recommended 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80XX0, 80XX1, 80XX2, and 80XX3.**

### C. Role of Independent Historian in Pathology Clinical Consult Codes

In the 2022 NPRM, CMS states that they will not include the element of "Assessment requiring an independent historian" as part of an element of Medical Decision Making (MDM). Although this element is included in the CPT prefatory language, CMS states below that they do not believe that pathologists interact with independent historians in the typical scenario. The agency is also concerned that interaction with independent historians is not included in the Pathology Consult Codes descriptors or description of work. *NPRM Excerpt:*



*The proposed Levels of Decision Making for Table for Pathology Clinical Consult codes includes “Assessment requiring an independent historian(s)” as an element of “Amount and/or Complexity of Data to be Reviewed and Analyzed \* - Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.” Neither the code descriptors nor the descriptions of work indicate that this type of assessment is typical in a pathology clinical consult as was discussed for the office visit Levels of Decision Making table. For these reasons, **CMS proposes that this element not be included as an element that CMS would recognize as an element of medical decision making.** We note that CMS will monitor the use of these replacement codes per our usual practice to ensure appropriate billing and inform future rulemaking as needed. We are also seeking comment on how these replacement codes would most typically be billed relative to use of existing pathology coding. Such information would also inform future rulemaking as needed.*

It is important to state that the Pathology Consult Codes were valued based on the assumption that pathologists would be able to use elements from the MDM table stated in the following CPT introductory language (***The appropriate level of pathology clinical consultation services may be based on either the total time for pathology clinical consultation services performed on the date of the consultation; or the level of the medical decision making (MDM) as defined for each service***) when it was appropriate. Below we have listed the following scenarios where the pathologist needs to utilize the independent historian:

#### **Complex toxicology cases –**

- Independent historians (e.g., spouse/significant others, other family members, close friends, external treating physicians/QHPs, clinical staff and counselors, outside lab providers involved in treatment monitoring programs, etc.) often provide valuable information in pathology clinical consultations on complex and unexpected toxicology results and the evaluation of drug-drug interactions.
- This is most common in individuals who have been undergoing chronic pain management, substance abuse treatment, or both, where clinical and medication history from the patient may be poor, incomplete, or deemed unreliable (and, especially, when the patient is acutely confused, delirious, unresponsive or in a comatose state).
- Gaining as much insight as possible on specific types/doses of prescription and over-the-counter medications, potential use of illicit drugs and/or herbal and other supplements (that enhance pharmacologic effects or alter drug metabolism)—as well as past patterns of misuse/abuse and non-compliance with treatment programs—are critical in the overall assessment of the patient’s clinical condition and correlation of diagnostic findings.
- When unknown substances may have been ingested, independent historians are frequently helpful as they may have access to the patient’s source material.
- Discussions with clinical and technical staff at external laboratories performing prior testing as part of ongoing treatment monitoring programs, may be necessary when complex, atypical or clinically inconsistent findings are observed by current definitive testing (eg, liquid chromatography/mass spectrometry) or should more detailed information be required than typically provided in outside lab reports.

#### **Genomic testing cases –**

Genomic testing scenario 1 - oncologist requests a consultation from a molecular pathologist



to assist in the care of a patient with stage 3 ovarian cancer, including tumor genomic profiling results. After reviewing the patient's medical, surgical, pathologic and treatment history, he reviews the genomic test results. The results identify specific mutations relevant to the efficacy of specific therapies and to the patient's overall prognosis. In addition, the pathologist notes a specific mutation that suggests a heritable condition. However, the true somatic or germline status of the variant cannot be confidently determined by the somatic-only sequencing that was performed on the tumor. Furthermore, the available medical record did not include the necessary level of detail for personal and family history to determine whether suspicion for a hereditary cancer syndrome was warranted.

- During the patient's next clinic visit, the pathologist interviewed the patient and the patient's sister to obtain information to better interpret the genomic test result.

Genomic testing scenario 2 - An oncologist requests a consultation from a molecular pathologist to assist in the care of a patient with metastatic colon cancer, including tumor genomic profiling results. After reviewing the patient's medical, surgical, pathologic and treatment history, he reviews the genomic test results. The results identify specific mutations relevant to the efficacy of specific therapies and to the patient's overall prognosis. In addition, the pathologist notes a specific mutation that suggests a hereditary cancer syndrome not usually associated with colon cancer. However, the true somatic or germline status of the variant cannot be confidently determined by the somatic-only sequencing that was performed on the tumor. Furthermore, the available medical record did not include the necessary level of detail for personal and family history to determine whether suspicion for a hereditary cancer syndrome was warranted.

- During the patient's next clinic visit, the pathologist determined that the patient was not reliable and interviewed the patient's caretaker and family to obtain information to better interpret the genomic test result and determine whether genetic counseling and germline evaluation are warranted.

#### **Other clinical scenarios –**

- An elderly Russian speaking patient with Alzheimer disease presented with soft tissue bleeding and normal conventional laboratory assays (PT, aPTT, TT) and abnormal TEG (significant fibrinolysis). Patient was accompanied by his wife who was the patient's historian.
- Newborn with congenital heart disease, on aspirin and with intracranial bleeding. Question was raised about possible Bernard -Soulier syndrome, congenital bleeding disorder. Parents provided relevant personal history.
- Young woman with multiple "strokes" and positive MTHFR mutation was accompanied by her husband who contributed to her history. Referred patient for a second opinion to re-review imaging. As a result, diagnosis was multiple sclerosis and not strokes.

## **2. Changes to Direct PE Inputs for Specific Services, Clinical Labor Pricing Update- (FR section II.B.b)**

For CY 2022, CMS proposes to update all of the direct practice expense input clinical labor rates, as an update has not been made since 2002. The crosswalks CMS has developed appear appropriate and accurate at this time. However, the CAP is concerned about the potential effects that the clinical labor pricing update will have on specific codes, practices, and specialties. There are significant relative value and payment impacts that necessitates a phase in of the updated clinical labor rates





that is also limited so that the PE RVUs for any one CPT code are limited to a 5% reduction each year.

The potential effects of the clinical labor pricing update on specialty payment impacts are largely driven by the share of labor costs represented in the direct PE inputs for each code and specialty. Since the overall size of the practice expense component is static, increasing payment for clinical labor shifts funds that were previously directed to supplies and equipment. In other words, by increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. This rescaling of direct expenses, puts a huge and unfair burden on subspecialties of pathology that require expensive supplies and other direct costs to care for their patients.

The proposed ruling for CY2022 indicates the range of total RVU changes, for codes that did not have a change in physician work, is from -46% to +59.2%. Additionally, the policy unevenly redistributes the PE RVUs away from codes distinguished with a TC modifier. This is evident from the fact that under this proposal, out of all the codes with TC modifiers that experienced a change in total RVUs (unrelated to physician work), 61% and their related volume will be negatively impacted. In addition, 64% of those TC modifier codes that experienced a change in total RVUs (unrelated to physician work) will have changes exceeding +/- 5%.

Physician practices that provide focused services that use minimal clinical labor in relation to their use of supplies and equipment will have markedly significant losses beginning in 2022 that they may not be able to recover from. This policy proposal could severely disrupt or ruin physician practices and therefore should be phased in over at least four years rather than implemented entirely in CY 2022. While the increase in clinical labor is appropriate, it is not appropriate that physicians and other qualified health care professionals, representing a proposed 30% of Medicare allowed charges (or 34% of the 56 specialties listed on Table 6 of the proposed rule), are negatively impacted by the change. Additionally, the underlying unfairness that the real increase in clinical labor costs is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years. **To promote payment stability and to smooth out the increases and decreases in payment caused by the proposed pricing update, the CAP recommends that the CMS phase in the change in clinical labor rates over multiple years (at least 4) so that the PE RVUs for any one code is limited to no more than a 5% reduction each year.**

**3. Solicitation of public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. (FR section II.B.c.)**

CMS is soliciting public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. The CAP offers some comments for CMS consideration.

The rapid growth of digital technologies and their role in clinical care has the potential to improve patient care and outcomes. At present these technologies are far from widespread or typical. Present experience with these applications is insufficient to draw conclusions which may have an impact across the payment schedule. Therefore, we caution against establishing precedent-setting policy based on limited experience and data.



Following please find responses to the specific questions requested in the NPRM pertaining to the resource costs for services involving the use of innovative technologies:

*1. To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work? For example, CPT code 92229 is a PE-only code in which the software algorithm may be substituting for some work of an ophthalmologist to diagnose/detect diabetic retinopathy. CPT code 77X01 is a service in which the trabecular bone score software may be supplementing physician work to predict and detect fracture risk. CPT code 0503T may be both substituting for, and supplementing physician work to detect coronary artery disease.*

We believe services involving innovative technologies such as software algorithms and/or AI are **not** substitutes for physician work. There is a popular tendency to imagine “strong” AI as, at best, a form of neutral, “objective” decision-making, a pristine mathematical process that takes only “the facts” into account, independent of human judgment. However, an AI derived algorithm “is only as good as the data it works with” and the data sets on which AI algorithms have been trained were created by humans and are imperfect. Moreover, although industry has touted a number of benefits for the use of software algorithms and/or AI, relative to what they represent as the labor-intensive, time-consuming, and error-prone manual processes currently employed, pathologists will still be responsible for verifying, monitoring, and determining clinical appropriateness of software deployed for use by the laboratory, including machine learning software. These responsibilities require substantial professional involvement due to their tight integration with the diagnostic process. This increase in data correlation requirements does not amount to a net reduction in pathologist professional interpretive involvement and may in fact **increase** the overall physician work and intensity per patient case.

*2. How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries? For example, if a new software algorithm or AI technology for a diagnostic test result in a reduction in the amount of time that a practitioner spends reviewing and interpreting the results of a diagnostic test that previously did not involve such software algorithm or AI technology, and if the software algorithm or AI could be considered in part a substitute for at least some physician work, it may follow that the intensity of the service decreases. It is also possible that a software algorithm for a diagnostic test that is supplementing other tests to establish a diagnosis or treatment pathway for a particular condition could result in an increase in the amount of time that a practitioner spends explaining the test to a patient and then reviewing the results.*

Although industry has touted a number of benefits for the use of software algorithms and/or AI, relative to what they represent as the labor-intensive, time-consuming, and error-prone manual processes currently employed, pathologists will still be responsible for verifying, monitoring, and determining clinical appropriateness of software deployed for use by the laboratory, including machine learning software. These responsibilities require substantial professional involvement due to their tight integration with the diagnostic process. There may also be additional work in explaining to patient or other clinician that a digital application is being used and the way the application operates. There may be instances where the new data is contradictory or inconsistent with other clinical data or the physician’s clinical intuition, increasing the intensity of decision making. This increase in data correlation requirements does not amount to a net reduction in pathologist professional interpretive involvement and may in fact increase the overall physician work and intensity per patient case. It is



possible that the total time may decrease at the same time as the intensity increases, thereby maintaining or increasing the total work involved.

3. *How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? As discussed previously, the PPI Survey data that underlie the PE methodology were last collected in 2007 and 2008, which was prior to the widespread adoption of electronic health records and services that involve care management, non-face-to face and/or asynchronous remote care; the need to use electronic clinical quality measure data to support quality improvement, disparity identification and resolution, and value based payment; and the emergence of software algorithms and/or AI and other technologies that use data to inform, augment, or replace physician work in the delivery of health care. Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?*

The PPI Survey data preceded the most recent electronic and digital advances in clinical care and it the additional clinical requirements facing physicians, such as the use of Laboratory Information Systems (LIS) and Electronic Health Records (EHR), and other technology adoption would increase physician costs. Costs for innovative digital technologies vary based on the individual application and the business model of the associated technology company. This is true across services, specialties, types of practice and patient cohorts. As such, determinations about cost will require individual per-code or per-encounter analysis. Costs of innovative technology such as software algorithms and/or AI to furnish services to patients are specific to the patient service and the details need to be identified and appropriately costed.

In order to stay on the forefront of medical care, these technologies will have multiple costs structures among an array of AI business models, where one-time investments may be rare and recurring costs will be the norm. Additionally, costs incurred will not always fall into any specific supply or equipment bucket depending on the technology, its purpose, and patient care usage. Patient data, previously collected as part of another service and incorporated into software algorithms may best be categorized as a supply rather than an equipment item as patient data may have a short-term shelf life to be applicable for patient care.

As experience with these applications grows, trends may become apparent such as how physician offices pay for technology, including hardware, software as a medical device, servers, support services, and maintenance. General trends or practice expense packages may emerge. But, at this early juncture, it is too soon to make such a precedent setting policy. Likewise, it is too early to determine which, if any, costs will decrease, increase, or stay the same over time. We urge CMS to be flexible in its assumptions and categorization these data with all technologies. At this time, it is impossible to predict the future of these costs as their growth and adoption within the practice of medicine advances.

4. *How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? For example, it is possible that services that involve software algorithms and/or AI may allow a practitioner to furnish care more efficiently to more Medicare beneficiaries, potentially increasing access to care. Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to*



*Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions, frailty, etc.) in obtaining health care?*

Digital technology, including AI, has the potential to increase access to care and broaden the patient population for whom a certain diagnostic service is applicable or increase the number of potential diagnoses the physician would need to consider. These technologies have improved access in some rural and underserved areas where access to medical care may be limited. The barriers CMS mentions may be overcome by this greater access. Nevertheless, these technologies may involve patient (consumer) expense including access to broadband internet access. Where such access is limited, especially in rural areas, there is the potential to create or exacerbate health disparities across populations. Health care is not the only area where digital/broadband access is important to quality of life. To that end, broader public policy is necessary to enable universal access.

Some examples of how pathologist use of AI could benefit patients are as follows: AI-based tools might improve the prognostic capability of pathologists while decreasing diagnostic error and improving practice might also reduce variability in diagnoses among pathologists. AI might offer various benefits to the practice of pathology in the future, including augmenting the capabilities of pathologists to enhance their accuracy, as well as reducing costs by improving their efficiency in providing a primary diagnosis. AI might thus streamline health care workflow and improve triage of patients, while reducing pathologist fatigue and increasing the efficiency and efficacy of training.

5. *Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As we are considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. For example, section 218(b) of the Protecting Access to Medicare Act (PAMA) required that we establish an Appropriate Use Criteria Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries<sup>1</sup>. To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?*

Payments for these technologies should be objectively based on resource costs. Appropriate use criteria, as mandated under PAMA, are only loosely comparable. Innovative technologies, by definition, are new and lack the evidence base to create applicable appropriate use criteria at this time. Services that are driven by or supported by innovative technology such as software algorithms and/or AI are not at any greater risk of overutilization or more subject to fraud, waste, and abuse. Software algorithms and/or AI will assist the practice of medicine just like any other technologies introduced for patient care. Appropriate use criteria programs, more often than not, inhibit proper timely medical care and therefore should only be used sparingly, if at all.

6. *Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? For example, increased access to services to detect diabetic retinopathy such as the service described by CPT code 92229 could eventually lead to fewer beneficiaries losing their vision. Because CPT code 92229 can be furnished in a primary care practice's office and may not require the specialized services of an ophthalmologist, more beneficiaries could have access to a test, including those who live in areas with fewer ophthalmologists. Additionally, taking into consideration that a software algorithm and/or AI may*



*introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?*

Software algorithms and AI stand to improve health care disparities. However, there is a popular tendency to imagine “strong” AI as, at best, a form of neutral, “objective” decision-making, a pristine mathematical process that takes only “the facts” into account, independent of human judgment. However, an AI derived algorithm “is only as good as the data it works with” and the data sets on which AI algorithms have been trained were created by humans and are imperfect. It is the pathologist who must be responsible for verifying, monitoring, and determining clinical appropriateness of software deployed for use by the laboratory, including machine learning software. These responsibilities include ensuring that there is no bias in the source of a software algorithm and/or AI that would influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged. This increase in data correlation requires pathologist professional interpretive involvement and may in fact increase the overall physician work and intensity per patient case. Thus, Medicare should, as part of its codification of software algorithm and/or AI, include the role of pathologists.

7. *Our proposals to use crosswalks to set values for codes describing diabetic retinopathy and trabecular bone score would allow us to account for overall resource costs involved in furnishing the services. The possible crosswalks for FFRCT may also account for overall resource costs involved in furnishing the service. We also believe it is important to accurately account for resource costs for innovative and emerging technologies such as ongoing service specific software costs and, as explained above, such costs are not well accounted for in the PE methodology. We continue to be interested in potentially refining the PE methodology and updating the underlying data, including the PPI Survey data that are the data source that underpins the Appropriate Use Criteria Program. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program>. indirect PE allocation. How might CMS consider updating such data to reflect ongoing advances in technology so that we could establish appropriate relative values without resorting to crosswalks?*

Costs of innovative technologies used for patient care are often specific to the patient service and the details need to be identified and appropriately costed on a case-by case basis. Specifically, staff, supplies and equipment costs should be resource-based. Today, expenses related to approved AI technology should be considered a direct expense within CMS’ practice expense methodology.

The AMA RUC processes that utilize the medical expertise of hundreds of physicians and stakeholders is the best way to fully analyze and account for the costs of each patient service. We urge the CMS to engage through the RUC process and accept its recommendations.

#### **4. General Comments on Evaluation and Management Services Valuation (FR section II.F.)**

##### **C. Office Visits Included in Codes with a Surgical Global Period**

As stated in previous communication with the Agency, the CAP strongly believes that it is inappropriate to apply the increased 2021 valuation of the office E/M visits to the visits incorporated in the surgical global packages and agrees with the CMS proposals to not apply the office E/M visit





increases to the visits bundled into global surgery payment. **The CAP urges the Agency to 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.**

## 5. Medicare Shared Savings Program

The Medicare Shared Savings Program (Shared Savings Program) was established to “facilitate coordination and cooperation among health care providers to improve the quality of care of Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B.” Specifically, providers may participate in the program through Accountable Care Organizations (ACOs), which incentivize on the basis of outcomes rather than the number of services. As diagnosticians, pathologists apply their expertise to the diagnosis and management of a wide variety of medical conditions, and thus are integral in any care coordination initiatives. By virtue of their capabilities and roles, many pathologists already coordinate care and undertake efforts targeted at increasing integration to improve patient care and the patient care experience overall. However, we have continually commented to CMS that pathologists face challenges participating in many alternative payment models (APMs), including ACOs.<sup>1</sup>

As the proposed rule acknowledges, CMS has made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Additionally, policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute.

The CAP is committed to increasing the availability and adoption of innovative payment models, like ACOs, that afford an opportunity for the participation of pathologists. Indeed, pathologists are key to ensuring the quality of laboratory tests by collecting, surveying, analyzing, and using patient population clinical results to guide therapy, best practices, and safety for individual patients and patient populations. These activities provide the infrastructure and foundation for effective and appropriate care. **Thus, we appreciate the flexibility proposed by CMS in implementing increased performance standards and other changes to quality measurement.** Specifically, CMS proposes to delay changes proposed last year and allow ACOs to continue to use the Web Interface reporting option in 2022 and 2023, phasing in the new electronic clinical quality measure (eCQM) reporting requirement over three years. 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. Further, the CAP continues to believe considerable accommodations or alternate measures are necessary for non-patient-facing clinicians. **More is needed to increase opportunity for pathologist involvement in APMs, including the Shared Savings Program, and to appropriately incentivize and recognize the role of pathologists in successfully achieving the ACO goals of reducing costs and improving quality and safety.**

## 6. Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

In this proposed rule, CMS states that the agency expects the increased specimen collection fees for COVID-19 Clinical Diagnostic Laboratory Tests (CDLTs) to end at the termination of the public health

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<sup>1</sup> <https://documents.cap.org/documents/CAP-Medicare-Shared-Savings-Program-CMS-1701-P-Comments.pdf>



emergency (PHE) for the COVID-19 pandemic. However, as we stated in earlier comments, the CAP believes a separate, increased payment is needed beyond the PHE, as resources required to collect these specimens – including increased/special training, time, expenses, and personal protective equipment (PPE) – will still be limited. Further, there may continue to be a need for increased safety precautions and to reduce Medicare patients’ exposure to the general population and alleviate patients’ unease with leaving the home, despite an official end of the PHE. The need for diagnostic and screening tests will not terminate automatically when the PHE is over, and we do not know the duration of a SARS-CoV-2 vaccine’s protective immunity. Even after the end of the PHE, the risks to those collecting specimens will remain, as will the costs associated with mitigating those risks (e.g., personal protective equipment, testing for specimen collectors themselves). For these reasons, the existence and reimbursement of codes G2023 and G2024 should remain in place until the risks to specimen collectors of contracting COVID-19 have been reduced significantly, regardless of the timing of the PHE’s termination. Our recent experience with “breakthrough infections” of vaccinated people by the Delta variant demonstrates the ongoing challenges posed by COVID-19, and we may still see it become a seasonal infectious disease event, as was contemplated in the comments referenced by CMS. It is not possible to predict how easily transmissible or dangerous future variants will be, how effective available vaccines will be against them, or how long we will have to exercise extreme caution about COVID-19 infection. No test is so simple and straightforward to perform that erroneous results or outcomes cannot occur, and the COVID-19 PHE has highlighted the importance of prompt and accurate testing for patients, which would be improved with increased specimen collection fees.

The Centers for Disease Control and Prevention (CDC) recently recommended that both vaccinated and unvaccinated individuals return to employing additional mitigation measures such as masking and social distancing when going about their daily lives, laboratory personnel will continue to need added protection beyond vaccinations, particularly because they cannot remain socially distant from those from whom they are collecting specimens. This will be the case even when collecting non-COVID-19 specimens, because as we have seen, even those who are vaccinated and asymptomatic can carry and spread the virus. As with other infectious diseases, we may expect that the heightened safety precautions, need for personal protective equipment, and special training for specimen collection will persist beyond the immediate PHE and become a permanent fixture in managing public health. Therefore, **codes G2023 and G2024 should not be deleted once the PHE ends. Instead, CMS should expand authorization of the additional specimen collection fee G2023 and G2024 for all clinical diagnostic laboratory tests in accordance with guidelines for safe specimen handling in an era of COVID-19.** Universal applicability of the specimen collection fee to all clinical laboratory tests as represented in the Clinical Laboratory Fee Schedule is logical and promotes safety, consistency and equity across the platform of diagnostic laboratory tests.

In addition, the CAP asks CMS to confirm that G2023 applies to any site where clinical laboratory personnel collect specimens—not solely to homebound and nonhospital inpatients. Insofar as it is established that PPE, additional supplies and training are necessary for safe specimen collection when COVID-19 may be present, the specimen collection fee (G2023 and G2024) universally should apply to all sites where clinical laboratory personnel are collecting specimens, including on-site collection at clinical laboratories, pharmacies billing as clinical laboratories, drive through testing locations, and urgent care clinics—anywhere that the clinical laboratory personnel collect specimens where the facility otherwise is not eligible to report specimen collection. The additional training, personal protective equipment, supplies and safety and sterilization measures are required across these sites of service as well as at home, nursing homes, in physician offices, or hospital outpatient facilities.



Regardless of whether CMS retains HCPCS codes G2023 and G2024 or not, it must increase the standard collection fee above the current reimbursement rate of \$3 (or \$5, in the case of a specimen collected from a Medicare beneficiary in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)). We live in a different world than the one that existed in 2004 when the specimen collection fee of \$3 first was established – and even the one that existed in 2014 when Congress directed the agency to pay an additional \$2 for SNF and HHA collections. The increase use of telemedicine, for example, will continue to affect the delivery of health care. The resources required for specimen collection a few years ago cannot cover the cost of specimen collection today. **We urge the CMS to take a comprehensive review of each of the four existing specimen collection codes for their direct and indirect expenses, being mindful of what has been learned from the COVID-19 PHE and reprice the services in today’s dollars.**

CDC guidance advises that “proper specimen collection and handling are critical for all COVID-19 testing, including those tests performed in point-of-care settings” and that “a specimen that is not collected or handled correctly can lead to inaccurate or unreliable test results.”<sup>2</sup> The guidance further instructs personnel collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2 maintain proper infection controls and use recommended personal protective equipment (PPE), including N95 or higher-level respirator (or face mask), goggles or eye shields, gloves, and a lab coat or isolation gown.”

Acting in accordance with the CDC guidance, CMS stated its belief that “in the context of and for the duration of the PHE for the COVID-19 pandemic, collecting specimens using NP or OP swabs or collection of sputum will require a trained laboratory professional, as well as additional precautions that must be taken to minimize exposure risks in handling specimens that are suspected or confirmed for COVID-19.” Furthermore, CMS stated “collecting a specimen for COVID-19 testing will incur higher costs than similar specimen collection services which require a trained laboratory professional ... to minimize exposure risks.” “Laboratory personnel will need to be trained on how to handle the specimen to maximize accurate test results for COVID-19” and “on how to minimize risks for spreading the virus to themselves and/or others in the chain of specimen handling before it arrives the laboratory for analysis.”

The following table itemizes the additional resources required to collect specimens for COVID-19 testing.

### **Additional Resources Expended for COVID-19 Specimen Collection**

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<sup>2</sup> Centers for Disease Control. Specimen Collection Guidelines. Last updated March 8, 2021.



Resource Category	Resource Item
Personal Protective Equipment (PPE)	N-95 or higher respiratory or mask
	Face shields
	Goggles
	Gloves
	Isolation Gown
Specimen collection supplies	Nasopharyngeal, oropharyngeal mid-turbinate or anterior nares swabs with collection kit
	Sputum collection kit
	Test tube(s) for collecting blood
Disinfecting and sterilization equipment	Cleaning supplies
	Sanitizers
	Sterile gauze and bandages
	Biohazardous material disposal receptacles and bags
Laboratory training and expertise	Cost and FTE time for existing and new clinical laboratory technicians or health care professionals to train on proper specimen collection and handling techniques
Additional staffing costs	Cost and FTE time for existing and additional new clinical laboratory technicians or health care professionals required to follow safe and accurate specimen collection procedures, enforce safe distancing requirements and fulfill administrative requirements such as logging information into infection control tracking databases at the institutional, local, state and/or federal level

CMS has announced that it will make permanent its policy option of allowing laboratories to use electronic travel logs, rather than paper travel logs, to document miles traveled of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample for any type of clinical diagnostic laboratory test. The CAP appreciates that the agency recognizes the reduction in administrative burden and increase in flexibility afforded by electronic travel logs. We look forward to forthcoming subregulatory guidance on this matter.

## 7. Physician Self-Referral Updates

The proposed rule explains that the physician self-referral (or “Stark”) law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

As we commented in response to the agency’s “Modernizing and Clarifying the Physician Self-Referral Regulations” propose rule, the CAP believes that any efforts to reform the Stark law must



include action to close the in-office ancillary services (IOAS) exception for anatomic pathology (AP) services. **An exclusion of AP services from the IOAS exception is the most effective means of preventing program abuses and protecting quality care for patients.**<sup>3</sup>

However, we appreciate CMS's efforts to add more detail to recent changes and provide additional definitions for relevant terms. **We especially appreciate the agency's work to continually assess certain compensation arrangements and how to determine if they pose a risk of program or patient abuse.** Physician groups continue to create new arrangements structured around any technical requirements to retain the ability to profit from highly selected pathology services. We continue to support appropriate guardrails to address improper utilization and protect patient care.

## 8. CY 2022 Updates to the Quality Payment Program

### a. Merit-based Incentive Payment System (MIPS)

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. These considerations will be especially important as CMS moves forward with implementation of MIPS Value Pathways. The CAP continues to believe considerable accommodations or alternate measures are necessary to meet this clause<sup>4</sup> in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments on the Quality Payment Program (QPP).

#### Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information

● Definition of Digital Quality Measures. We are seeking feedback on the following as described in section IX.A.2. of the preamble of this proposed rule:

++ Do you have feedback on the dQM definition?

The CAP has concerns about the proposed definition of a dQM as “a software”. This implies that the measure is capable of independent action, like any software on a computer, which is not the case for existing quality measures. Taken with other changes proposed in this RFI, this definition suggests a shift in CMS' thinking that aligns with the ONC model of measures: instruments are stored in and called from a central repository via an app and function

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<sup>3</sup> <https://documents.cap.org/documents/cap-comments-on-modernizing-and-clarifying-the-physician-self-referral-regulations12-19-2019.pdf>

<sup>4</sup> 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.





independently from a registry. As this does not align with the current structure of measures, we have concerns regarding the burden of shifting the entire CMS measure portfolio to a new type of measure without demonstrated gain in doing so.

We would also like to highlight remaining areas of vagueness in the definition, including whether end-to-end reporting from one electronic system to another is required for a measure to be considered a dQM. It is not clear whether the intention of dQMs is to eliminate any human interaction with the data between collection and generation of a measure score. CMS also lists “other sources” as an option for where dQMs can come from. It is unclear if they intend to fully define the list of options. Laboratory Information Systems are not currently captured in any of the defined categories and would therefore be “other”. If CMS intends to use the transition to dQMs to impose new requirements on measure composition or data sources, we suggest as much detail and transparency as possible be included in the definition. The existing definition lacks full details. We agree with the AMA’s statement that “realizing the full extent of digital quality measurement requires rethinking electronic health record (EHR) certification.”

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

Use of FHIR-based APIs would in theory reduce the burden on providers. **However, it is not clear that FHIR is sufficiently advanced in all fields to allow widespread use.**

Furthermore, it is not clear how CMS intends for such technology to be developed; who will be incentivized to develop, test, and maintain software that supports this functionality? The CAP feels that the data standards for data capture and metadata structure, the data exchange model (e.g., a FHIR-based API), and the data query model (e.g., CQL, SQL, FHIRPath) must be part of an integrated informatics solution that can be reused regardless of the data exchange use-case, and that can be thoroughly validated for multiple use cases.

● Use of FHIR for Current eCQMs. We are seeking feedback on the following as described in section IX.A.3. of the preamble of this proposed rule:

++ Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

**It remains unclear whether a transition to FHIR-based quality reporting would reduce burden on health IT vendors and providers.** In areas where FHIR resources are fully developed and familiar to users, health IT vendors may already have infrastructure in place to support FHIR and the transition would reduce burden. However, it is unlikely that most providers are familiar with FHIR. Given the well-documented concerns about frequent changes to the MIPS program, any transition should be done in the background as much as possible rather than requiring providers to familiarize themselves with new standards or documentation.

In general, we suggest that CMS publish as much guidance about what is expected as possible as soon as possible. Among FHIR’s selling points is that it is very structured and a number of general resources are already available. However, specific resources are still lacking in many areas, and implementation of some existing resources remains a challenge due to their broad focus. Specifically with respect to pathology, current FHIR resources are insufficient and artificially separate pathology reports into “pathology” and “laboratory”, which can be confusing to clinicians and difficult to implement in practice. Current FHIR resources also rely too heavily on LOINC codes, which does not adequately capture pathology data. If



at a future date CMS expects that, for instance, all pathology quality measures will comply with the DiagnosticReport resource and/or other profiles in the US Core Implementation Guide (IG), CMS should make that clear as soon as possible to allow maximum time for compliance. We also suggest that CMS work with HL7 to ensure that opportunities for comment on IGs prior to balloting are publicized widely if CMS is intending to require them.

++ Would access to near real-time quality measure scores benefit your practice?

While access to near real-time quality measure scores would benefit most practices, this is unrelated to FHIR-based APIs. Current registry infrastructure allows most practices in most registries to see their scores on quality measures for MIPS in near real time as well as comparative and benchmarking data. FHIR-based APIs would not change this functionality.

++ What parts of the current CMS QRDA IGs cause the most burden?

No comment.

++ What could we include in a CMS FHIR Reporting IG to reduce burden on providers and vendors?

No specific comments

● Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We are seeking feedback on the following as described in section IX.A.4.a. of the preamble of this proposed rule:

--- Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR Implementation Guides suggested for consideration?

This approach is by its nature limited to data that is stored in certified health IT, which does not include significant amounts of data that would be necessary for dQMs. Currently a broad swath of data including such diverse sources as narrative data in pathology reports and patient responses to survey questions would not be included in this approach. It is possible that in the long run this approach would save providers time and burden. However, the benefits in the short term are less clear. The amount of data that is already captured as standardized, interoperable data is unknown; we suggest that before CMS implements requirements for such data to be used for quality measures, assessment of such data be completed and made public. The “interoperable standards” CMS intends to adopt should also be available for public comment before implementation.

**As it stands now, the suggested plan does not provide adequate detail for full assessment of the impact on providers.** We fully support efforts to reduce burden on providers by moving away from manual chart abstraction but significantly more information about future requirements, timelines, incentives and opportunities for input is required.

In terms of specific Implementation Guides, we do not believe the resources available for pathology are ready to be used for dQMs. Many diagnostic FHIR resources such as the “DiagnosticReport” event are overly broad, encompassing not just pathology but radiology and in some cases other diagnostic modalities such as gastroenterology and cardiology. The lack of specificity for pathology makes the resources less user-friendly to providers and results in large sections of the resource that would be left blank by users. A Quality Measure Implementation Guide already exists in FHIR; we suggest modification and/or expansion of this IG as it may already be familiar to some users. However, we also encourage a careful rollout of any requirements and potentially mitigation efforts for small practices. The burden in terms of time, cost, and effort to update electronic health systems is substantial. Even if



the majority of standards can be implemented by electronic health vendors rather than clinicians, practices will need to become familiar with the changes. Furthermore, practices would need to account for the costs associated with updating electronic health technology to comply with interoperability requirements.

--- How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

As above, we would support transparency on the part of CMS regarding development of data standards for “non-EHR” digital data. Non-standardized data presents a unique challenge to the efforts outlined in this RFI. Given the significant experience of the CAP with non-standardized data, which includes most pathology data, we recommend caution in applying existing standards and approaches to non-standard data.

Non-standardized data takes many forms and it is unlikely that any one approach will cover all forms. While it is critical to maximize inclusion of PGHD and other non-standardized data in quality measures, the CAP suggests a full evaluation of the current state of such data prior to imposing a data standardization approach. **We suggest CMS gather input from those who already generate and use such data on what standards would be appropriate and how they should be deployed.** While we support the idea behind CMS’s idea of “developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability”, steps must be taken to ascertain the current state of data before guidelines can be developed. We also suggest that any guidelines or requirements are developed in conjunction with stakeholders and specific to the non-standardized data in question, rather than attempting to produce new standards that cover all current non-standardized data or to fit data into existing standards.

--- What are possible approaches for testing data quality and validity?

Testing data quality and validity will be essential as CMS attempts to reduce provider burden by automating more data extraction. We know from experience that natural language processing requires a significant input of time at the outset to ensure accuracy of data extraction. CMS should consider how organizations will be incentivized to expend the resources needed to validate NLP extraction of data from PGHD; this burden should not fall on patients but it is not clear who is expected to shoulder it. In general, data quality and validity checks are a heavy lift and should not be undertaken by organizations without the authority to do so. If it is the expectation of CMS that measure developers create, implement, refine and maintain the NLP associated with quality measures, additional assistance such as access to contractors with subject matter expertise, expedited or provisional approval of such measures, and/or incentives to health IT vendors to work with measure developers should be considered. Furthermore, as many organizations have discovered, finding clinical sites with the necessary technical, information technology, and subject matter expertise to test measures is challenging. Practices already participating in the MIPS program, which can represent a significant investment of time and effort, are often reluctant to volunteer for additional activities regarding testing. We suggest that CMS consider ways to assist organizations in incentivizing sites, or consider establishing a network of pilot sites willing to provide assistance.

++ We are seeking feedback on the following as described in section IX.A.4.b. of the preamble of this proposed rule:



--- What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

**As noted regarding the definition of dQMs as “a software”, we have serious concerns about the idea of quality measures as free-standing tools that accomplish the functions described in this RFI.** This idea of a measure aligns more closely with the model ONC describes in some registry implementation guides, where “Instruments” are stored in a separate repository outside of a clinical data registry, and are populated by data from the EHR before the “results” are submitted to a registry. This would fundamentally shift the role of registries as well as the role and function of measures themselves. Considerably more information would be needed before this concept could be seriously considered for quality measures such as those used in the MIPS program.

Of specific concern are two areas: **first, even given standard instruments or measures as tools, variation in implementation is a significant possibility.** Obtaining standard scores from all users is a major goal of quality measures as tools. However, use by varying groups including hospitals, individual clinicians, payors and more, without oversight from a measure authority, could lead to scores that cannot be compared between entities especially given that these tools are expected to deploy advanced analytics such as NLP. If individual or entity users are able to modify the NLP of the tool, comparisons between scores are nullified; if they are not, however, it is likely that the measure would not work in all circumstances. In the experience of the CAP, who has been using NLP to extract data for quality measures, proper use of NLP requires ongoing maintenance and updating. By removing a centralized measure calculation body such as a registry, the chances that different stakeholders will implement the measure differently are increased. As the AMA notes, “vendors, practices, health systems, and consultants perform their own mapping, which leads to data inconsistencies and is a reason why no two EHRs can reliably calculate comparable results.”

**Second, by establishing measures as free-standing tools, CMS is disincentivizing use of registries and relegating them to a secondary role as simply data storage units.**

This not only goes against the policies stated in MACRA, but also increases burden on providers and reduces opportunities for quality improvement. As noted above, registries already provide the “near real-time quality measure score” CMS is considering. By removing the role of registries in quality measure calculation, CMS would force providers to find another way to get those scores. What’s more, in the absence of registries, information such as national averages and resources such as tool kits to promote quality improvement would no longer be available. Registries have played a key role in creation and implementation of specialty-specific quality measures that promote reporting by providers in many areas. Many of these measures would likely vanish without registries, thus reducing the opportunities for improvement for smaller specialties. Furthermore, by making measures free-standing tools, CMS incentivizes providers to operate independently rather than strive to meet standards set by their peers. CMS has recently increased the amount of comparative data that Qualified Registries (QR) and Qualified Clinical Data Registries (QCDRs) are expected to provide their users; establishing measures as free-standing tools moves in the opposite direction.

--- How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?



**We do not believe sufficient information is available to determine whether this approach would result in increased engagement with measure development.** Most clinicians are likely not familiar with FHIR, so it is possible that implementing new standards could increase the perceived burden on clinicians of measure development if they feel they need to learn a new system. While FHIR in theory would make resources more widely available by standardizing access methods, it is not clear whether use of tools for quality improvement, public health or research would immediately increase. We suggest a pilot project, funded by or conducted by CMS, to determine what additional resources are needed to ensure providers understand the new strategy. This would promote engagement in tool development and use.

++ We seek feedback on the following as described in section IX.A.4.c. of the preamble of this proposed rule:

--- Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

There are a number of policy considerations for aggregation of data from multiple sources. The experience of the CAP with obtaining data from hospitals suggests it will be a difficult process. Currently there is no incentive for hospitals to provide data to clinical data registries; it is difficult to see what incentive could be generated or what requirement could be put in place. If data aggregation remains voluntary or includes governmental programs only, its usefulness will be limited and aggregation could end up more of a burden than a help. As with other suggested policies, we recommend careful consideration of what stakeholders will be responsible for what aspects of aggregation of data to ensure burden does not fall disproportionately on clinicians. Many pathologists work with multiple hospitals and in our experience, it is incredibly time-consuming for them to navigate the bureaucracy of the hospitals trying to access data. The CAP encourages CMS to consider how Section 4004 of the Cures Act regarding information blocking could be used to facilitate data access and promote seamless aggregation from multiple sources.

--- Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

While we support the idea of standardizing policies and processes for data aggregation and measure score calculation by third party aggregators, it is not clear whether CMS intends to bring other aggregators up to the level of Qualified Registries or Qualified Clinical Data Registries (QRs/QCDRs), or whether CMS intends to impose additional requirements and expectations on all aggregators including QCDRs. In theory, aggregation of data from multiple sources is beneficial for all involved but in practice, we believe there are a number of potential policy actions to be avoided.

First, we do not believe CMS should define who QRs/QCDRs must aggregate data from, due to system-specific requirements of each QCDR. It remains unclear how aggregation between different QRs/QCDRs that serve different provider populations would occur but the details should be left to the QRs/QCDRs in question. In general, we also do not support addition of significant technical requirements to QRs/QCDRs, which already comply with strict rules regarding measure implementation, data collection and auditing, and feedback provided to users.

++ We seek feedback on the following as described in section IX.A.4.d. of the preamble of this proposed rule:





--- What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

**Initial priority areas should be limited to areas where an environmental scan to assess the state of structured data has already been done or can be done easily.** Areas where the state of data is unknown, or where most data is not structured cannot be the first priority, as it is not yet clear that dQMs will function as expected or that they are appropriate for all settings. As with other CMS programs, dQMs should be rolled out in as a pilot project to ensure that providers are not penalized for being early adopters of new technology but are incentivized to improve quality using new methodologies and are given opportunities to provide feedback.

In terms of specific resources to be created, we encourage transparency in expectations first and foremost. As previously noted, a large number of resources exist around FHIR but many lack the specificity required for full implementation; if CMS expects that a specialty or clinician comply with certain requirements, the exact guides and resources should be clearly stated and stakeholders given the chance to provide feedback. As much specificity around the definition of a dQM as possible should be established quickly.

We support AMA's comments on this section, particularly the idea that CMS should "incent the use of standardized semantic content from recognized developers."

--- We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

CMS is considering implementing standard measures across all programs and payors if possible. In their words "(t)his common portfolio would require alignment of: (1) measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements." We support the idea of aligning measure concepts/specifications including individual data elements across government programs and payors. **However, the idea of limiting data elements to standardized, interoperable elements is concerning. It is based on the assumption that all parts of all measures will be able to be expressed as standardized data elements; in practice this has not been demonstrated for very many measures.** The limited number of eQMs are not sufficient to conclude that all data elements in all measures can be defined in this way. Furthermore, limiting measures to standardized data elements runs the risk of creating "checkbox" measures that are clearly defined but not meaningful to patients or providers. It is likely that the easiest data elements to standardize will be the most basic and that measures constructed of these data elements, while standardized, will not represent complex, meaningful clinical quality actions. While CMS does acknowledge that this would be an ongoing effort in partnership with other interested parties, the basic assumption may be flawed. CMS should publicize any guidance about creation of standard data elements as soon as available so that subject matter experts can assess the feasibility of such guidance in their specific areas.

We recognize CMS' interest in reducing the number of measures, both within individual program and across programs. However, CMS should not use standardization of data elements and alignment across programs as a mechanism to winnow out measures.



Furthermore, CMS should be clear about the role of various parties in this process. That is, if dQMs are intended to be self-contained tools, the responsibility of ensuring that the tools function equally well on all platforms should not fall entirely on the measure developers, but on vendors as well if they intend to use these free-standing software packages. We are in agreement with AMA on this point. Fully digital measures will require a significant reassessment of the state of electronic health technology.

CMS should also consider the statutory requirements of various programs as they seek to align measures. Measures that have value in the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative may not satisfy the requirements of the Merit-Based Incentive Payment System and vice-versa. As noted previously, we do not support this alignment initiative as a mechanism to remove measures from programs simply to reduce the number of measures. We support a gradual rollout, starting with CMS's proposal to "identify which existing measures could be used or evolved to be used as dQMs". We also suggest concurrent identification of priority areas where new measures for an aligned measure set need to be developed and further suggest that CMS prioritize working with established measure developers and subject matter experts to address those gaps.

#### Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information

CMS acknowledges the persistent and often growing inequity in health care access and outcomes, and proposes modifications to CMS programs to begin to address the health equity gap. Specifically, CMS is beginning by increasing reporting of health disparities based on social risk factors to increase the actionable data available to hospitals and clinicians. The CAP supports the broad goal of improving health equity and is in general agreement with the definition of health equity proposed by CMS. However, we caution against actions that increase burden on providers and patients without clear benefit, particularly when such actions touch on potentially complex and delicate subjects for patients such as disability status and gender identity.

The CAP supports the inclusion of the anti-racism Improvement Activity (IA) suggested by CMS, and the modifications to other IAs to increase health equity. We also support additional policies aimed at reducing the burden on small practices, particularly small practices in underserved communities.

Going forward, the CAP encourages CMS to ensure that health equity is considered in all aspects of the program. While health outcomes are critical to measuring any program or care provided, an exclusive focus on outcomes risks ignoring potential levers for improvement by missing key actionable steps in the process. We support policies that ensure health disparity is addressed across the care continuum.

CMS also considers two potential future initiatives: stratification of quality measures results by race and ethnicity, and improving demographic data collection. For the former, CMS acknowledges that while self-reported race and ethnicity data is the gold standard, large amounts of this data are not currently collected. The CAP understands the need to stratify quality measure results and is supportive of the goal broadly. However, it is not clear that the current imputation methods described by CMS provide sufficiently granular data to stratify measures in a meaningful way. CMS states that the indirect estimation method "is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual." The utility of these methods for stratifying results of quality measures that are by definition attributable to an individual clinician and often measured at the individual patient level remains unclear. We recommend caution in the application of imputed race and ethnicity data to most MIPS measures due to the different levels of measurement: imputed data



can only be attributed to groups while measures are often at the patient or encounter level. We also recommend careful consideration of the meaning of stratified results to avoid overinterpreting such results or incorrect attribution to individual clinicians.

Regarding improving demographic data collection, the CAP understands the need for such initiatives and is broadly supportive of them. Importantly, the CAP encourages CMS to harmonize with existing projects and standards to avoid duplicative effort or potentially conflicting standards. Especially, the CAP highlights work already underway at the Office of the National Coordinator for Health Information Technology (ONC) such as Project US@. While this does not directly address race or ethnicity, it does represent a step forward in standardizing collection of some demographic data and should be included in any future CMS initiatives. Similarly, the Gravity Project has submitted prospective data elements for inclusion in USCDI version 2. Creating a new set of standards would be unnecessary and confusing.

Importantly, we ask that CMS consider the burden and benefit of adding any mandatory data elements to be collected in Quality Payment Program (QPP) measures. Not all clinicians have access to the full EHR data on a patient and therefore may not collect demographic data elements. If the benefit of collecting them is significant, the CAP recommends CMS engage with electronic health technology vendors, particularly those used by diagnostic specialties who typically do not collect demographic data from patients, to understand what is feasible. Given the breadth of available social determinants of health, the potential to add numerous required data elements, and therefore significant burden on clinicians, cannot be overlooked. The CAP suggests CMS rigorously investigate and make public the proposed use cases for any new mandatory data elements prior to requiring them to avoid unnecessary burden on patients and providers. These efforts have the potential to improve data collection but also make quality measure collection increasingly complicated and burdensome; the risks and benefits must be clearly outlined. Similarly, interpretation of measures in light of any new data elements should be clearly spelled out, as noted with respect to stratification of measure results by race and ethnicity.

The CAP stands ready to support improvement of health equity in diagnostic medicine by working with CMS and other federal partners to collect meaningful data on social determinants of health and utilize such data to benefit patients, families, and other stakeholders.

#### Transforming MIPS: MIPS Value Pathways

#### **MVP Framework and Implementation Considerations**

The MIPS Value Pathways (MVP) 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. As specialty societies move forward with creating MVP candidates, the CAP encourages CMS to be open to innovative thinking and have a willingness to test new ideas rather than simply reshuffling the current program. While the CAP agrees that the MIPS program must move to a more coherent and simplified state, the CAP appreciates that CMS is delaying implementation of MVPs to 2023. This delay provides specialty societies a much-needed reprieve to consider developing an MVP while ensuring their members are able to prioritize addressing the spread of COVID-19 within their practices and communities.

In addition, the CAP appreciates CMS' finalization of the MVP framework's guiding principles and development criteria. **While the additional guidance and criteria are helpful, the CAP believes**



**that further clarifications are needed for specialty societies as they work to develop MVP candidates.** For example, CMS finalized in the 2021 QPP final rule that it will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year prior to the publication of the proposed rule. This creates a lack of transparency for specialty societies that take on the burden of developing MVP candidates with no indication of whether their MVP candidate will be accepted by CMS. The CAP hopes that development of MVPs can be a collaborative and iterative process working closely with CMS instead of a siloed activity that could lead to investment of numerous resources on the part of specialty societies with no assurances from CMS of a successful MVP candidate.

Another obstacle to developing MVPs is the timeline for implementing a measure into MIPS. Multiple stages in the measure development timeline and CMS' requirements for measure developers to propose a measure for MIPS significantly delay acceptance of a new measure. For example, to propose a measure for the 2022 MIPS program, a measure developer must have submitted their application to CMS by June 1, 2020. **We urge CMS to consider changes to the existing timelines for reviewing clinician measures to shorten the review time and better align with Physician Fee Schedule/QPP rulemaking cycle.** The Measure Application Partnership (MAP) is set up to align with the Inpatient Prospective Payment System rulemaking cycle. We welcome a conversation with CMS on ways to improve the MAP process, including better ways to enhance engagement and physician specialty involvement and feedback.

CMS is considering MVP reporting would be voluntary for the CY 2023 through the CY 2027 MIPS performance periods. Further, CMS is planning for potential future mandatory MVP reporting to coincide with the sunset of traditional MIPS possibly by the end of the CY 2027 performance period. The CAP strongly urges CMS to allow the same gradual ramp up and sufficient time for MVP implementation as it did for traditional MIPS. The development and implementation of MVPs, as well as the campaign to educate clinicians regarding the new program, will take time. The CAP predicts that it will be several years before we can develop an appropriate candidate MVP. Some barriers to MVP development include lack of applicable MIPS measures that apply to pathologists, lack of benchmarks for existing QCDR measures, and lack of relevant cost measures. At this point in the MVP implementation process, it is simply too early to contemplate a timeline for sunseting traditional MIPS. As such, we ask that CMS delay its implementation timeline and extend the time period for voluntary MVP reporting. We do not believe that making MVP reporting mandatory and sunseting traditional MIPS by the end of the CY 2027 performance period would allow enough time for clinicians to become familiar with MVP reporting, especially as some specialties may not be able to develop and implement MVPs for another few years.

### **MVPs for Non-Patient Facing Clinicians**

The CAP believes that there are several aspects of the MVP framework that do not take non-patient facing, diagnostic specialties such as pathology into account. For example, 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.

The CAP urges CMS to finalize its proposal to maintain the current special statuses for MIPS as it moves to the MVP framework. This will allow non-patient facing clinicians such as pathologists to



have the option to develop and participate in MVPs. This flexibility is especially important for pathologists as they are already subject to additional quality oversight. While these special status clinicians may not be able to participate in some measures and activities for MIPS such as cost, population health, and Promoting Interoperability (PI), they can continue to demonstrate their value to patient care in MVPs within the afforded special statuses.

### Subgroup Composition

The CAP agrees that large multispecialty group reporting on primary care type measures are usually not relevant or meaningful to all specialists that participate within a multispecialty group. This leads to multispecialty groups submitting data that is not necessarily representative of all the clinicians that make up that group. Furthermore, The CAP agrees that data submitted at the subgroup level would provide increased data granularity to allow specialists within the group to make data-driven quality improvements in care. However, the **CAP urges CMS to keep subgroup reporting optional beyond the 2024 MIPS performance year and to provide appropriate incentives to multispecialty groups to take on the administrative burden of forming multiple specialty specific subgroups to report MVPs when they could report traditional MIPS instead.** While we agree with CMS' suggestion of offering Continuing Medical Education (CME) credit or credit towards Maintenance of Certification (MOC) requirements for reporting MVPs, we do not believe this would be sufficient incentive. The CAP also encourages CMS to offer additional incentives for reporting MVPs, such as continuing bonus points.

### MVP Requirements

The CAP believes that MVP reporting requirements need to be structured appropriately to effectively improve the relevance of MIPS to clinical practice and reduce unnecessary paperwork burdens. While the MVP framework bundles measures together in a specific clinical area, we are concerned the framework still requires clinicians to report in each performance category and maintains the status quo with the Improvement Activities (IA) category. **CMS should eliminate the need for clinicians to report in four separate performance categories and revise the IA reporting requirements to eliminate reporting for the sake of reporting.** Rather than a clinician having to attest to IAs, the developer of each MVP should note to CMS which IAs clinicians are inherently performing as part of a particular MVP, and corresponding IA credit should be automatic. This is similar to how MIPS alternative payment models (APMs) and recognized patient-centered medical homes are currently scored in the IA performance category.

In addition, CMS proposes that an MVP Participant must register for the MVP (and as a subgroup) beginning on April 1st and ending on November 30th of the applicable performance period. When establishing the deadline to register an MVP Participant, we urge the agency to consider QCDR deadlines. We also request that CMS offer MVP Participants the opportunity to change their registration after the deadline if the Participant wishes to move from the selected MVP back to traditional MIPS before submission for the 2023 and 2024 performance years. Such flexibility may be necessary for MVP participants as they get used to the MVP pathway.

### MIPS Performance Category Measures and Activities

#### Quality Performance Category

The CAP does not agree with the 2022 pathology measure set as proposed by CMS. **The CAP asks that CMS remove measure 440, Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician**





**from the proposed 2021 pathology measure set.** The CAP acknowledges that previously we have supported addition of this measure to the pathology measure set. However, since then we have discovered numerous issues that pathologists face while trying to report on this measure. This measure is stewarded by the American Academy of Dermatology (AAD) and is not tested for feasibility for pathologists. As outlined below, this measure creates significant implementation challenges for pathologists, as the measure was specified without consideration to how general pathology practices code information.

1. For 2021, AAD updated the specification of 440 to include the statement “*Only biopsy results should be reported for this measure. Do not include specimens sent for wide local excision or re-excision*”. Practically speaking, this is extremely difficult for practices. QPP 440 includes the following CPT codes: 88304 and 88305. In terms of skin samples, 88304 includes “Skin - cyst/tag/debridement” and 88305 includes “Skin, other than cyst/tag/debridement/plastic repair”. That is, all skin samples are captured by 88304 and 88305; there is no way to identify wide excisions/re-excisions using structured data elements (i.e. codes).
2. In 2021, AAD has also clarified that in cases where multiple types of specimens are present in the same report (i.e. a re-excision and biopsies of nearby tissue), only biopsies should be included this measure. Practically speaking, this does not align with how pathologists practice. Multiple specimens with the same Accession ID are assessed and verified at once, not as individual specimens. Therefore it is not possible to only report on biopsies; they are not signed out separately. Additionally, this will artificially depress scores: a report with a re-excision and biopsies will probably take longer to sign out than a report with only biopsies. However, since the biopsies on the “mixed” report are not signed out separately, they will be scored with the turnaround time of the more complicated sample(s).
3. Also in 2021, AAD has requested that each biopsy be reported separately as an individual denominator instance. As described above, this does not align with how pathologists practice. Multiple specimens are given the same Accession ID and treated as a single case or report. Further this is not clear in the specifications, which repeatedly refer to “All pathology reports” and “final pathology reports”. A pathology report by definition can include multiple specimens. To use “pathology report” to indicate an isolated specimen from a report is not correct.

**For these reasons, the CAP strongly believes that measure 440 be removed from the pathology measure set going forward.** We understand that CMS might like there to be six measures available for reporting within the pathology measure set, but addition of this measure causes multiple implementation challenges for pathologists trying to report on the measure. The CAP believes that measures should not be added to another specialty's measure set unless they have been fully tested in that other population of providers.

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 or on a high priority/outcome measure. The CAP has also discovered that when a practice reports less than 6 measures via Medicare Part B claims, CMS does the look-back on Medicare claims to see if the practice could have reported on other measures to determine if EMA should be applied. However, when the data is submitted via a qualified registry, the burden is on the practices to provide CMS with a list of all CPT codes billed as part of their Targeted Review to have CMS apply EMA and correct their scores. **For these reasons, 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.** Additional burden is placed on registry practices to submit Targeted Reviews and supply CMS with the necessary data in order to have their scores corrected.

In addition, based on the previously released pathology clinically related measures for the 2021 EMA process, the CAP has discovered that these are not necessarily clinically related measures. We identified the following pathology clinically related measures for Medicare Part B Claims and MIPS CQM collection types in CMS' [2021 EMA and Denominator Reduction Guide](#):

\*Denotes a High Priority Measure  
\*\*Denotes an Outcome Measure (all outcome measures are high priority measures)

Clinical Topic	MIPS CQM	Medicare Part B Claims
Pathology	249: Barrett's Esophagus	249: Barrett's Esophagus
	250: Radical Prostatectomy Pathology Reporting	250: Radical Prostatectomy Pathology Reporting
	395*: Lung Cancer Reporting (Biopsy/Cytology Specimens)	395*: Lung Cancer Reporting (Biopsy/Cytology Specimens)
	396*: Lung Cancer Reporting (Resection Specimens)	396*: Lung Cancer Reporting (Resection Specimens)
Pathology – Skin Cancer	397*: Melanoma Reporting	Not Applicable
	440*: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	Not Applicable

While these clusters may appear related in scope, due to diverse practice settings and case mixes these clusters are negatively impacting many pathologists and/or practices that simply do not examine specimens that pertain to all the clustered measures and therefore are 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 for future MIPS performance years, 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 little to no cancer resections. In this example, the group could possibly report on measure 395 but would be unable to report on measure 396 because they do not handle lung cancer resection cases. This group would then be unfairly penalized under EMA methodology using these clusters.

**The CAP asks that CMS take the above into account before finalizing the EMA pathology clinically related measure clusters for future MIPS performance years. Further, the CAP urges to use the formal rulemaking process for publishing the EMA clinically related measure clusters.** This would allow appropriate input from specialty societies and MIPS eligible clinicians so that measure clusters are related in scope, at least until specialties are able to create MVPs and in a way define their own measure clusters.

### Cost Performance Category

CMS is proposing to establish a process outside of the current process for the development of cost measures that would allow external stakeholders to develop cost measures and could expand the inventory of episode based cost measures. While the CAP agrees that more cost measures are needed to allow more clinicians from different specialties and sub-specialties to be assessed under



the cost performance category, we urge CMS to provide much needed resources for external cost measure development. This is an expense that nonprofit medical societies cannot bear without any assistance and funds from CMS for these activities. Cost measure development and maintenance would be onerous and costly processes for specialty societies with limited resources. As such, the CAP urges CMS to provide as much support and funding as possible for external stakeholders such as specialty societies for cost measure development.

### **Improvement Activities Performance Category**

The CAP appreciates our ongoing and productive collaboration with the CMS regarding the Improvement Activities (IA) category. The CAP was able to collaborate with CMS on an IA submission earlier this year and was pleased that CMS included the submission entitled “Implementation of a Laboratory Preparedness Plan” in the proposed rule. **The CAP urges CMS to finalize this IA in order to expand the limited number of activities available to pathologists for reporting in this category.**

Regardless of this addition to the IA inventory, we appreciate CMS’ continued policy to allow non-patient facing clinicians and groups to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit (regardless of the weight of the activities) to meet the IA submission criteria.

### **Promoting Interoperability Performance Category**

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. We appreciate the recognition of the non-applicability of the PI category to pathologists by CMS and support the continuation of the automatic reweighting policy for non-patient facing clinicians for the PI category.

### MIPS Final Score Methodology

#### **Quality Measure Scoring**

CMS is proposing to remove the 3-point floor for measures that can be scored against a benchmark (these measures would receive 1-10 points), for measures without a benchmark that have been in the program for more than 2 years (these measures would receive 0 points), and measures that do not meet the case minimum requirements (these measures would receive 0 points). These proposals would not apply to small practices of 15 or fewer clinicians. **The CAP opposes these proposals and asks that CMS maintain the 3-point floor for quality measures for all practices. The CAP also asks that CMS not finalize its proposal to end the high priority bonus points that is currently available for reporting additional outcome/high priority measures beyond the 1 required.** The CAP believes that the continuation of the 3-point floor and high priority bonus points are necessary to not disadvantage those clinicians in large practices as the program gets more complicated and as MVPs are introduced as a new pathway for reporting MIPS. Maintaining the 3-point floor and high priority bonus points would also counter the presence of several topped out and non-benchmarked measures and allow clinicians who report these measures to not be penalized for something that they do not have control over.

The CAP supports CMS’ proposal of a 5-point floor for new measures that do not have benchmarks. We believe that this will incentivize clinicians to report on new measures in the program and will



increase the possibility of these new measures receiving a benchmark. Under the current policy new measures run the risk of not having enough data to receive a benchmark since clinicians have previously only earned 3 points for reporting these measures that do not have a benchmark.

### Quality Measure Benchmarks

The CAP supports CMS' proposal to use performance period benchmarks for the 2022 MIPS performance period, using the data submitted during the 2022 performance period rather than baseline period historic data. The CAP agrees that using 2022 performance period benchmarks for the year where there are gaps in baseline data will ensure that data continues to be reliable and accurate. This will also allow accurate results for benchmarking purposes for the 2022 performance period and could capture any changes in care that have occurred because of the national COVID-19 public health emergency.

### Assigning Measure Achievement Points for Topped Out Measures

For the 2021 performance year CMS is proposing to apply the seven measures achievement point cap to measures that (1) have been topped out for two or more years based on the published 2021 performance year historic benchmarks (which are based on submissions for the 2019 performance year); and (2) remain topped out after the 2022 performance year benchmarks have been calculated. The CAP believes that CMS should suspend the topped out measure scoring caps altogether rather than revising the criteria for the 2021 performance year. This would provide further relief to clinicians dealing with the COVID-19 public health emergency.

### Redistributing Performance Category Weight for Small Practices

The CAP agrees with CMS' proposal that for small practices, when both the cost and PI performance categories are reweighted, the weight be redistributed equally to both the quality and IA performance categories so that both categories are weighted at 50% each. We believe that this reweighting policy will greatly assist small practices by providing further flexibilities so that these practices are able to meet MIPS requirements. Clinicians and groups who work in small practices face unique challenges and burdens related to financial resources and health information technology and may not have the infrastructure to collect, analyze, and report MIPS measures. **As such, the CAP believes it is appropriate to place more emphasis on a performance category that poses a reduced reporting burden such as the IA category and we urge CMS to finalize its proposed reweighting policy for small practices.**

### Third Party Intermediaries

### QCDR Measure Testing Requirements

CMS finalized in the 2021 final rule that QCDR measures that were approved for the 2020 performance period must be face valid prior to being self-nominated for the 2022 performance period and that QCDR measures approved for the 2022 performance year with face validity must be fully tested prior to being self-nominated for any subsequent performance periods (that is, 2023 performance year and beyond) in order to be considered for inclusion in the MIPS program. In addition, CMS requires that for a *new* QCDR measure to be approved for the 2022 performance year, the measure must be face valid. Face validity measure testing must be completed prior to submission. To be approved for the 2023 performance year and future years, CMS requires that a *new* QCDR measure must be face valid for the initial MIPS payment year for which it is approved



and fully tested for any subsequent MIPS payment year for which it is approved. QCDR measures that are not fully tested by the second self-nomination date would not be considered for approval for the second year.

The CAP strongly opposes these requirements because we firmly believe it is not attainable for most, if not all, QCDRs and will, therefore, either cause QCDRs to submit far fewer measures or drop out of the MIPS program altogether. In addition, many QCDRs have faced limitations around data access due to a significant decline in participation as many QCDR participants received hardship exemptions during the recent public health emergency (PHE). **The CAP asks that CMS allow face validity alone to suffice for existing measures for an additional two-years post COVID-19 PHE** to acknowledge that the PHE has impacted the ability of clinicians and groups to collect and report MIPS data.

**The CAP also asks that CMS provide a two-year grace period for reliability and empirical validity testing for new QCDR measures.** The lack of sufficient data for new measures limits the ability to assess reliability and validity. Providing a two-year delay to submit reliability and empirical validity testing (data element OR measure score) would align with the CMS requirement that measures without any data submitted will be removed from the QCDR program. For example, providing additional time would allow registries to leverage the results of the annual data validation audits since those findings could be used to provide data element validity for each of the measures.

The CAP also asks that CMS offer clinicians and groups an incentive for participation in QCDR measure testing. Similar to how CMS is proposing that clinicians and practices that choose to report new measures would earn a minimum of five points rather than three, CMS should award bonus points in the quality performance category or provide IA credit for clinicians and practices that choose to assist in measure testing.

**The CAP continues to believe that CMS's measure testing requirement will impose unreasonable cost and other burdens on QCDRs and that such costs will impede measure development, lead to increases in registry participation fees for clinicians, and may cause QCDRs to cease measure development altogether.** This requirement fails to recognize the many steps used in developing QCDR measures to ensure their reliability and validity. For these reasons, we continue to believe that this rule is contrary to MACRA's requirement to encourage the use of QCDRs for reporting measures.

#### Public Reporting on the Compare Tools hosted by the U.S. Department of Health & Human Services

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.





**b. APM Incentive and Advanced APMs**

As CMS explains, under the Advanced APM track, eligible clinicians who are Qualifying APM Participants (QPs) for a year are eligible to receive an APM Incentive Payment in the corresponding payment year for payment years 2019 through 2024. The APM Incentive Payment is a critical component in rewarding high-quality treatment of patients and in increasing participation in Advanced APMs. We appreciate the agency's efforts to improve and expand the ways CMS identifies the TIN(s) to which it makes the APM Incentive Payment for a QP in a timely and efficient manner. Certainly, given the significant investment and work required to reach QP status under the Advanced APM track, every effort should be made to quickly and accurately disburse the payment to QPs and we support proposed amendments to the APM Incentive Payment decision hierarchy that accomplish this goal. Further, in addition to any revised hierarchy or other approach to disbursement, we also encourage CMS to consider policies that increase opportunity and incentives for specialty physician involvement in Advanced APMs to ensure more providers can earn the bonus payment for delivering high-quality value-based care to patients.

As we continue with implementation of the Quality Payment Program, the CAP acknowledges CMS's work to reduce barriers to clinician participation in Advanced APMs, to promote efficiency and effectiveness, and to respond to stakeholder feedback. As we emphasized above and in earlier comments, 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. We reiterate our general support for changes that facilitate more APMs achieving Advanced APM status and that create more opportunities for specialty providers of all kinds to become QPs under the Advanced APM track of Medicare's Quality Payment Program.

The College of American Pathologists is pleased to have the opportunity to comment on these issues and appreciates your consideration of our comments. Please direct questions related to items 1-4 of these comments to Maurine Dennis at [mdennis@cap.org](mailto:mdennis@cap.org) or Todd Klemp at [tklemp@cap.org](mailto:tklemp@cap.org) ; for items 4-9 contact Elizabeth Fassbender [efassbe@cap.org](mailto:efassbe@cap.org), and for item 10, contact [lisingh@cap.org](mailto:lisingh@cap.org)