COLLEGE of AMERICAN PATHOLOGISTS

September 10, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1693-P

Subject: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1693-P entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019." 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.

The CAP comments on the various elements of the proposed rule are detailed below. Due to the significance and impact of the "QCDRs Seeking Permission From Another QCDR To Use An Existing, Approved QCDR Measure" section (p. 829), the CAP would like to take the opportunity to emphasize concerns of this section before all other comments. Despite our shared goals for a successful Quality Payment Program, the CAP strongly opposes the proposal that QCDRs submitting measures for MIPS are required to enter a licensing agreement with CMS to allow for the use (without modification) of any submitted and approved measures at no cost to other QCDRs. This mandatory licensing requirement would strip away the intellectual property rights of measure owners without justification or just compensation. Specialty societies including the CAP have made a significant financial commitment with regard to measure development and creation of QCDRs to support physicians participating in MIPS. This has included significant resources on the CAP's part for measure development of $100,000 - $150,000 per measure and $5 million for the creation of the Pathologists Quality Registry. Without the contribution of specialty societies, the measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance. If third parties can routinely use these measures and, in the case of commercial QCDRs, profit off of the societies' time and expense, specialty societies may no longer be able to dedicate resources to developing QCDR measures. The in-depth analysis of our concerns and additional comments on the QCDR provisions of the proposed rule are on pages 12 – 14 and 25 – 28 of this letter.

In addition, CMS's requirement that QCDR measure owners agree to enter into a measure licensing agreement ***prior to the closing of the NPRM comment period*** raises serious issues under the Administrative Procedure Act. We urge CMS to remove this requirement for the 2019 QCDR Self-Nomination Application until after the publication of the Final Rule. We urge CMS to not finalize the requirement that QCDRs permit CMS to allow for the use (without modification) of any submitted and approved measures at no cost to other QCDRs and consider a more cautious QCDR measure

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

evaluation process that can be phased in over a period of time to ensure successful participation and meaningful system reform.

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

1) Proposed Valuation of Specific Codes for CY 2019:
2) Updates to Prices for Existing Direct PE Inputs
3) Market-Based Supply and Equipment Pricing Update
4) Evaluation & Management (E/M) Visits
5) Clinical Laboratory Fee Schedule
6) Merit-Based Incentive Payment System (MIPS) Proposals
7) Advanced APMs and the All-Payer Combination Option
8) Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

1) Proposed Valuation of Specific Codes for CY2019:

a) Fine Needle Aspiration Biopsy (CPT codes 10021, 10X11, 10X12, 10X13)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
10021	**Fine needle aspiration biopsy; without imaging guidance; first lesion**	**1.03**	**1.20**
10X11	Fine needle aspiration biopsy; without imaging guidance; each additional lesion	0.80	0.80
10X12	**Fine needle aspiration biopsy, including ultrasound guidance; first lesion**	**1.46**	**1.63**
10X13	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	1.00	1.00

The CMS has proposed the RUC recommended work RVUs for CPT codes 10X11 and 10X13. **The CAP agrees with this proposal and urges the Agency to finalize the RUC recommended physician work RVUs of 0.80 for 10X11 and 1.00 for 10X13.**

However, the CMS rejected the RUC work recommendations for 10021 and 10X12. The rationale for both of the CMS' proposed reduced values is based on the notion that the work RVU should be reduced with a reduction in time. This belief led the agency to propose a direct crosswalk to CPT code 36440 (Push transfusion, blood, 2 years or younger) (work RVU = 1.03, 15 minutes intra-service time, 35 minutes total), which departs from the well-established physician work survey process by elevating the time component to the sole criterion for valuation. This change in the methodological processes devalues the true physician work provided by failing to consider the intensity, complexity, and details of patient care.

The physician work, intensity, and complexity of 10021 is very different from 36440. The difference in skill and risk levels between the performing a push transfusion in a newborn and a free hand needle biopsy of a lesion in the submandibular region is significant. These two services are <u>not</u> similar to each other in physician work, physician time, nor patient population and they should not be equated.

When these codes were reviewed, the RUC noted that the current physician time components in the RUC database were from 1995 and resulted in an inappropriately low IWPUT of 0.034. Therefore,

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

the RUC agreed that the drop in total time did not warrant a proportional change in work RVU as the previous times had not been appropriate. The 10 minutes of pre-service time is required to explain the procedure to the patient, including potential complications, obtain informed consent, position and prep the patient, and clean the biopsy site with disinfectant, inject the local anesthesia and wait for it to take effect. The 8 minutes of post-service time is necessary to prepare a report of the procedure for the medical record. The smears and/or cells in solution/suspension (for ancillary tests or additional slides preparation) are checked to insure proper sealing and transportability to pathology (either locally or via mail). The appropriate clinical history documents, labeling, and requisition forms are packaged in the sealed, transportable packaging and sent to the appropriate pathology agency. The patient is monitored for evidence of hematoma, bleeding, drug reaction, or other complication(s). The RUC reviewed the survey 25th percentile work RVU of 1.20 and agreed that this value appropriately represents the physician work involved.

The RUC's recommended work RVU and service period times are supported by the two most commonly chosen key reference services:

- 32554 *(Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance),* (work RVU = 1.82, 21 minutes of pre-service time, 20 minutes intra-service, and 15 minutes post time) chosen by 27% of respondents, and
- 99214 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.),* (work RVU = 1.50, 5 minutes of pre-service time, 25 minutes intra-service, and 10 minutes post time) chosen by 8% of respondents.

The difference between the chosen key reference services and the surveyed code reflects the multiple specialties participating in the survey and the limitations of the reference service list. Specifically, there are few appropriate XXX global procedure codes to compare with this service. Even with the wide time and RVU ranges spanned by these comparisons, the relativity of the values is appropriately reflected. The surveyed code, 10021, has less intra-service time than both key reference codes, more pre-time than the E/M but less than the thoracentesis, less post-time than both procedures, and less total time than both procedures. These differences are reflected in the recommended WRVU, whereby 10021 has an appropriately lower recommended WRVU.

In addition, the RUC's recommended RVU of 1.20 for 10021 is supported by two MPC codes with XXX global periods:

- 99283 *(Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity*.), (work RVU = 1.34, 5 minutes pre-service time, 18 minutes intra-service, and 7 minutes post service) which has slight more intra-service time and slightly shorter total time, and
- 70470 *(Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections)* (work RVU = 1.27, 5 minutes pre-service time, 15 minutes intra-service, and 5 minutes post service)

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

To maintain the proper valuation and rank order throughout the physician fee schedule, the CAP therefore urges the Agency to accept the RUC recommended physician work value of 1.20 for 10021.

For CPT code 10X12, the Agency proposes to base the value on its proposed value of 10021. Again, the CAP urges the Agency to recognize the deficiencies of time ratios to value physician services and accept the integrity of the RUC and its physician survey processes. The RUC noted that the current times in the RUC database for 10022 were from 1995 and resulted in an inappropriately low IWPUT of 0.034. Therefore, the RUC agreed the drop in total time did not warrant a proportional change in work RVU as the previous times had not been appropriate.

The RUC's recommended work RVU and service period times fall between the two most commonly chosen key reference services (KRS):

- 32555 *(Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance),* (work RVU = 2.27, 22 minutes of pre-service time, 20 minutes intra-service, and 15 minutes post time) chosen by 45% of respondents, and
- 76536 *(Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation),* (work RVU = 0.56, 4 minutes of pre-service time, 10 minutes intra-service, and 4 minutes post time) chosen by 9% of respondents.

The difference between the chosen key reference services and the surveyed code 10X12 reflect the multiple specialties participating in the survey and the limitations of the reference service list. Specifically, there are few appropriate XXX global procedure codes to compare with this newly bundled service. Additionally, since the imaging guidance was bundled into these new codes, it was unavailable as a comparison for the survey respondents.

Even with the wide time and RVU ranges spanned by these comparisons, the relativity of the values is appropriately reflected. The surveyed code, 10X12, has twice the intra-service time of 76536, more pre- and post-time, and is an invasive procedure as opposed to a diagnostic imaging study. These differences are appropriately reflected in the recommended WRVU. While 10X12 has the same intra-service time as 32555, it has much less pre- and post-service time, as well as being a relatively safer invasive procedure, whereby, 10X12 has an appropriately lower recommended WRVU.

The surveyed code (10X12) is bracketed by two non-radiology MPC codes with XXX global periods:

- 99203 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*, (work RVU = 1.42, 4 minutes of pre-service time, 20 minutes intra-service, and 5 minutes post time)) which has identical intra-service time and slightly shorter total time, and
- 93351 *(Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional)*, which has a higher WRVU, (work RVU = 1.75, 10 minutes of pre-service time, 20 minutes intra-service, and 10 minutes post time) identical intra-service time, and slightly more total time.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

The surveyed code (10X12) has 6 more minutes of pre- and post-service time than 99203 and 10X12 has the same intra-service time as 93351, as well as more pre-service time, but a lower WRVU recommendation. We believe that 10X12 is appropriately positioned in the RBRVS at its recommended value given these comparisons. **In order for the proper valuation and rank order throughout the physician fee schedule, the CAP therefore urges the Agency to accept the RUC recommended physician work value of 1.63 for 10X12.**

b) Blood Smear Interpretation (CPT code 85060)

For CPT code 85060 *Blood smear, peripheral, interpretation by physician with written report,* the CMS disagrees with the RUC-recommended work RVU of 0.45 and is proposing a work RVU of 0.36 based on the total time ratio between the current and survey intra-service time. The difference of three minutes between the current and survey intra-service time for 85060 does not constitute a "significant decrease" as the CMS states. Especially when examining such a small amount of time, a time ratio should not be used because any decrease will result in a large ratio and a correspondingly large and inappropriate decrease to the physician work RVU. Rather than using time ratios, the CMS should examine the magnitude estimation between the physician work, time and intensity. Additionally, the current time is "CMS/Other", which means that the time was not based on a survey and it, is unclear how the time was determined or what it represents. CMS/Other time has historically been deemed invalid through the RUC process. The flawed methodology of constructing a time ratio to determine work value in a relative value scale is even more conspicuously unreasonable when the ratio is between CMS/Other time source and survey data.

The CMS states that the recommended work value of 0.45 is higher than "nearly all of the other global XXX codes with similar time values". A search of the RUC database contradicts this finding showing that eleven XXX codes with 12 minutes of intra-service time have values lower than 0.45 and thirteen XXX codes with 12 minutes of intra-service time have values the same or higher than 0.45 RVUs. None of these services are pathology services and are not comparable, except for CPT code 88388 *Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (eg, nucleic acid-based molecular studies); in conjunction with a touch imprint, intraoperative consultation, or frozen section, each tissue preparation (eg, a single lymph node) (List separately in addition to code for primary procedure)* (work RVU = 0.45 and 12 minutes intra-service time), which was the reference code cited in the RUC recommendation. The "crosswalk" service that the CMS compared the survey code to, CPT code 95930 *Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report* (work RVU = 0.35 and 10 minutes intra-service time), is not a pathology service and describes the physician work to perform a vision test whereas 85060 describes comparing blood samples, lab results and review of a blood smear under the microscope to determine the features of the red blood cells, white blood cells, and platelets.

The work value that the CMS proposes would create significant rank order anomalies within the array of pathology services. When a pathologist performs this service, there are a number of variables that must be considered in the evaluation of a blood smear when compared to others, including red blood cell count size, shape and morphology, platelet morphology and number, white blood cell morphology and the presence of white blood cell precursors. The diagnostic considerations of an abnormal complete blood cell count ("CBC") are remarkably diverse, including a wide gamut of causes for anemias, multiple types of acute and chronic leukemias, and platelet disorders. The evaluation of all patients who have peripheral blood abnormalities must be based on multiple clinical factors including age. To assess the significance of the peripheral smear morphologic features, correlation to the CBC results and careful consideration of the patient's condition as reflected in their medical record is necessary

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

Comparison of 85060 to 95930 is inappropriate. As 95930 has pre and post service time and 2 minutes less intra-service time, it is clearly appropriately valued less than the RUC recommended work value of 0.45 for CPT code 85060. Finally, the CAP would like to clarify that when the RUC uses the term "crosswalk," it means that the two services have identical intra-service time and should be valued identically. By this definition CPT code 95930 is not a crosswalk, but rather what the RUC refers to as a reference code and the other codes that CMS cites as "crosswalks," CPT codes 99152 and 93923, are also reference codes.

The survey results for CPT code 85060 were reviewed by an expert panel of pathologists, including many who perform the service. The expert panel agreed that the survey results, although robust, overestimated the physician work of a peripheral blood smear interpretation. The expert panel, considering the total work, time, intensity, and complexity of the patient case, agreed that the current existing work RVU of 0.45 is appropriate for CPT code 85060. Again, CPT code 85060 has "CMS/Other" time, which was not from any physician survey and it has never been determined how it was derived nor what it represents. It is therefore not appropriate to compare the survey time to the current CMS/Other time. The expert panel and the RUC agreed that the median surveyed time is representative of the physician work involved in the service. It was also agreed that the survey respondents overestimated the physician work RVU (median WRVU = 0.75) and therefore they agreed the physician work RVU for 85060 should be maintained with the current value of 0.45 with the survey median time of 12 minutes.

For comparison purposes, the following other services have identical physician work RVUs:
88314 – Special stain including interpretation and report; histochemical stain on frozen tissue block (List separately in addition to code for primary procedure) (*Work RVU = 0.45, 13 minutes total time, RUC reviewed February 2011)*
93923 - Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests, or measurements with reactive hyperemia*) (Work RVU= 0.45, 16 minutes total time, 10 minutes intra-service time, RUC reviewed April 2010).* **The CAP therefore urges the Agency to accept the RUC recommended work RVU of 0.45 for CPT code 85060, which maintains the code's current work value and preserves its rank order.**

c) Bone Marrow Interpretation (CPT code 85097)

For CPT code 85097 *Bone marrow, smear interpretation,* CMS disagrees with the RUC-recommended work RVU of 1.00 and is proposing a work RVU of 0.94 based on the current work value. CMS states that "…significant decreases in time should be reflected in decreases to work RVUs," however this argument is out of place in this context because the survey respondents indicated that the service requires 25 minutes to perform rather than the current time of 30 minutes, yet CMS proposes to maintain the current work value. Additionally, the current time is CMS/Other, which means that the time was not based on a survey, and the code was not reviewed by the Harvard studies or through the RUC process. CMS/Other codes were gap-filled for physician work and time, most often via crosswalk to some other service by CMS. It is actually unknown how this time was ever determined and what it actually represents. CMS/Other time has historically been deemed invalid. When the RUC reviewed the physician work of this service, they agreed with the CAP that incorrect assumptions were made in the previous valuation of this service because it was

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

based on a crosswalk of indeterminate significance by CMS. The RUC also agreed with the CAP that it is not appropriate to compare the surveyed time to the current CMS/Other time, as CMS/Other time is of unknown significance and must therefore be considered quantitatively invalid

The RUC agreed with the specialty that given the total work, time, intensity, and complexity of the patient case, the current work RVU of 0.94 was too low for the physician work involved. The RUC chose the crosswalk to CPT code 88121 *Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology* (work RVU = 1.00 and 25 minutes intra-service time), specifically because it is a similar pathology code with a value between the current work value of 0.94 and the survey 25th percentile of 1.15. The overall work effort is identical to 88121. The "crosswalk" service that the CMS compared the survey code to, CPT code 88361 *Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology* (work RVU = 0.95 and 25 minutes intra-service time), is less intense and complex to perform. The physician work involved in 88361 is evaluating a single antibody and determining the percentage of tumor cells that are positive for that antibody. For 85097, the work involves evaluating all blood cell precursors for quantitative and morphologic abnormalities, as well as evaluating for metastatic tumor cells, evidence of infection (eg. granulomas), or evidence of lymphoid neoplasms (eg, lymphoma, myeloma), on multiple smears. Additionally the end result of the work of 88361 is a numerical score. In contrast, the end result of 85097 is an interpretation with a clinically actionable diagnosis. This is clearly much more complex and intense than 88361. Finally the CAP would like to clarify that when the RUC uses the term "crosswalk" it means that the two services have identical intra-service time and should be valued identically. By this definition, CPT code 88361 is not a crosswalk, but rather what the RUC refers to as a reference code because the work value is 0.95, not 0.94 the work value that the CMS is proposing.

The CMS stated "We also considered a work RVU of 0.90 based on double the recommended work RVU of 0.45 for CPT code 85060 (Blood smear, peripheral, interpretation by physician with written report). However, we believe that this thinking was derived from a RUC member question. The CAP explained that in a peripheral blood smear, typically, the practitioner does not have the approximately 12 precursor cells to review, whereas in an aspirate from the bone marrow, the practitioner is examining all the precursor cells. Additionally, for CPT code 85097, there are more cell types to look at as well as more slides, usually four, whereas with CPT code 85060 the practitioner would typically only look at one slide. While we do not propose to value CPT code 85097 at twice the work RVU of CPT code 85060, we believe that this analysis also supports maintaining the current work RVU of 0.94 as opposed to raising it to 1.00." The CAP wishes to clarify that this explanation was put forward to a RUC member whom was simply asking why this service requires twice the time of CPT code 85060 *Blood smear, peripheral, interpretation by physician with written report.* Simply doubling the RUC recommended work RVU of 0.45 for 85060 based on the amount of time does not account for the considerably greater intensity and complexity of 85097 over 85060 described in the explanation above. **The CAP therefore urges the Agency to accept the RUC recommended work RVU of 1.00 for CPT code 85097.**

For the direct practice expense inputs for CPT codes 85097, the CAP urges the CMS to consider pathology clinical staff activities apart from the standard practice expense clinical activities, In fact, we would like to remind the Agency that is the exact reason that the RUC's PE Subcommittee determined that separate and distinct clinical activities codes were needed when the PE Spreadsheet Update Workgroup developed the codes for clinical activities. Although the CAP understands that the clinical activity description for PA001 *accession and enter information* and PA008 *file specimen, supplies and other materials* sounds like data entry and filing, it is *very* different in the pathology lab. These clinical activities are integral elements performed by health care

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

professionals in order to analyze a specimen and are not administrative tasks that go into the indirect practice expense. **The CAP assures the CMS that these clinical activities are allocable to a particular patient and should not be considered a form of indirect expense. The CAP therefore urges the Agency to accept and implement the direct practice expense inputs for CPT code 85097 recommended by the RUC.**

d) Fibrinolysins (CPT code 85390)

The CMS has proposed the RUC recommended work RVU of 0.75 for CPT code 85390. **The CAP agrees with the CMS proposal and requests that the Agency finalize the RUC recommended physician work RVU of 0.75 for CPT code 85390.**

2) Updates to Prices for Existing Direct PE Inputs

On tables 15 and 16 of this proposed ruling, the CMS proposed updates to prices for existing direct practice expense inputs. Specifically, the Agency proposed a price change for pathology supply SL140 stain, Wright's Pack (per slide) and pathology equipment EP121 slide stainer, automated, hematology as recommended by the RUC. **The CAP agrees with this proposal and urges the Agency to finalize these updates.**

3) Market-Based Supply and Equipment Pricing Update

The CMS proposes to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. These prices were previously updated in about 2005. The CMS proposes to transition the updated prices for over a 4-year period beginning in CY 2019 because of the potentially significant changes in payment that would occur. The CAP agrees with the process of updating the prices of supplies and equipment. However, when reviewing the proposed changes, we have noticed that there are a number of new prices that appear to be inaccurate. In particular for some pathology codes, we noticed that proposed prices that may not reflect the proper product, quantity and/or unit of measure associated with the service. For example, we believe that some of the StrategyGen recommended supply or equipment prices for many of the CMS items may have not been adjusted for their proper unit of measure or may not be the correct product. Below is a small sample of supplies and equipment we believe may be in error:

Supply items

SA024	kit, photopheresis procedure
SC085	tubing set, plasma exchange
SD186	plasma LDL adsorption column (Liposorber)
SD309	Immunofluorescent mounting media
SL012	antibody IgA FITC
SL182	mounting media (DAPI II counterstain)
SL493	Antibody Estrogen Receptor monoclonal
SL497	(EBER) DNA Probe Cocktail

Equipment items

EP024	microscope, compound
EP001	DNA/digital image analyzer (ACIS)
EP045	chamber, hybridization
EP050	scanner, AutoVysion
EP088	ThermoBrite
EP092	Olympus BX41 Fluorescent Microscope (without filters or camera)

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

The CAP also notes that the proposed changes as listed also do not appear to reflect the "typical" price that a typical physician practice would pay. Another area of concern is the impact that the implementation of an aggressive new pricing strategy would have on smaller practices which typically operate on smaller margins and who are more likely to be immediately affected by these changes. Further, we believe that the time allotted in this comment period is not nearly sufficient to evaluate all of the proposed pricing changes for typicality and to correct any obvious and egregious errors and obtain the appropriate invoices. Therefore, **the CAP urges the Agency to postpone, for one year, the implementation of updated prices for supplies and equipment to allow affected stakeholders to recommend corrections for the most obvious errors. In addition, the CAP urges the CMS to accept comments from the public on all practice expense supplies and equipment for this one year and throughout the entire four year price transition period, so that the all products are defined, priced appropriately, and reflect the typical price paid by stakeholders.**

To maintain relativity between the clinical labor, supplies, and equipment portions of the PE methodology, the CMS seeks comment on whether to update the rates for clinical labor staff used to develop PE RVUs in future calendar years during the transition period or whether it would be more appropriate to do at the conclusion of the transition period. **The CAP agrees with the CMS that the clinical labor staff rates should be updated, however we recommend that the AMA RUC be involved to evaluate any and all appropriate clinical staff types be added or revised. The CAP recommends that the Agency update the clinical labor rates yearly and have any proposed rates be subject to public comment. In addition, the CAP would welcome an updated set of rates within a proposed ruling during or outside of the 4-year transition period.**

The CAP is also concerned that the proposed repricing of supplies and equipment may trigger the unintended consequence of specific CPT codes becoming identified, by CMS or the RUC, as potentially misvalued. **The CAP recommends that the Agency correct this supplies and equipment repricing exercise when applying the various screening mechanisms used to identify potentially misvalued codes.**

4) Evaluation & Management (E/M) Visits

The CMS has proposed to collapse payment rates for eight evaluation and management office visit services to two codes. The CAP believes there are a number of unanswered questions and potential unintended consequences that would result from this change in coding policies. The proposal could hurt physicians in specialties that treat the sickest patients, as well as physicians who provide comprehensive primary care, and ultimately hurt the ability of the Medicare beneficiary to access care.

The CAP urges the new multiple service payment reduction policy in the proposed rule not be adopted as the issue of multiple services on same day of service has explicitly already been accounted for in the work relative values and practice expense in prior valuations of the affected codes. This proposal by the CMS would therefore result in a duplicative, unjustified reduction in reimbursement. The proposal also has significant impact to certain physician services, such as chemotherapy administration, that may be an unintended consequence of altering the current practice expense methodology to accommodate the proposal.

The CAP strongly supports the American Medical Association's creation of a workgroup of physicians and other health professionals with deep expertise in defining and valuing codes, and who also use the office visit codes to describe and bill for services provided to Medicare patients. The charge to this workgroup is to analyze the E/M coding and payment issues in order to arrive at concrete solutions that provide the CMS time for implementation in the 2020 Medicare Physician Fee

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

Schedule. The CAP urges the CMS to fully embrace the assistance of the workgroup, and the entire physician community, over the next year in the development of a solution that will achieve our shared goal of simplifying E/M documentation burdens while mitigating any unintended consequences, and also ensuring the best possible outcome for patients.

In addition, the CAP urges CMS to delay finalizing any of its E/M proposals related to coding and payment for outpatient/office visits (i.e., the proposed collapsing of 99202-99205 and 99212-99215, the proposed multiple procedure reduction, and the proposed G codes for primary care and specialty adjustments and prolonged services). Finally, the CAP feels strongly that additional data analysis is required to ensure that any proposal to modify E/M payment and associated documentation requirements does not have unintended consequences including negative effects on patient care, and the CAP urges the Agency to work with the physician community to compile these data.

5) Clinical Laboratory Fee Schedule

Given the integral roles pathologists play in directing clinical laboratories, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the CAP and its members have a significant stake in the implementation of the Protecting Access to Medicare Act ("PAMA") of 2014. Like CMS, the CAP seeks to minimize disruption to the laboratory community and ensure the ongoing provision of laboratory services to Medicare beneficiaries. However, the CAP and many other stakeholder groups have identified flaws in PAMA's underlying data collection, including the CMS interpretation of the PAMA statute in regard to the definition of applicable laboratories subject to data reporting.

Specifically, the CMS states that the data used to calculate the CY 2018 Clinical Laboratory Fee Schedule (CLFS) rates was "sufficient and resulted in accurate weighted medians of private payor rates." Yet the CMS' definition of the term "applicable laboratory" continues to exclude the overwhelming majority of hospital laboratories. CMS' failure to include in payment reporting such a large portion of the laboratory market results in a skewing of the PAMA payment rates to reflect a disproportionate weighting of large commercial clinical laboratories. As we have continually expressed to CMS, the CAP is significantly concerned about the impact this will have on quality patient care and access to medically necessary laboratory testing. The CAP believes that more complete data collection is necessary to increase the accuracy of the resulting rates.

We appreciate the CMS' willingness to evaluate policies that could lead to including a greater representation of the laboratory market for the next data reporting period. While immediate action is needed to address the harmful cuts to the CLFS that are now in effect, the CAP here provides specific comments on the majority of Medicare revenues threshold, other approaches to defining applicable laboratories, and the low expenditure threshold. We urge CMS to make the PAMA methodology changes necessary to include all segments of the industry, thereby ensuring more accurate PAMA rates and continued access to laboratory tests for Medicare patients.

<u>Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory</u>

PAMA defines the term "applicable laboratory" to mean *a laboratory* that receives a majority of its Medicare revenues from CLFS payments or physician fee schedule (PFS) payments. Despite the statutory definition, the CMS specified an applicable laboratory in such a way that it may be determined based on the Medicare revenues from the aforementioned sources of the *entire organization*, including non-laboratory operations. These extra, non-laboratory revenues dilute the significance of CLFS and PFS laboratory revenues as compared to the entity's entire Medicare revenues, which thus excludes laboratories that would otherwise be included in the data collection.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

The CAP appreciates CMS proposing a change to the majority of Medicare revenues threshold, but PAMA data will not meaningfully reflect market rates for clinical laboratory services as long as CMS is basing the majority of Medicare revenues on the collective amount of an entire organization's Medicare revenues, for the reasons explained above. In particular, despite the CMS' efforts to account for hospital outreach laboratories in the new CLFS payment rates, the current approach continues to deny CMS access to data from these laboratories, which are vital for accurate payment rates. For example, where a hospital outreach laboratory shares a national provider identification number (NPI) with the overall hospital, the majority of Medicare revenues calculation means these laboratories are likely still excluded from data reporting. The CMS' suggestion that hospital outreach laboratories are assigned a "unique NPI, separate from the hospital of which it is a part" is not reflected in the reality that fewer than two dozen hospital laboratories were permitted to report payment data under the most recent data collection period. Unless this issue is addressed, CMS will not capture data for an essential segment of laboratory services and it will continue to undermine the accuracy of its calculations and future reimbursements for these and all other laboratories providing clinical laboratory services. The full range of payment data, including from hospitals, must be included.

With that said, the CAP supports the proposed change to exclude Medicare Advantage (MA) plan revenues from total Medicare revenues, and therefore include more laboratories in the definition of applicable laboratory. As we continue to emphasize, it is critical that CMS ensure data is collected from all segments of the industry, and this move is a step in that direction, though only a partial solution.

Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

While we acknowledge CMS' earlier willingness to address concerns related to the NPI over the Taxpayer Identification Number (TIN) for purposes of an applicable laboratory, the reality of the current approach is that a significant number of hospital laboratories are still excluded. Specifically, because most hospital outreach laboratories bill under the NPI used by the entire hospital, as expressed above, this criterion excludes the private payment rates received by a large segment of the nation's laboratories and skews the resulting reimbursement calculation. Appropriately calculating the majority of Medicare revenues threshold, or an alternative approach, is necessary to better ensure the appropriate number and type of laboratories reporting private sector data for use in calculating PAMA rates.

Further, in finding a balance between collecting enough private payor rate data and limiting the administrative burden on laboratories, the CAP also encourages CMS to explore options to collect applicable information from a randomly selected and statistically valid subset of applicable laboratories – including hospitals, large independent laboratories, small independent laboratories, and physician office laboratories – and use the information reported to determine Medicare rates for subsequent data collection periods.

The CAP also welcomes discussion on the approaches outlined in the proposed rule, including using Form CMS-1450 14x bill type and defining the term "laboratory" as a facility identified by a Clinical Laboratory Improvement Amendments (CLIA) number. However, the CAP believes the CLIA option would be a considerably more complex approach.

Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

Acknowledging the burden on all laboratories subject to the reporting requirement, the CAP supports reducing the low expenditure threshold by 50 percent so that private payor data from additional physician office laboratories is not excluded from weighted median calculations. Further, a shortened data collection period (for example, 90 days) would help alleviate some of the administrative burden.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

6) Merit-Based Incentive Payment System (MIPS) Proposals

The CAP is looking forward to continuing our engagement with the CMS on elucidating the challenges of the Merit-Based Incentive Payment System (MIPS) in order to determine how to appropriately measure providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. Through the years, the CAP has advocated to increase flexibility for pathologists in a way that recognizes and accounts for the value pathologists play in patient care as non-patient-facing clinicians in an inherently patient-facing program. The CAP continues to believe considerable accommodations or alternate measures are necessary to meet this clause[1] in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments on the Quality Payment Program (QPP), specifically on MIPS.

While there are several subjects from the proposed rule that the CAP has included in its comments below, we would like to **emphasize that we are in strong opposition of the CMS proposal to make available Qualified Clinical Data Registry (QCDR) measures for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.** The CAP asks that CMS support measure development by respecting and supporting the ownership rights of QCDR measure developers consistent with intellectual property rights. We also believe this proposal is an arbitrary and capricious reversal of the policy that CMS adopted just last year to protect the intellectual property rights of QCDR measure owners in violation of the Administrative Procedure Act and the U.S. Constitution.

Further, during the August 28 QCDR Vendor Support call and the August 30 2019 MIPS Self-Nomination call, CMS stated that QCDRs would be required to agree to license their QCDR measures as part of the 2019 Self-Nomination Application, even though the proposal is part of this Proposed Rule and not yet finalized. CMS also indicated that if we did not agree to the above during the 2019 QCDR Self Nomination Application process, then CMS would not accept those QCDR measures (see language below pulled from the August 28 Call Agenda as circulated by CMS):

One proposed component is that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. We also propose that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

The CAP is very concerned that CMS is making the licensing agreement a requirement for the 2019 QCDR Self-Nomination and before the CY 2019 Final Rule for the Quality Payment Program being posted. We strongly object to CMS's decision to require QCDRs, in their Self-Nomination Applications, to attest to willingness to license their QCDR measures to CMS while this

[1] 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.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

rulemaking is pending. QCDRs are put in the position of having to agree to what we believe to be an unlawful policy reversal and an unjustified taking of their intellectual property before the agency has finalized its proposal. It also exposes the irrationality of proposing to make the new policy effective for the 2021 MIPS payment year, which essentially requires the unlawful policy to be implemented in 2019. At a minimum, QCDRs should only be required to make the licensure attestation if and when the proposed rule is finalized. However, it would make much more sense for CMS to delay the effective date of the proposal at least one year to allow a fuller discussion of the concerns expressed about the new policy and to give QCDRs a meaningful opportunity to decide whether they want to participate in a program that forces them to give up effective control over their QCDR measures.

The CAP understands that having multiple QCDRs report on the same QCDR measure allows CMS to collect a larger pool of measures, which statistically helps establish more reliable benchmarks and a wider performance range. However, this approach disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease-, condition-, procedure-, or therapy-specific patient populations.

The CAP and other medical societies devote extensive resources to measure development, data collection, and data validation. The data collected through QCDRs are used not only for MIPS reporting, but also for research and analysis used to support guideline development and quality initiatives. Allowing CMS to permit any QCDR to report another QCDR's measures would place a significant strain on QCDR and medical specialty staff as any data collected from an outside source would have to be subject to the same extensive quality review process prior to use for research.

CMS should not finalize the requirement that QCDRs permit CMS to allow another QCDR to submit data on the first QCDR's measure. CMS must keep in mind that the QCDR reporting mechanism allows QCDRs to develop their own quality measures for use in the MIPS program. QCDRs should not be required to license a measure from another QCDR in lieu of developing their own measure.

QCDR measures clearly constitute works of authorship that are subject to copyright protection. CMS has already acknowledged this fact in its decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner. Even the proposed rule recognizes that CMS must have a license from QCDRs to sublicense those measures to other QCDRs. The problem is the proposal requires QCDRs to give CMS a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval. This radical reversal of CMS's existing policy violates both judicial and agency judicial precedent.

Specialty societies including the CAP have made significant financial, staff and member volunteer investments with regard to measure development and creation of QCDRs to support physicians participating in MIPS. This has included significant resources on the CAP's part for measure development of $100,000 - $150,000 per measure and $5 million for the creation of the Pathologists Quality Registry. **The CAP strongly believes that it is beyond CMS' mandate to require that our investments in measure development and the Pathologists Quality Registry be nullified by making our QCDR measures available to others without a fee.** Specialty societies including the CAP would have been hard pressed to put in millions of dollars in resources, if others could benefit -- purely for profit --from our investments. Moreover, if CMS finalizes this proposal, it would prohibit the CAP and other specialty societies from developing measures in the future that are much needed for quality improvement programs such as MIPS.

The CAP highlights the following comments for CMS' reference, including expanding on proposals related to QCDRs:

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

1. **Proposals related to Qualified Clinical Data Registries (QCDRs):** The CAP asks that CMS support measure development by respecting and promoting the ownership rights of QCDR measure developers consistent with intellectual property rights. CMS is currently proposing that, as a condition of a QCDR measure's approval for purposes of MIPS, QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS, beginning with the 2021 MIPS payment year. Our understanding is that, should this proposal be adopted, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

   The CAP strongly opposes this proposal because it undermines QCDR measure ownership and development. The ability of QCDRs to license measures incentivizes organizations to invest in developing new and improved measures, and is crucial to ensure users respect the intellectual property rights of measure developers. Medical societies have invested a tremendous amount of time and money into developing viable platforms and valid measures—a single measure takes a minimum of one year to develop and additional time to test. Testing new measures is also extremely expensive, and several medical specialties have made this investment in order to aid their clinician members. However, without the ability to license measures and collect royalties to offset the cost of developing measures, QCDR measure owners have no way to control the appropriate use of their measures and cannot responsibly invest in measure development.

   The CAP agrees with comments from the Physician Clinical Registry Coalition (PCRC) and urges CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require third parties to enter into licensing agreements with measure owners before they can properly use QCDR measures. The CAP and the PCRC would like to work with CMS to create safeguards to protect the proper implementation of these measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

2. **Removal of three of the eight pathology QPP measures:** The CAP strongly opposes the CMS proposal to retire three of the eight current QPP pathology measures developed by the CAP for the Quality category. These measures are:

   Measure #99 – Breast Cancer Resection Pathology Reporting
   Measure #100 – Colorectal Cancer Resection Pathology Reporting
   Measure #251 - Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

   Removal of these measures will leave pathologists with only five QPP measures whereas the CMS requirement is to report on a minimum of six quality measures. This will significantly hinder successful participation by pathologists in the Quality category. Further, removal of these measures is counter to the CMS' previously finalized topped out measure removal policy where CMS proposes to remove a measure via the notice and rulemaking cycle if it is designated as topped out for three consecutive years. The CAP also believes that topped out designations for measures are based on flawed benchmarks. QPP measure benchmarks are based on historical Physician Quality Reporting System (PQRS) data. PQRS was not a performance-based program and thus it is likely that benchmarks for measures were higher for PQRS than they would be for performance-based MIPS resulting in artificially high benchmarks for QPP measures. We do not believe that CMS should define

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

measures as topped out based on historical benchmarks derived from PQRS. Finally, Measure #251 (IHC HER2 Testing for Breast Cancer Patients) has had updates in guidelines recently and thus the existing performance data on this measure is not valid so it is not possible to know whether the measure is topped out. **For these reasons, the CAP asks that CMS not finalize its proposal to remove three of the eight pathology QPP measures.**

3. **MIPS Performance Feedback and Payment Adjustments:** CMS recently released 2017 MIPS performance feedback to eligible clinicians and groups. The CAP was disappointed to note that the maximum upward adjustment for 2019 will be +2.02% for individuals and practices who scored 100 points and this includes the adjustment for the exceptional performance bonus. This is especially challenging as physicians have put in an enormous amount of resources and efforts in order to comply with MIPS and with the ever-changing requirements of the program. Many of our members have expressed that the time and resources required to be successful for full participation in MIPS is in stark contrast to the return in investment. The CAP asks that CMS release the scaling factor used to determine the payment adjustments and ensure budget neutrality. The CAP understands that budget neutrality is mandated in the statute. However, we ask that CMS be transparent in how payment adjustments are determined. Further, the CAP members have indicated that performance feedback has been confusing and incomplete. The CAP encourages the CMS to indicate clearly how the quality measures submitted count towards the final score. We also ask that CMS make available beneficiary level data for cost measures as it did in the Quality and Resource Use Reports (QRUR) for the Value Based Modifier (VBM).

   The CAP encourages CMS to provide real time feedback to ECs as they submit MIPS data. At the very least, the CAP requests that feedback be made available at least quarterly on all four MIPS categories, but that more frequent feedback would contribute the most to performance improvement and allow ECs to adjust their practice. The CAP encourages the CMS to make the reports easier to access and more relevant for non-patient facing specialties.

4. **Attribution to the Medicare Spending Per Beneficiary (MSPB) cost measure:** CMS has acknowledged that many patient-facing and non-patient-facing MIPS ECs may not have sufficient measures and activities available to report and would not be scored on this category. Based on this, the CAP has generally believed that it would be hard to attribute pathologists to the Total Per Capita Cost (TPCC) and the Medicare Spending Per Beneficiary (MSPB) cost measures based on the CMS' attribution mechanisms. However, based on 2017 MIPS performance feedback, the CAP has learned that there was at least one pathology group practice that was attributed to the MSPB measure. Since the MSPB measure is attributed to the provider who provides plurality of Medicare Part B services, as measured by Medicare standardized allowed amounts, during an MSPB episode's index admission, we are struggling to understand how a pathology group could have provided the plurality of services compared to other providers during the episode. Since CMS has not provided beneficiary level data for the cost measures in 2017, it is difficult to determine how exactly the pathologists were attributed. We ask that CMS make available beneficiary level data on cost measures that can provide an opportunity for clinicians to improve and to learn how they were attributed to the cost measures.

   Moreover, while pathologists routinely contribute to team-based care, the CAP does not believe it is appropriate to attribute them to the MSPB measure under the current methodology. The CAP feels that until appropriate measures are developed,

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

pathologists as non-patient facing clinicians should be excluded from this category or alternatively, certain laboratory specific codes be excluded from the attribution calculation.

5. **Facility-based scoring:** The CAP supports the CMS proposal to allow facility-based measurement based on the Hospital Value Based Purchasing (VBP) program starting with the 2019 MIPS performance period. However, the CAP asks that the CMS not automatically apply facility-based scoring to MIPS eligible clinicians and groups who qualify. Instead, the CAP believes that ECs who are eligible to utilize facility-based measures should be able to voluntarily opt into the program via attestation instead of opting out. The opt in option would allow ECs full control over their MIPS submission and score and allow them to choose to either report MIPS measures and activities or choose to use their facility-based score instead. The CAP also encourages CMS to allow facility-based clinicians to get credit for the PI category via their hospital's Meaningful Use (MU) program as outlined further in our comments below.

   We support the proposed definition of facility-based clinicians as those physicians who perform 75 percent or more of their services in inpatient (Place of Service or POS 21), on-campus outpatient (POS 22) or emergency room (POS 23) settings, and have at least one service billed with the POS code used for inpatient (POS 21) or emergency room (POS 23). The CAP believes the modified definition that includes outpatient settings will capture significantly more pathologists as facility-based clinicians. The CAP asks that the CMS conduct a similar analysis of pathologists as it did of the number of anesthesiologists that would meet the definition of facility-based clinicians. We encourage CMS to provide as much information as possible to ECs to allow them to opt into this option, including whether they meet the facility-based definition and their potential facility-based scores before the data submission period. The CMS could accomplish this via its QPP participation look-up tool.

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

MIPS Program Details

The CAP strongly opposes the CMS proposal to retire three of the eight current QPP pathology measures developed by the CAP for the Quality category. These measures are:

- Measure #99 – Breast Cancer Resection Pathology Reporting
- Measure #100 – Colorectal Cancer Resection Pathology Reporting
- Measure #251 - Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

Removal of these measures will leave pathologists with only five QPP measures whereas the CMS requirement is to report on a minimum of six quality measures. This will significantly hinder successful participation by pathologists in the Quality category. In addition, removal of these measures in conflict with CMS' previously finalized policies for removal of topped out measures. In the 2018 QPP Final Rule, CMS finalized a four-year timeline for identifying and proposing to remove topped out measures. This timeline allows CMS to identify a measure as topped out for three consecutive years, and propose to remove the measure through comment and rulemaking for the fourth year. In the fourth year, if finalized through rulemaking, CMS would remove the measure and it would no longer be available for reporting. The CAP was in strong favor of this 2018 finalized rule as it allowed for better transparency and measure development planning. However, in this proposed rule CMS is proposing to remove three of the eight pathology measures going counter to its previously finalized topped out measure timeline.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

Also, of note, Measure #251 (IHC HER2 Testing for Breast Cancer Patients) has had updates in guidelines recently and thus the existing performance data on this measure is not valid so it is not possible to know whether the measure is topped out.

Further, the CAP believes that the topped out status of these measures is based on flawed benchmarks. The CMS uses different benchmarking methodologies for MIPS and for Physician Compare. An eligible clinician might look like a high performer under one methodology, but a low performer under a different methodology. We also have concerns that the methodology does not accurately reflect performance because the benchmarks are based on data from a small number of clinicians and are based on various legacy programs such as the Physician Quality Reporting System (PQRS) which did not measure performance. Additionally, there are several differences between MIPS and PQRS that would result in flawed benchmarks for MIPS based on historical PQRS data. Since CMS designates topped out measures based on these benchmarks, the CAP believes that many topped out measures may not be actually topped out. **We encourage CMS to create more meaningful and accurate benchmarks and to not remove topped out measures based on inaccurate benchmarks. The CAP also encourages the CMS to work closely with specialty societies, such as the CAP, before removal of measures to accurately assess the impact of measure removal.**

Another disadvantage pathologists face in the Quality category of MIPS is that none of the CAP measures are designated as outcomes measures. While pathology does not fit into the current definition of outcomes as defined by the CMS, the CAP believes that the rendering of a timely, accurate and complete diagnosis is a patient related outcome and we encourage CMS to expand the definition of outcomes measures. As a diagnostic specialty, pathology contributes to understanding the patient's condition; thereby enabling patients and the clinical team to make appropriate medical care decisions. The diagnosis and all the steps needed to reach it are critical and provide a basis for important clinical and patient outcomes. Previously, CMS had designated the following measures as outcomes measures:

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

However, CMS summarily changed the designation of the above measures from outcome to high priority without appropriate notice and explanation. **The CAP asks that the CMS once again designate these measures as outcomes measures to allow pathologists the opportunity to score bonus points by reporting additional outcomes measures and be able to maximize their score in the Quality category.** Alternatively, CMS should allow additional high priority measures to score 2 bonus points (same as additional outcome measures) so as not to disadvantage those clinicians who have high priority measures available but not outcome measures.

<u>Low-Volume Threshold (p. 514)</u>

The CAP supports the CMS proposals to amend the definition of the low-volume threshold to implement the Bipartisan Budget Act of 2018. Specifically, for the 2020 MIPS payment year, the CMS will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group. The CAP believes this will reduce burden by excluding more clinicians.

The CMS is proposing to add a third criterion to determine the low-volume threshold. The CMS is proposing to exclude those individual ECs or groups that provide 200 or fewer covered professional

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

services under the Physician Fee Schedule (PFS). This is in addition to the previous two criteria to exclude individual ECs or groups who have allowed charges for covered professional services less than or equal to $90,000 or who provide covered professional services to 200 or fewer Part B-enrolled Medicare beneficiaries. The CAP encourages CMS to finalize this proposal as it will reduce burden and will help mitigate adverse effects on solo and small practices.

The CAP supports the CMS proposal to allow clinicians or groups to opt-in to MIPS if they meet or exceed one or two, but not all, of the low-volume threshold criterion. Many clinicians have invested significant resources towards being able to comply with MIPS; they should have the opportunity to benefit from upward MIPS adjustments. The CAP believes that CMS should provide as much support as possible for these ECs and not discourage them from participating in the program. The CAP also asks CMS to clarify if the agency will increase, decrease, or keep the low-volume threshold at the current level for future years of MIPS. Especially if CMS plans to gradually decrease the low-volume threshold in the future, the voluntary opt-in policy will help ECs prepare for MIPS participation in the coming years. The CAP also asks CMS to clarify whether the data submitted by those clinicians who are not eligible but voluntarily report for MIPS will be used for benchmarking purposes.

MIPS Performance Category Measures and Activities (p. 541)

a. Performance Category Measures and Reporting

The CMS is proposing to revise existing and define additional terminology:

- Collection type as a set of quality measures with comparable specifications and data completeness criteria including, as applicable: electronic clinical quality measures (eCQMs); MIPS clinical quality measures (CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures; the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey measure; and administrative claims measures.
- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities.
- Submission type as the mechanism by which the submitter type submits data to CMS, including, as applicable: direct, log in and upload, log in and attest, Medicare Part B claims, and the CMS Web Interface. There is no submission type for cost data because the data is only submitted for payment purposes.

While the CAP appreciates the CMS attempt to clarify these terms by revising existing terminology, we believe that it will cause unnecessary confusion among clinicians as they try to keep up with the other changes in an already cumbersome program. As such, the CAP urges CMS to keep existing definitions to which clinicians are already accustomed.

While the CAP is pleased that the CMS has proposed to expand the Medicare Part B claims collection type to small practices for group reporting, the CAP disagrees with the CMS proposal to limit claims-based reporting to those individuals and groups in small practices defined as 15 or fewer clinicians. This significantly limits the availability of Medicare Part B claims measures for pathologists who are in large practices and reporting as individuals as they will not be able to utilize this reporting option. **We urge CMS to maintain all existing collection types, including claims for all individual clinicians regardless of their practice size.**

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

The CMS is proposing to allow individual MIPS eligible clinicians and groups to submit a single measure via multiple collection types (e.g. MIPS CQMs, QCDR measures, and Medicare Part B claims measures). The CMS will score the individual ECs or groups on the data submission with the highest score. The CAP supports this proposal and believes that this will provide much needed flexibility to clinicians without undue complexity and provide an opportunity for clinicians to maximize their MIPS score.

b. Quality Performance Category (p. 549)

The CAP is disappointed that the CMS has maintained an absolute minimum number of measures that ECs have to report, especially in light of the CMS proposal to remove three of the eight pathology QPP measures, potentially leaving pathologists with only five QPP measures from which to choose. The CAP recommends that CMS not require a minimum number of measures that an EC should report. The current measures list is insufficient to cover all practice types, and the challenge of participating will only be exacerbated by imposition of a minimum number of measures and the removal of three pathology measures. The measure development process is difficult and requires numerous resources that many specialties do not have readily available. In addition, the turnover of measures due to changing guidelines adds to the challenge of maintaining a selection of appropriate measures that may be used by the many specialties and sub-specialties.

The CAP also encourages CMS to publish additional guidance on the Eligible Measure Applicability (EMA) process that determines the number of measures a physician should have reported on when a physician reported on less than the required six quality measures or did not submit an outcome or high priority measure in the quality category of MIPS. The CAP previously provided feedback on the pathology clinical clusters that CMS had drafted for the EMA process. We identified two pathology clinical clusters for claims data submission mechanism:

Quality ID	Outcome/ High Priority	Quality Measure Title
99	N/A	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
100	N/A	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
249	N/A	Barrett's Esophagus
250	N/A	Radical Prostatectomy Pathology Reporting
251	N/A	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

AND

395	Outcome	Lung Cancer Reporting (Biopsy/ Cytology Specimens)

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

396	Outcome	Lung Cancer Reporting (Resection Specimens)

We also identified two pathology clusters for registry data submission mechanism:

Quality ID	Outcome/ High Priority	Quality Measure Title
99	N/A	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
251	N/A	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

AND

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

While these clusters may appear related in scope, due to diverse practice settings and case mixes the proposed clusters would likely negatively impact many pathologists and/or practices that simply do not examine specimens that pertain to all the clustered measures and therefore would be unable to report on one or more of the clustered measures. In other words, just because a pathologist can report on one measure, does not indicate he/she can report on the others. **The CAP asks that CMS SHOULD NOT include these clusters as part of the EMA process.**

- Case Example: If a pathologist is performing measure 99 (Breast Cancer Resection Pathology Reporting) in the claims data submission, it does not mean that he/she could also report on measure 100 (Colorectal Cancer Resection Pathology Reporting) which is in the same cluster. This pathologist would be unfairly penalized under the EMA methodology using this cluster.
- Case Example: A practice may primarily receive biopsy type specimens and no cancer resections. In this example, the group could possibly report on measure 395 but would be unable to report on measure 396 because they do not handle lung cancer resection cases. This group would then be unfairly penalized under EMA methodology using these clusters.

Further, the Lung Cancer Reporting (Biopsy/Cytology Specimens) and the Lung Cancer Reporting (Resection Specimens) are listed as outcomes measures in the EMA materials in the CMS resource center. However, these measures are not listed as outcomes measures on the CMS QPP website. We ask that CMS update its materials to be consistent as to reduce confusion among pathologists looking for guidance on which measures to report.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

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

c. Cost Performance Category (p. 564)

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

However, based on 2017 MIPS performance feedback, the CAP has learned that there was at least one pathology group practice that was attributed to the MSPB measure. The MSPB measure is calculated by CMS to assess costs during episodes of care initiated by acute inpatient hospital stays. It includes the cost of Medicare Part A and B services 3 days before and 30 days after an Inpatient Prospective Payment System (IPPS) hospital admission. The MSPB measure is calculated based on all Medicare Parts A and B final action claims during the performance period, including: inpatient hospital; outpatient; skilled nursing facility; home health; hospice; durable medical equipment, prosthetics, orthotics, and supplies; and Medicare Part B Carrier (non-institutional Physician/Supplier) claims. It's attributed to the provider who provides plurality (largest share of costs) of Medicare Part B services, as measured by Medicare standardized allowed amounts, during an MSPB episode's index admission (the period between admission date and discharge date of the hospital stay, inclusive). The case minimum is 35.

Since the MSPB measure is attributed to the provider who provides plurality of Medicare Part B services, we are struggling to understand how a pathology group could have provided the plurality of services compared to other providers during the episode. Since CMS has not provided beneficiary level data for the cost measures in 2017, it is difficult to determine how exactly the pathologists were attributed. We ask that CMS make available beneficiary level data on cost measures that can provide an opportunity for clinicians to improve and to learn how exactly they were attributed to cost measures.

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

d. Improvement Activities Performance Category (p. 581)

The CAP appreciates our ongoing and productive collaboration with the CMS regarding the Improvement Activities (IA) category and the CMS' recognition that non-patient-facing MIPS ECs and groups will have a limited number of measures and activities to report in this category. The pathologist specific IA guidance that the CAP has worked with CMS to provide

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

for its members is invaluable and will go a long way in educating pathologists on this category and activities.

We appreciate CMS' continued proposal to allow non-patient-facing ECs 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.

e. Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category) (p. 604)

The CAP appreciates that CMS acknowledges the importance of interoperability and health information exchange by changing the name of the Advancing Care Information performance category of MIPS to the Promoting Interoperability (PI) performance category which now aligns with the Medicare and Medicaid's Promoting Interoperability (PI) Program, formally known as the "Meaningful Use" (MU) program. The CAP encourages alignment across the MIPS Promoting Interoperability performance category and PI Program, including efforts that would streamline the requirements across healthcare settings.

The CAP appreciates the CMS' recognition that many of the measures proposed under the PI performance category require face-to-face interaction with patients and that sufficient measures are not applicable to non-patient-facing MIPS ECs.

Most pathologists can currently only participate in two of the four categories of MIPS. This means that 85% of the MIPS final score for pathologists is based on quality measures which places a disproportionate amount of weight on that category for these ECs. While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists that recognize their efforts in promoting the electronic exchange of health information, while ensuring their participation in the PI category is not administratively burdensome.

MIPS Final Score Methodology (p. 710)

The CAP appreciates the consideration the CMS gave to non-patient-facing specialties in all of the categories but in particular to the IA requirements of requiring only two activities. The CAP encourages the CMS to keep the requirements minimal for non-patient-facing specialties until they can ensure there are enough activities applicable to these specialties, especially since a majority of pathologists are not able to participate in Cost and PI categories at this time.

a. Converting Measures and Activities into Performance Category Scores (p. 710)

Quality Measure Benchmarks (p. 713)

The CAP does not believe that the CMS benchmarks are accurate. We urge CMS to reconcile the differences between the MIPS and Physician Compare benchmarking methodologies. An eligible clinician might look like a high performer under one methodology, but a low performer under a different methodology. We also have concerns that the methodology does not accurately reflect performance because the benchmarks are based on data from a small number of clinicians and are based on various legacy programs such as the Physician Quality Reporting System (PQRS) which did not measure performance. Additionally, there are several differences between MIPS and PQRS that would result in flawed benchmarks for MIPS based on historical PQRS data. Since CMS designates topped

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

out measures based on these benchmarks, the CAP believes that many topped out measures may not be actually topped out. We encourage CMS to create more meaningful and accurate benchmarks and to not remove topped out measures based on inaccurate benchmarks.

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements (p. 718)

The CAP also opposes scoring of measures that do not meet the minimum case number criteria or do not have benchmarks at 3 points and the scoring of measures that do not meet the data completeness criteria at 1 point. The CAP encourages CMS to raise the points available for these measures. ECs should not be penalized if they successfully meet the quality requirements of a measure just because they may have fewer than the minimum case number and data completeness required or if the measure does not have a benchmark. Capping the score of those measures who do not have benchmarks at 3 points strongly discourages ECs from reporting on those measures, which results in a lack of benchmark in subsequent years as well. The CAP asks that CMS encourage clinicians to report on measures without benchmarks by providing incentives, such as not capping measures without benchmarks to 3 points. This would encourage reporting of these measures so that an appropriate amount of data can be gathered in order to create benchmarks.

The CAP strongly opposes the CMS proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period. This would create undue burden on pathologists struggling to meet the requirements of an ever-changing program.

Small Practice Bonus (p. 724)

While the CAP supports the small practice bonus for MIPS ECs who are in small practices with 15 or fewer ECs, the CAP does not agree with the CMS proposal to transition the bonus to the Quality category instead of the overall MIPS score. The CAP also opposes the CMS proposal to lower the bonus points from five points added to the final score to three points added to the Quality category. The CAP believes that this bonus is important in mitigating the disproportionate negative impact on solo and small practices in which many pathologists practice. This bonus goes a long way in encouraging small practices to participate in MIPS and to do so successfully. Therefore, the CAP asks that the CMS continue to award 5 bonus points to the MIPS final score of small practices.

Incentives to Use CEHRT to Support Quality Performance Category Submissions (p. 728)

CMS proposes to continue to assign 1 bonus point for each quality measure submitted with end-to-end electronic reporting via CEHRT. The CAP asks that this bonus also be made available to quality measures reported via a Qualified Clinical Data Registry (QCDR) so as not to disadvantage those clinicians that do not have a CEHRT available but are utilizing alternative electronic reporting.

Facility-Based Measures Scoring Option (p. 740)

The CAP supports the CMS proposal to allow facility-based measurement based on the Hospital Value Based Purchasing (VBP) program starting with the 2019 MIPS performance period. However, the CAP asks that the CMS not automatically apply facility-based scoring to MIPS eligible clinicians and groups who qualify and would benefit by having the facility-

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

based score for their quality and cost performance, as long as they submit data under the IA or Promoting Interoperability PI categories. Instead, the CAP believes that ECs who are eligible to utilize facility-based measures should be able to voluntarily opt into the program via attestation instead of opting out. The opt in option would allow ECs full control over their MIPS submission and score and allow them to choose to either report MIPS measures and activities or choose to use their facility-based score instead.

The CAP also encourages CMS to allow facility-based clinicians to get credit for the PI category via their hospital's Meaningful Use (MU) program. This is consistent with the CMS' policy as outlined in the Hospital Inpatient Prospective Payment System (IPPS), to which the CAP submitted comments earlier in 2018. The CAP encourages alignment across the MIPS PI category and the hospital PI program, including efforts that would streamline the requirements across healthcare settings. While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists to engage. One possible solution would be to allow facility-based eligible clinicians such as pathologists to earn points in the PI category of MIPS through their hospital's participation in the PI program. Laboratory testing and pathology diagnostic information are without question a key influence on health care decision making. Thus, allowing a pathway for facility-based pathologists to earn points for supporting hospitals that meet PI program requirements would recognize the important role pathologists play in diagnosis and management of patient health care. It would support facility-based MIPS eligible pathologists' efforts in promoting the electronic exchange of health information across Laboratory Information Systems (LISs) and hospital Electronic Health Records (EHRs), while ensuring their participation in the PI category is not administratively burdensome.

We support the proposed definition of facility-based clinicians as those physicians who perform 75 percent or more of their services in inpatient (Place of Service or POS 21), on-campus outpatient (POS 22) or emergency room (POS 23) settings, and have at least one service billed with the POS code used for inpatient (POS 21) or emergency room (POS 23). For groups, 75 percent or more of the National Provider Identifiers (NPIs) billing under the group's Tax Identification Number (TIN) must be eligible for facility-based measurement as individuals. The CAP believes the modified definition that includes outpatient settings will capture significantly more pathologists as facility-based clinicians. In this proposed rule, the CMS has presented an analysis of the number of anesthesiologists who would meet the previous definition of facility-based clinicians versus the number who would meet the proposed definition that includes POS 22. The CAP asks that the CMS conduct a similar analysis of pathologists. We encourage CMS to provide as much information as possible to ECs to allow them to opt into this option, including whether they meet the facility-based definition and their potential facility-based scores before the data submission period. The CMS could accomplish this via its QPP participation look-up tool.

CMS is proposing to use the facility-based score to determine the MIPS quality and cost performance category scores, unless CMS receives another submission of quality data for that clinician or group and that combined quality and cost category score for the other submission results in a higher combined quality and cost performance score. If the other submission has a higher combined quality and cost score, then CMS would not apply the facility-based scores for either the quality or cost categories. The CAP asks for clarification on how CMS would score a facility-based clinician who submits data on quality but does not have a cost score and thus that clinician's cost category score is reweighted to the quality category. We ask CMS to clarify whether that clinician would receive a facility-based cost

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

score or if that clinician's reweighted quality score would count as a combined quality and cost score.

b. Calculating the Final Score (p. 767)

Redistributing Performance Category Weights (p. 784)

The CMS has proposed that if a MIPS EC does not receive an PI category score, to reassign the weight of the PI category to the Quality performance category or to both the Quality and IA performance categories.

CMS' current reweighting policies place undue weight on the Quality category. **Hence, we ask that ECs who cannot be scored for the PI performance category should have their PI score reweighted to the IA category, so that the IA category is weighted at 40% and the Quality category remains at 60% if an EC is not scored in cost and PI.** Alternatively, we ask that CMS finalize its alternate proposal to redistribute the weight of the PI category to both the quality and IA categories such that the Quality category is weighted at 70% and the IA category is weighted at 30% if an EC is not scored in cost and PI. CMS has summarized these alternate reweighting proposals in the proposed rule in Table 52: Alternative Performance Category Redistribution Policies Considered for the 2021 MIPS Payment Year. The CAP strongly encourages CMS to adopt alternate reweighting policies to help in mitigating the impact of the Quality category on the final score.

<u>Proposals related to Qualified Clinical Data Registries (QCDRs)</u>

a. Proposed Update to the Definition of a QCDR (p.822)

The Proposed Rule would modify the definition of a QCDR at 42 C.F.R. § 414.1305 to require that an approved QCDR have clinical expertise in medicine and quality measure development beginning with the 2022 MIPS payment year. Under this proposal, entities may also meet this definition through a signed, written agreement with an external organization with expertise in medicine and quality measure development.

The CAP strongly supports this modification to the definition of QCDRs. We agree with CMS that entities without expertise in medicine and quality measure development do not satisfy the intent of QCDRs. These vendor-led registries do not have quality improvement or population health management as their primary purpose and do not have clinical expertise or in-depth understanding about quality measurement. Instead, they are created only for commercial purposes. For-profit companies, such as EHR vendors, do not appear to have any population health impact, as measured by published articles in the scientific peer-reviewed literature and practice guidelines for clinicians. As a result, we agree with CMS that approval of commercial QCDRs does not fulfill CMS' intent for the broad population health and public health use of QCDRs.

There are currently no assurances to practices participating in MIPS, or to the Medicare program, that EHR companies and other commercial organizations are able to interpret, extract and calculate the quality measures accurately. Commercial entities operating qualified registries and/or QCDRs are also at a greater risk of having increased inaccuracy due to their lack of operational experience with measure science. If measures are not used properly, CMS is not able to accurately assess the performance of physicians and reward

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

those with superior performance. As a result, provider payment may be based on the random process used by a particular QCDR to interpret the data.

We are also concerned that the problems of inaccurate use of measures by commercial QCDRs would be exacerbated by CMS's prior requests for harmonization of similar MIPS measures to allow for the broader use of measures developed by clinician-led QCDRs by other qualified registries and other non-clinician-led QCDRs, including commercial entities. While we understand that CMS's goal for this policy is to avoid redundant measures and facilitate cross-cutting comparisons, the real-world implementation of harmonized measures often yields incomparable results. There is no accountability for how commercial QCDRs report on the same measures and no standardization for how they use data. Registries with less expertise on how to accurately implement measures may employ different methods for risk adjusting data, obtaining data, and aggregating data, which creates variation in how providers are measured and how their care is classified. Often, clinician-led registries will develop clinical quality measures for use in MIPS and other commercial-led registries will report these measures but employ their own methodology for analyzing and interpreting the data. Therefore, given the inconsistencies in implementation and methods, harmonizing measures across registries does not ensure accurate benchmarking and is not always ideal. We urge CMS to review this misuse of measures by some vendors to ensure the integrity of the data and the quality of feedback to physicians as well as performance comparison.

For all these reasons, the CAP strongly recommends that CMS adopt its proposal to require an entity to have clinical expertise in medicine and quality measure development in order to become a QCDR.

b. Mandatory Licensing of Approved QCDR Measures (p. 829)

CMS proposes that, as a condition of a QCDR measure's approval for purposes of MIPS, QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS, beginning with the 2021 MIPS payment year. Our understanding is that, should this proposal be adopted, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

The CAP strongly opposes this proposal because it undermines QCDR measure ownership and development. The ability of QCDRs to license measures incentivizes organizations to invest in developing new and improved measures, and is crucial to ensure users respect the intellectual property rights of measure developers. In addition, the CAP is in strong opposition that CMS is making the licensing agreement a requirement for the 2019 QCDR Self-Nomination and before the CY 2019 Final Rule for the Quality Payment Program being posted. It is fundamentally unfair to require measure owners to grant a mandatory license to CMS even before the mandatory licensing proposal has been subject to notice and comment and final rulemaking.

CMS's mandatory licensing proposal raises serious issues under both the Administrative Procedure Act and the U.S. Constitution. If finalized as written, the proposal would violate the APA because it would represent arbitrary and capricious agency action. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."). Because the proposal strips away CAP's intellectual property rights without just compensation, it would also raise serious issues under the Fifth Amendment's takings clause. *See Horne v. Department of Agriculture,* 569 U.S. 513 (2015) (DOA requirement that raisin growers set aside a portion of their crops for government use violates Fifth Amendment's takings clause); *Ruckelshaus v. Monsanto Co.,* 467 U.S. 986 (1984) (mandatory data licensing imposed by EPA violated Fifth Amendment by disrupting pesticide manufacturer's trade secrets protections without just compensation).

Medical societies put in a tremendous and costly effort to develop valid measures—a single measure takes a minimum of one year to develop and require significant effort and time from physicians and society staff, and additional time to test, maintain, and implement. Testing new measures is also extremely expensive. Without the ability to license measures and collect royalties to offset the cost of developing measures, QCDR measure owners have no way to control the appropriate use of their measures and cannot responsibly invest in measure development.

If third parties can routinely use these measures and, in the case of commercial QCDRs, profit off of the societies' time and expense, medical societies may no longer be able to dedicate resources to developing QCDR measures. Without the contribution of medical societies, the measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance. In fact, many societies do assert copyright protection over the QCDR and QPP measures they develop. The copyright statements they affix to their measures usually prohibit commercial use of the measures. The goal is not to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures by limiting inappropriate use and preventing commercial entities from profiting off of the societies' intellectual property.

CMS's proposal also unjustifiably reverses the agency's decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner. In the CY 2018 final rule, CMS finalized its proposal, requiring assignment of QCDR measure IDs for all approved QCDR measures, and required QCDRs that have received permission to report the measure to use the same QCDR measure ID. CMS stated that it may request that a borrowing QCDR provide proof that it has received permission to use a QCDR measure owned by another QCDR. CMS also clarified that the borrowing QCDR must use the exact measure specification provided by the QCDR measure owner. CMS is now backtracking on this prior rule to protect the intellectual property rights of measure owners—as discussed above, this action would threaten quality measure development.

QCDR measures are subject to the same copyright protection as the American Medical Association's (AMA) Current Procedural Terminology (CPT) code. The AMA owns and collects royalties on the use of its CPT code set. This right was strongly affirmed by the Federal Court of Appeals for the Ninth Circuit in Practice Management Information Corporation v. American Medical Association (PMIC). From an intellectual property perspective, there is no meaningful distinction between the AMA's ownership of the CPT and QCDRs' ownership of their measures. Both require substantial time and resources to develop and qualify as original works of authorship equally subject to copyright and other intellectual property protections. CMS has always honored and supported the AMA's right to license and charge royalties for the use of the CPT Code even though it has been incorporated by the agency as an integral part of the Medicare reimbursement system. It should continue to do the same with QCDR performance measures.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

In fact, the PMIC court specifically held that the AMA's right to license the CPT code to other parties that needed access to the code was not nullified by the fact that the Medicare program had adopted the code as a significant part of its physician payment system. In doing so, it stated:

. . . copyrightability of the CPT provides the economic incentive for the AMA to produce and maintain the CPT. "To vitiate copyright, in such circumstances, could, without adequate justification, prove destructive of the copyright interest, in encouraging creativity," a matter of particular significance in this context because of "the increasing trend toward state and federal adoptions of model codes." As the AMA points out, invalidating its copyright on the ground that the CPT entered the public domain when HCFA [now CMS] required its use would expose copyrights on a wide range of privately authored model codes, standards, and reference works to invalidation. Non-profit organizations that develop these model codes and standards warn they will be unable to continue to do so if the codes and standards enter the public domain when adopted by a public agency.

The same principles apply to QCDR measures. The ability of QCDRs to license measures (and charge reasonable licensee fees or royalties) allows QCDRs to ensure the appropriate use of their measures and incentivizes organizations to invest in developing new and improved measures, and is crucial to ensuring users respect the intellectual property rights of measure developers. Medical societies put in a tremendous and costly effort to develop valid measures—a single measure takes a minimum of one year to develop requiring significant effort and time from physicians and society staff, and additional time to test, maintain, and implement. Testing new measures is also extremely expensive. Without the ability to license measures and collect reasonable royalties to offset the cost of developing measures, QCDR measure owners would have no way to control the appropriate use of their measures and cannot responsibly invest in measure development.

The PMIC court upheld the AMA's right to assert copyright protection in the CPT Code in part because there was no evidence that the AMA was limiting access to the code. The court reached this conclusion knowing full well that the AMA charged royalties for the use of the CPT code.

Similarly here, many societies justifiably assert copyright protection over the QCDR and QPP measures they develop. The copyright statements they affix to their measures usually prohibit commercial use of the measures. But, the goal is not to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures by limiting inappropriate use and preventing commercial entities from profiting off of the societies' intellectual property. There is no evidence that QCDRs are withholding access to their measures to qualified QCDRs—i.e., those who have clinical expertise and experience in measure development.

Thus, CMS's proposal to force QCDRs to license their measures to the agency without fee as a condition of approving such measures effectively nullifies the right of QCDRs to enforce their copyright in such measures and to collect a reasonable royalty from other qualified QCDRs that wish to use them. This policy conflicts with the agency's treatment of the CPT code and the PMIC court's clear affirmation of the AMA's rights to enforce its copyright in that code.

CMS has utterly failed to provide a rational explanation or evidence for this sudden reversal in its existing policy to protect the intellectual property rights of QCDR measure owners. The

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

general conclusion in the proposed rule that the existing policy is creating unintended burdens on QCDRs seeking to use the measures of other QCDRs is completely unsubstantiated. CMS provides no evidence that qualified QCDRs are being deprived access to approved QCDR measures. Nor does the agency make any attempt to consider the negative effects of reversing its existing policy. CMS also fails to consider any alternatives to the proposed policy change, such as requiring QCDRs to make their measures available to other qualified QCDRs intending to use the measures through license agreements that contain commercially reasonable terms, including reasonable royalties.

Based on the agency's failure to (a) provide any evidence to support its decision to adopt a radical policy change that violates the intellectual property rights of QCDR measure owners, (b) consider the negative effects of this policy reversal on the development of QCDR measures, and (c) consider reasonable alternatives, the proposed new policy is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

As noted above, there are much less intrusive options for ensuring that QCDR measures are widely available to all qualified QCDRs, especially if CMS finalizes its proposal to modify the QCDR criteria to ensure that all QCDRs have clinical expertise and experience in quality measures. However, if adopted as proposed, requiring QCDRs to license their QCDR measures to CMS without fee as a condition of approval of such measures for MIPS purposes would be patently unlawful.

We urge CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require other qualified QCDRs to enter into licensing agreements with measure owners (not CMS) before they can properly use QCDR measures. QCDRs must also be able to charge a reasonable fee for licenses to use their measures. We would like to work with CMS to create safeguards to protect the proper implementation of these measures and ensure that QCDRs can enforce their intellectual property rights in the measures they develop, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development. We would appreciate the opportunity to meet with CMS on this issue.

The CAP as consistent with comments from the Physician Clinical Registry Coalition (PCRC) urges CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop. The CAP and the PCRC would like to work with CMS to create safeguards to protect the proper implementation of these measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

c. Self-Nomination Process (p. 831)

The CAP agrees with the revisions of the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. While this will allow more time for building the measures in the QCDR, it does impact the life cycle of measure development and maintenance. Therefore, CMS should allow for a transition year for adjustments to measure development. If CMS does adopt these proposed changes to the self-nomination period, it is essential that the agency change its expectations for providing data for measures accordingly, as it is not feasible to have data to support a measure so early in the calendar year.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

Additionally, the CAP recognizes and appreciates that the CY 2018 proposed rule details a simplified self-nomination process where existing QCDRs in good standing can continue participating in MIPS by attesting that there are no changes from the previous year's MIPS performance period, or can go through an expedited review by only making changes where necessary. However, we still urge CMS to increase the length of QCDR approval from one to two years. Even with a simplified self-nomination process, it is still administratively burdensome to report changes on an annual basis. Many registries may not seek QCDR status because of the escalating administrative burden required to participate on a long-term basis. This result could stifle quality measure innovation, which was the premise for creating QCDRs in the first place.

Public Reporting on Physician Compare (p. 838)

As the CAP has stated in prior comments to the CMS, we believe that all ECs 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 implementation of MIPS. 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.

Summary

The CAP appreciates the opportunity to comment on this Proposed Rule. We look forward to continuing our conversation with CMS to establish appropriate pathways for pathologists to participate in MIPS. In summary, the CAP offers the following recommendations:

- The CAP urges CMS not to remove three of the eight pathology QPP measures in order to allow pathologists to have the required minimum number of six quality measures to report and to be consistent with the previously finalized four year topped out measure identification and removal timeline.
- The CAP asks that CMS provide accurate and meaningful performance feedback to clinicians and clarify how payment adjustments were calculated.
- The CAP requests that CMS exclude pathologists from the Cost MSPB measure as their attribution to this measure is not indicative of the pathologists' role in resource use. We also ask that CMS make available beneficiary level data on cost measures that can provide an opportunity for clinicians to improve.
- The CAP encourages CMS to make facility-based scoring an opt-in option instead of automatically attributing clinicians. We also ask that CMS conduct an analysis of the number of pathologists that would meet the definition of facility-based clinicians and that CMS notify clinicians of their facility-based status and their attributed facility MIPS score via the CMS QPP website and participation look-up tool.
- The CAP asks that CMS support measure development by respecting and supporting the ownership rights of QCDR measure developers consistent with intellectual property rights. We urge CMS to not require QCDR measures to be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

The CAP is in strong opposition to CMS calling for the licensing agreement a requirement for the 2019 QCDR Self-Nomination and before the CY 2019 Final Rule for the QPP is posted. We urge CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require other qualified QCDRs to enter into licensing agreements with measure owners (not CMS) before they can properly use QCDR measures. QCDRs must also be able to charge a reasonable fee for licenses to use their measures. We would like to work with CMS to create safeguards to protect the proper implementation of these measures and ensure that QCDRs can enforce their intellectual property rights in the measures they develop, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development. We would appreciate the opportunity to meet with CMS on this issue as soon as possible.

7) Advanced APMs and the All-Payer Combination Option

The CAP acknowledges CMS' interest in increasing availability and adoption of alternative payment models (APMs) and looks forward to the addition of new Advanced APMs under the Quality Payment Program, particularly where they afford an opportunity for participation for those specialists – including pathologists – who have not been able to participate meaningfully under existing models. 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. In fact, 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, of the Advanced APMs currently available under the Quality Payment Program, pathologists are only able to participate in at most three models, and only to a very limited extent. Even with the All-Payer Combination Option, physicians are not able to attain Qualifying APM Participant (QP) status without some participation in an Advanced APM within the Medicare program, where options remain limited.

Certainly, the fact that CMS has yet to take up any of the models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) demonstrates the complexity in creating appropriate physician-developed APMs as envisioned under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Yet physician input and buy-in is critical to effective delivery system reform. More innovative health care payment and delivery models must be developed in an open and transparent fashion with the input of those specialties impacted by the models.

To that end, the CAP appreciates the opportunity to comment on the CMS' proposals related to Medicare's Advanced APMs and the All-Payer Combination Option. Generally, we support those changes that facilitate more APMs achieving Advanced APM status and that provide additional opportunities for appropriately-developed physician focused payment models, especially those within Medicare where they stand to impact qualification for the Advanced APM pathway under the Quality Payment Program.

Use and Evidence of CEHRT in Advanced APMs

Pathology was one of the earliest specialties to embrace health information technology, utilizing computerized laboratory information systems (LIS) to support their work of analyzing patient specimens and generating test results. It is with an LIS that electronic health records (EHR) systems or enterprise-wide clinical information systems exchange laboratory and pathology data. However, most LIS cannot attain Certified EHR Technology (CEHRT) status, and, as non-patient facing clinicians, pathologists face unique challenges in meeting many of the typical EHR and health information technology requirements in both MIPS and the APM CHERT use thresholds. Generally, the CAP appreciates CMS' goal to encourage continued EHR and CEHRT adoption but urges CMS

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

to consider the contributions of diagnostic specialties in the exchange of electronic patient data, which is key in APMs' ability to effectively coordinate care.

Further, we are concerned that increasing the CEHRT use criterion for APMs to qualify as Advanced APMs will create additional barriers for Advanced APM participation. As mentioned above, opportunities for specialists to participate meaningfully in APMs under the Quality Payment Program are limited and any additional requirements that exacerbate the current environment should be avoided.

However, the CMS proposal to allow participants in Other Payer Advanced APMs to describe their compliance with CHERT requirements through relevant documentation, regardless of whether CEHRT use is explicitly required under the terms of the payment arrangement, is a helpful step. The CAP supports additional flexibility in validating these kinds of other payer arrangements (discussed further below), and we believe this proposal works towards that end.

Financial Risk

The CAP agrees with CMS that maintaining the generally applicable revenue-based nominal amount standard at eight percent is appropriate at this time for both Medicare Option Advanced APMs and Other Payer Advanced APMs. Currently, it is important to focus on increasing opportunity and incentives for specialty physician involvement in Advanced APM before unnecessarily pursuing increased financial risk. Additionally, as CMS highlights in this proposed rule, "maintaining a consistent standard for several more years will help APM Entities to plan for multi-year Advanced APM participation." For these reasons, we also believe the eight percent standard should not be increased for the foreseeable future.

Other Payer Advanced APMs and the All-Payer Combination Option

The CAP appreciates the CMS' efforts to factor Other Payer Advanced APMs into achievement of a participant's Advanced APM threshold. Other Payer Advanced APMs include alternative payment arrangements that are similar, but not identical, to Medicare's Advanced APMs, and may include Medicaid, Medicare Health Plans, payers in CMS multi-payer models, and commercial and other private payers. As the CMS notes, the All-Payer Combination Option allows eligible clinicians to become QPs through a combination of Advanced APM and Other Payer Advanced APM participation, and therefore this pathway represents a potentially valuable option for providers under the Quality Payment Program.

The CAP is especially supportive of the voluntary payer-initiated process that would allow payers to report payment arrangements and request CMS determine whether they qualify as Other Payer Advanced APMs. While we had asked that the CMS implement the payer-initiated process for all payers in the 2019 QP performance year, the CAP is pleased that CMS is aligning the payer-initiated process for Year 3 to include remaining other payers in addition to Medicaid, Medicare Advantage, and CMS multi-payer models. The payer-initiated process, which CMS notes "is designed to reduce reporting burden for APM Entities and eligible clinicians while allowing CMS to collect the information needed to make Other Payer Advanced APM determinations," is a necessary tool to ensure those practitioners who are actively participating in commercial and other payer APMs can potentially receive credit for that participation under the All-Payer Combination Option.

In order to successfully utilize the payer-initiated process, provision of the guidance and submission forms for both payers and clinicians for each other payer type is needed with as much lead-time as possible. As we have previously commented, provision of this information early in the calendar year prior to each All-Payer QP performance period does not provide sufficient time, especially where QP status hinges on the inclusion of an Other Payer Advanced APM.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

Finally, the CAP also underscores the importance of ensuring that the process for submission of information for purposes of determining the All-Payer Combination Option not be administratively burdensome nor otherwise deter those who truly have transitioned or are transitioning to APMs from fulfilling the All-Payer Combination Option. For this reason, we support the CMS' efforts to streamline and reduce the burden on payers and eligible clinicians through its proposal to allow multi-year payment arrangements for Other Payer Advanced APMs for up to five years.

Physician-Focused Payment Models

While there are other flexibilities proposed related to the All-Payer Combination Option and Other Payer Advanced APMs, the CAP continues to stress that these options are complex opportunities with limited availability for specialty participation. As mentioned above, the All-Payer Combination Option is not available for many providers given the limitations for participation in an Advanced APM within Medicare. The CAP again stresses that more innovative health care payment and delivery models must be developed in an open and transparent fashion with the input of those specialties impacted by the models.

In particular, while not discussed in this proposed rule, PTAC provides an important opportunity for specialists to develop their own models and submit them for review, but the CAP remains significantly concerned that models are being submitted to the PTAC without input of those specialties impacted by the model. Model submitters should be required to include physician societies impacted by their models and receive input prior to their submission so that PTAC is making recommendations on models that are truly physician-focused and enable meaningful contribution of their participants to enhance the care of patients. The CAP is supportive of pursuing innovative models but seeks to ensure that physicians, especially the societies that represent physicians participating in and affected by new payment models, have input into their development. Again, the CAP believes it is only with physician input and buy-in that we can ensure effective delivery system reform that will benefit Medicare patients and achieve the goals of value-based care.

8) Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

Within this proposed ruling, the CMS mentions its concern that challenges continue to exist for patients due to insufficient price transparency, and that such "challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals, and patients being surprised by facility fees and physician fees for emergency room visits." In general, out-of-network billing occurs in situations wherein patients cannot access in-network physicians in the private insurance market. Accordingly, this scenario is of concern in the health insurance exchanges for Qualified Health Plans (QHPs), but it is not germane to the Medicare program where balance billing is prohibited. We therefore are unclear of the context for the CMS discussion on "out-of-network bills" in this rule-making.

In order to remedy the problem of inadequate insurance networks for the health insurance exchanges, CMS should assess whether health plan networks with in-network hospitals have actually contracted with facility and hospital-based physician specialties at that hospital. QHPs should not be legally allowed to claim compliance with State or Federal network adequacy standards when the plan represents to regulators that it has an in-network hospital, but does not undertake the obligation to contract with the specialties of emergency medicine, anesthesiology, radiology and radiation oncology, pathology, and other hospitalists at such facility. With respect to this issue, current American Medical Association (AMA) Policy on Network Adequacy (H-285.908.11) states: "Our AMA advocates that health plans should be required to document to regulators that they have met requisite standards of network adequacy including facility and hospital-based physician

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org

specialties, (i.e., radiology, pathology, emergency medicine, anesthesiologists and hospitalists) at in-network facilities, and ensure in-network adequacy is both timely and geographically accessible."

We note that CMS finalized policy that relies on State reviews for network adequacy in States in which a Federally-Facilitated Exchange (FFE) is operating, provided the State has a sufficient network adequacy review process, rather than performing a time and distance evaluation. In States without the authority or means to conduct sufficient network adequacy reviews, CMS would rely on an issuer's accreditation (commercial or Medicaid) from an HHS-recognized accrediting entity (i.e., the National Committee for Quality Assurance (NCQA), URAC (formerly the Utilization Review Accreditation Commission), and Accreditation Association for Ambulatory Health Care (AAAHC)). Unaccredited issuers would be required to submit an access plan as part of the Qualified Health Plan (QHP) Application that demonstrates that the issuer has standards and procedures in place to maintain an adequate network consistent with the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act.

The network adequacy standards established as part of the NCQA Health Plan Accreditation (HPA) program, the Accreditation Association for Ambulatory Health Care (AAAHC) QHP Accreditation program, and the URAC Accreditation for Marketplace Plans, do not ensure access to in-network pathologists; rather, the standards simply ask if there are sufficient numbers of practitioners available to its members.

The CAP believes patient notification of cost prior to the performance of a health care service jeopardizes patient care by requiring a potential delay in the performance of a pathology service for a patient. For example, some surgical specimens require prompt analysis to be reported to a surgical team while the patient is under anesthesia and undergoing a surgical or diagnostic procedure. This analysis cannot be delayed without the potential for patient harm. In the case of anatomic pathology, which involves the diagnosis of tissue specimens (i.e. biopsies), a pathologist cannot predict the type or number of specimens or anticipate what separate studies may be necessary. The type of specimen or complexity of the analysis is often not known in advance of the initial microscopic analysis conducted by the pathologist, making it impossible to provide a reliable estimate of charges or cost. Quite simply, ethical and legal standards of care do not allow for the performance of these services to be delayed by insurance considerations, as such could be detrimental to quality and to the actual performance of the service. Furthermore, in the case of the private insurance market, only health insurance carriers can calculate the actual out-of-pocket cost of a health care service based on the particular provisions of the health insurance policy and the patient's contribution to the deductible. Health care providers do not have the information to make such assessments prior to the service. It is for all these reasons that the requirement for prior notification of cost was rejected by both the National Association of Insurance Commissioners (NAIC) and the National Conference of Insurance Legislators (NCOIL) in their consideration of model state legislation on this issue. **The CAP recommends that health care providers <u>not</u> be required to inform patients how much their out-of-pocket costs for a service will be before patients are furnished that service.**

* * * * *

The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions on these comments to: Maurine Dennis (202) 354-7136 / mdennis@cap.org, or Todd Klemp (202) 354-7105 / tklemp@cap.org. For questions regarding MIPS, please contact Loveleen Singh (202) 354-7133 / lsingh@cap.org. For questions regarding the CLFS, Advanced APMs, and the All-Payer Combination Option, or price transparency please contact Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

1001 G Street, NW
Suite 425 West
Washington, DC 20001
800-392-9994 | cap.org