COLLEGE of AMERICAN PATHOLOGISTS

September 11, 2017

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

Attention: CMS-1676-P

Subject: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018.

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1676-P entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018." The CAP is a national medical specialty society representing over 17,000 physicians who practice anatomic and/or clinical pathology. The CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals, and federal and state health facilities.

The CAP's comments focus on the following subjects included in the proposed rule:

1) Proposed Valuation of Specific Codes for CY 2018:
    a) Flow Cytometry Code Interpretation (CPT codes 88184 – 88185)
    b) Therapeutic Apheresis (CPT Codes 36511, 36512, 36513, 36514, 36516, and 36522)
    c) Diagnostic Bone Marrow Aspiration and Biopsy (CPT codes 38220, 38221, 382X3, and 2093X)
    d) Pathology Consultation During Surgery (CPT codes 88333 and 88334)
    e) Morphometric Tumor Immunohistochemistry (CPT Codes 88360 and 88361)

2) Standardization of Clinical Labor Tasks
    a. Preservice Clinical Labor for 0-Day and 10-Day Global Issues
    b. Obtain Vital Signs Clinical Labor

3) Updates to Prices for Existing Direct PE Inputs

4) Adjustment to Allocation of Indirect PE for Some Office-Based Services

5) Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

6) Value-Based Payment Modifier and Physician Feedback Program

7) Protecting Access to Medicare Act (PAMA)

8) Request for Information on CMS Flexibilities and Efficiencies

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1) Proposed Valuation of Specific Codes for CY2018:

a) Flow Cytometry Direct Practice Expense Inputs (CPT codes 88184 – 88185)

In the CY 2018 PFS Proposed Rule, CMS reports receiving conflicting information about the direct PE inputs for CPT codes 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker) and 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)). Specifically, CMS is proposing these codes as potentially misvalued so that they can be reviewed again because some stakeholders have suggested the clinical labor and supplies that were previously finalized are no longer accurate.

The CAP agrees that the current direct inputs for these two codes are inaccurate as implemented by CMS, and that the accurate direct inputs are those which were recommended by the RUC. There is absolutely no need for CPT codes 88184 and 88185 to be reevaluated as they have been through the RUC process just last year. **The CAP recommends that CPT codes 88184 and 88185 be removed from the list of potentially misvalued services and that CMS accept the January 2016 RUC recommended direct practice expense inputs for CY 2018.**

The AMA RUC, the CAP, as well as numerous other stakeholders, have already devoted a great deal of time and resources to this process and ask the Agency to accept the RUC recommendations. We once again offer our comments made in response to the CY 2017 PFS Final Rule on the following refinements:

- **Code 88184**: The CMS finalized the time for the lab technician (L033A) to enter data into the laboratory information system (LIS), multiparameter analyses and field data entry, complete quality assurance documentation from 4 minutes recommended by the RUC to 0.
  We disagree and urge the Agency to alter its decision and accept the RUC recommended time: These tasks must be performed for each individual patient case. The results are manually entered as there is no automated interface capable of performing this function. These tasks are the standard of care for reporting the results into the LIS of this service and for providing quality assurance. The laboratory technician carefully reviews, and checks the information, then enters the reporting results into the LIS. The Agency maintains that the clinical labor staff function is an indirect PE function. **The CAP disagrees and maintains it is a direct practice expense with work attributable to a specific patient.** A trained lab technician is the typical staff who perform these tasks that are directly associated with the specific patient specimens, patient care and service.

- **Code 88184**: The CMS finalized the time for the lab technician (L033A) to Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure) from 2 minutes recommended by the RUC to 1.
  We disagree and urge the Agency to alter its decision and accept the RUC recommended time. CMS stated that commenters did not provide a rationale as to why CPT code 88184 required additional clinical labor time above the RUC standard of 1 minute. The CAP reiterates its rationale from our proposed rule comment letter below. Time for this task is allocated over entire patient case. 88184 is billed once per case. It is typical and critical to clean the equipment between patient cases. The laboratory technician cleans the equipment and workspace thoroughly by decontaminating (purging) the equipment and work bench surfaces. Decontamination eliminates patient case carryover. Waste management after the procedure is the responsibility of the laboratory technologist as well. These activities are in addition to cleaning equipment, instruments, and work areas at the end of

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the shift and throughout the day. The individual case time to clean the equipment instruments and work areas is above and beyond the RUC standard of 1 minute. The laboratory technician must thoroughly decontaminate the equipment between cases which typically takes 2 minutes or more.

- **Code 88184**: The CMS finalized the time for;
  - Cytotechnologist (L045A) Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling from 15 minutes recommended by the RUC to 13.
  - Cytotechnologist (L045A) to load specimen into flow cytometer, run specimen, monitor data acquisition, data model, and unload flow cytometer from 10 minutes recommended by the RUC to 7.

  We disagree and urge the Agency to alter its decision and accept the RUC recommended time: The CMS finalized these two reductions in time for the Cytotechnologist (L045A) for 88184 by comparing these tasks to those of another pathology service (88182).
  Comparison to 88182 is not appropriate. 88184 uses 4-6 or more color channels, while 88182 uses 1-2 channels. The use of 4-6 or more color channels requires an increased level of technologist expertise and more time. The more colors that are run, the more complicated the profiles become and the more difficult and time consuming it is to evaluate the data. The time allocated to these tasks is allocated over the entire typical patient case. They should not be assimilated into or assumed to take the identical time as other services. CPT code 88182 is a different patient service used for cell cycle and DNA analysis, which can be performed on older/simpler technology available on earlier generation cytometers.

  With the increased complexity, these services now require longer operating cycles (run-time and data acquisition) for each individual patient case. The cytotechnologist's hands-on time for data capture, modeling, acquisition, and computational analysis is substantially longer for 88184 than for 88182. Ten additional minutes for 88184 and 2 additional minutes for 88185 are necessary for the use of the more advanced instrument operating and analytics software. Accurate data modeling by the cytotechnologist is a critical time consuming step and essential for ensuring quality assurance throughout all phases of testing.
  The CAP urges the Agency to accept the cytotechnologist time for these tasks as recommended by the CAP and RUC.

- **Codes 88184 and 88185**: The CMS finalized the quantity of medical supply SL186 antibody, flow cytometry (each test) from1.6 recommended by the RUC to 1.0.

  We disagree and urge CMS to revert to the quantity of 1.6 units for SL 186. It is a necessary standard of practice to use individual antibodies (such as CD45 or CD19) multiple times during the flow analysis. Some of these antibodies are necessary to correctly identify a particular cell type such as lymphocytes, whereas other antibodies are needed to provide specific subclassification of these cell types (e.g., B-cell lymphocytes). However, each reportable antibody/cell surface marker can only be billed once per analysis. The use of multiple units of a specific antibody reagent is needed for gating and comparative expression analyses to the cell markers analyzed in the other tubes, which is integral to the testing and reporting process.

  The use of 1.6 units of antibody reagent (SL186) is typical for each reported and billed marker. The quantity of 1.6 units of antibody reagent per marker is derived from a 2015

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survey of experts performing these services at multiple facilities, laboratories, and using a variety of different protocols based on a typical flow cytometry panel consisting of 24-billed markers. In the flow cytometry workflow, multiple sample aliquot tubes derived from a single patient specimen are set up, each of which has a limitation in the number of distinct flow color signals (i.e., different fluorescently-labeled antibody reagents) that can be separately detected by the analyzer in an individual tube. Because certain antibodies must be run across multiple tubes to accurately characterize different cell populations, typically more than a single reportable unit of antibody reagent is required to be evaluated among these tubes. For a typical immunophenotyping panel, it takes 38 units of different antibody reagents to identify 24 distinct cell surface markers across 10-12 separately analyzed tubes.

A ratio of 1.6 units of antibody reagent for each reportable and billable surface marker is thus required—not the 1:1 ratio the Agency maintains. Although multiple units of the same antibody reagent are required to furnish a typical patient reportable result, multiple units of the same cell surface marker cannot be not billed separately. However, these are valid reagent supply costs required to produce a single patient reportable result for each cell surface marker that is allowed to be billed separately.

The CAP urges the Agency to accept the quantity of 1.6 units of antibodies for 88184 as recommended by the CAP and the RUC.

- **Codes 88184 and 88185**: The CMS finalized the time for the printer, dye sublimation (photo, color) from 5 minutes recommended by the RUC to 2.

  We disagree and urge the Agency to alter its decision and accept the RUC recommended time: The CAP reiterates that the flow cytometry services and the dedicated equipment time for dye sublimation (photo, color) (ED031) printing are not performed all at one time. The cytotechnologist works with the cytometry analytics software to analyze the data generated from the service, then reviews the histograms and gating with the pathologist where they meticulously select what to print out. Typically, 25-30 pages of information and data are printed over at least a 5 minute time span. The printer waits for each group of information and data to be selected by the cytotechnologist and pathologist to be printed. The wait time was never included in the 5 minutes but should have been, as the equipment item cannot be used for any other patient service or case at that time. This time cannot be linked directly to one particular clinical labor task line.

- **Code 88185**: The CMS finalized the time for the lab technician (L033A) to enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation from 1 minute recommended by the RUC to 0.

  We disagree and urge the Agency to alter its decision and accept the RUC recommended time: These tasks must be performed for each individual patient case. The results are manually entered as there is no automated interface capable of performing this function. These tasks are the standard of care for reporting the results of this service into the LIS. The laboratory technician carefully reviews, and checks the information, then enters the reporting results into the LIS. The Agency maintains that the clinical labor staff function is an indirect PE function. **The CAP disagrees and maintains it is a direct practice expense with work attributable to a specific patient.** A trained lab technician is the typical staff who perform these tasks that are directly associated with the specific patient specimens, patient care and this service.

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- **Code 88185**: In 2017, the CMS finalized the medical supply SL089 Lysing reagent (FACS) from the RUC recommended 3 ml to 2 ml, which is derived from the allocation of 50-55 ml across 24 markers. For 2018, the CMS proposes to maintain the quantity of the "lysing reagent" supply (SL089) at 2 ml for CPT Code 88185.

  We disagree and urge the Agency to alter its decision and accept the RUC recommended quantity: Current Medicare data indicates a patient case of 24 markers is typical, but an analysis of the 2014 Medicare 5% Sample Carrier Database showed that over 50% of individual providers bill fewer markers per patient case. Flow cytometry TC is often billed as part of either an inpatient DRG, hospital OPPS, or client billed. That data is not captured in the Medicare database. A patient case of fewer than 20 markers using 50ml of bulk lysing reagent requires more than 2ml per marker, therefore, reducing the ml of lysing reagent from 3ml to 2ml underestimates the amount of lysing reagent needed for more than half of all providers that perform flow cytometry.

  The CAP urges the Agency to consider these cases in their analyses, and accept 3 ml of lysing reagent for CPT code 88185, as recommended by the CAP and RUC.

b) Therapeutic Apheresis (CPT codes 36511, 36512, 36513, 36514, 36516, and 36522)

The CMS noted that the Therapeutic Apheresis code 36516 was nominated as potentially misvalued in the CY 2016 PFS proposed rule. The CPT Editorial Panel deleted CPT code 36515 and made revisions to CPT code 36516 to include immunoadsorption. The RUC then reviewed the code family for physician work and direct practice expense inputs.

For CY 2018, CMS is proposing the RUC-recommended work RVUs for all six codes in the family: These work RVUs are as follows: 2.00 for CPT code 36511, 2.00 for CPT code 36512, 2.00 for CPT code 36513, 1.81 for CPT code 36514, 1.56 for CPT code 36516 and 1.75 for CPT code 36522. **The CAP urges the CMS to finalize these proposed physician work RVUS.**

The CMS is also proposing to use the RUC-recommended direct practice expense inputs for these codes without refinement. **The CAP urges the CMS to finalize these proposed direct practice expense inputs.**

However, the CAP is concerned that CMS is considering refining the clinical labor time for the activity "Prepare room, equipment, and supplies" from 20 minutes to 10 minutes for codes 36514 and 36522. For CPT code 36516 they are considering an adjustment from 30 minutes to 10 minutes. For this activity CMS states that there was no rationale that was presented to them justifying these changes in clinical labor time and whether or not these clinical labor tasks typically require additional time.

As discussed at the RUC; the specialties explained that the clinical staff time hadn't been accurately accounted for when these services were last reviewed in 2004. At the time of that review although Pathology was one of the dominant providers of that service but Pathologists were not included in the survey process or the development of any practice expense inputs. The development of the current recommendations included all of the dominant providers which were carefully reviewed by the RUC prior to their submission to CMS. It appears that Agency staff inadvertently overlooked this section of the RUC recommendation. The RUC recommendation stated:

> The Subcommittee discussed the significant time needed to prepare the room, equipment, and supplies. The specialties explained that the clinical staff time hadn't been accurately accounted for when it was last reviewed in 2004. The PE Subcommittee also discussed that

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much of the time requested in the post-service time was duplicative of the monitoring time and removed most of that time while maintaining the specialty recommended 10 minutes for monitoring in the service period.

The CAP urges the agency not to refine the clinical labor staff and accept the current RUC recommendations.

The Agency is also seeking comment on whether these procedures are creating a new point of venous access or utilizing a previously placed access. **We believe the vignettes for these services as well as the descriptions of work agree that the typical patient has a previously placed venous access that is then utilized. While in some cases a revision to the access site may need to be made, or initial access achieved, this is not representative of the typical patient scenario.**

In response to the CMS request for Therapeutic Apheresis invoices that were not handwritten the CAP has attached the following recently obtained invoices:

- Blood Warmer (EQ072)
- Cell Separator System (EQ084)
- Photopheresis System (EQ206)

Finally, the CAP would like to note that a critical practice expense equipment component was mistakenly left of the RUC recommendation that was submitted to the Agency. Specifically, a Cell Separator System (EQ084) was left off the RUC recommendation for CPT code 36516. **The CAP urges the Agency to add this piece of equipment (EQ084) to the direct inputs of CPT code 36516 with 324 minutes of use.** This particular equipment item is critical for all of the Therapeutic Apheresis services. CPT code 36516 also uses a piece of equipment (Liposorber - EQ174) that attaches to this missing equipment item.

c) Diagnostic Bone Marrow Aspiration and Biopsy (CPT codes 38220, 38221, 382X3, and 2093X)

CPT code 38221 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. The descriptors for CPT codes 38220 and 38221 were revised to reflect changes in practice patterns, and two new CPT codes (382X3 and 2093X) were created to more accurately describe new services that are now available. The RUC agreed with the compelling evidence submitted by the CAP for this family. Specifically, the physician work and times have changed relative to the amount and types of specimens that are obtained today which are greater in number than in 1995 when 38220 and 38221 were discussed at the 1st five year review. For CY 2018, CMS is proposing the RUC recommended work RVUs for each code in this family as follows: a work RVU of 1.20 for CPT code 38220, a work RVU of 1.28 for CPT code 38221, a work RVU of 1.44 for CPT code 382X3, and a work RVU of 1.16 for CPT code 2093X. **The CAP urges the CMS to finalize the proposed work RVUs for CPT codes 38220, 38221, 382X3, and 2093X as recommended by the RUC.**

CMS also received a RUC recommendation to change the global periods for CPT codes 38220, 38221 and 382X3 from XXX to 0-day. As a result of this recommendation from the RUC, CMS is proposing to refine the pre-service work time for CPT codes 38220, 38221 and 382X3 so that they are more closely aligned with the pre-service time of other recently reviewed 0-day global codes. Specifically, if this proposal is finalized the pre-service work time will be lowered to 9 minutes of evaluation time, 1 minute of positioning time and 5 minutes of scrub, dress and wait, from the current

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15 minutes. **The CAP agrees with this CMS proposal to refine the pre-service work time for CPT codes 38220, 38221, and 382X3 to more closely align with the preservice times of other recently reviewed 0-day global procedure codes.**

The Agency also is proposing to eliminate payment using HCPCS code G0364 for CY 2018 since the changes to the set of CPT codes now accurately describe the services currently reported by G0364.**The CAP agrees with the CMS proposal to eliminate payment for HCPCS code G0364 for CY 2018.**

CMS is proposing to refine the clinical labor for "Lab Tech activities" from 12 minutes to 9 minutes for CPT code 38220, from 7.5 minutes to 7 minutes for CPT code 38221, and from 12.5 minutes to 10 minutes for CPT code 382X3. CMS is maintaining the current time value for the two existing codes, The CAP disagrees with this refinement of the clinical labor time associated with these services from what the RUC recommended. Each CPT code is unique and the time that is recommended reflects typical time of those activities associated with each service. **The CAP urges the Agency <u>not</u> to refine the clinical labor time for these laboratory technician clinical labor tasks from the RUC recommended times.**

The Agency is also proposing to remove the breakout lines for the lab activities. The CAP disagrees with the CMS assertion that the breakout of activities into numerous sub activities generally tends to inflate the total time assigned to clinical labor activities. In fact, the generally accepted methodology at the time of this review was to provide as much detail as possible regarding the sub activities associated with a specific code. Just because these sub activities are fully displayed does not mean that they have been double counted. and this was taken into account by the RUC in its recommendations forwarded to CMS. Since each code is considered a separate and distinct service, detailed information provides the basis for accurate determination of resources used in performing the service.

CMS considered refining the clinical labor for "Provide preservice education/obtain consent" for CPT codes 38220, 38221, and 382X3 from 12 minutes to 6 minutes. The Agency has concerns regarding whether 12 minutes would be typical for education and consent prior to these procedures, as much of the patient education takes place following the procedure, in the clinical labor activity described under the "Check dressings & wound/home care instructions" heading. Preservice education/obtain consent is typical for this patient service. Current clinical practice requires that there be full education and patient consent obtained before the start of any of these procedures. The information that is disseminated prior to the procedure in no way overlaps with "check dressings &wound/home care instructions". Those activities pertain to the post-op period and serve separate and distinct purposes. **The CAP urges the Agency not to refine the clinical labor time for these services from what has been recommended by the RUC.**

d) Pathology Consultation during Surgery (CPT codes 88333 and 88334)

CMS has proposed to retain the current work relative values for both codes in this family as recommended by the RUC (work RVU of 1.20 for CPT code 88333 and work RVU of 0.73 for CPT code 88334). **The CAP urges the Agency to finalize the work RVUs for 88333 and 88334 as recommended by the RUC.**

CMS proposes to remove the clinical labor task, Prepare room, filter and replenish stains and supplies (including setting up grossing station with colored stains). CMS believes that this clinical labor is not currently included in the direct PE inputs for CPT code 88333, and also believe that this

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is a form of indirect PE that is not individually allocable to a particular patient for a particular service.

The CAP disagrees with the CMS assertion that this clinical labor activity is a form of indirect PE that is not individually allocable to a particular patient for a particular service. Stains must be filtered, changed, cryostats must be cleaned, chucks must be cleaned etc. The CAP also disagrees with the proposed reclassification of replenishing stains and supplies as an indirect practice expense. This task, is a direct practice expense with work attributable to a specific patient. The replenishment of stains and supplies is a necessary function of directly providing patients' important lab services associated with these particular services and should not be construed as keeping the shelves stocked. **The CAP urges the CMS not to remove the clinical labor task time for "prepare room, filter and replenish stains and supplies (including setting up grossing station with colored stains)" within code CPT 88333, but to accept the RUC recommended clinical labor time of 10 minutes for all these activities.**

CMS is proposing to eliminate the clinical labor time of 5 minutes associated with "Clean room/equipment following procedure" activity for CPT code 88333, consistent with the standard clinical labor time assigned for room cleaning when used by laboratory services, of one minute.

The CAP is aware that there is a specific standard clinical labor time for "clean room/equipment" for this code. However in this case, following the RUC methodology we looked to the typical patient scenario as well as similar services to arrive at a time estimate. The time encompasses the entire patient case, and includes these tasks performed when add-on service 88334 is also provided (0 time for this is task allocated to 88334). **The CAP urges the CMS to retain the RUC recommended time of 5 minutes for Clean room/equipment following procedure for 88333.**

CMS seeks comments related to the equipment time assigned to the "grossing station w-heavy duty disposal" (EP015) for both CPT codes 88333 and 88334. The Agency stated that they are unclear how this equipment time is derived. The time assigned to EP015 grossing station w-heavy duty disposal is derived from a combination of the total clinical labor time for the service and the physician time of examining the specimen at the same grossing station. The current time of 10 minutes represents a reduction from 25 minutes for code 88333 and 20 minutes for code 88334 from the direct inputs in 2014. **The CAP urges the Agency to accept the RUC recommended time of 10 minutes for equipment item EP015 for CPT codes 88333 and 88334.**

e) Morphometric Tumor Immunohistochemistry (CPT codes 88360 and 88361)

The CAP agrees with the Agency's proposal to accept the RUC-recommended work RVU of 0.85 for CPT code 88360 and the RUC-recommended work RVU of 0.95 for CPT code 88361. **The CAP recommends the RUC-recommended work RVU of 0.85 for CPT code 88360 and the RUC-recommended work RVU of 0.95 for CPT code 88361, be finalized for CY 2018.**

These codes reflect how breast cancers are evaluated for estrogen and progesterone receptor and Her2 status. . Accurate evaluation affects therapeutic approach and was one of the first steps in personalized medicine. .88360 refers to the manual counting while 88361 uses a computer assisted digital image analyzer.

The Agency proposes to refine the time associated with the clinical labor task; Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer" activity for both 88360 and 88361. The Agency states that this would be "consistent with the standard time for this clinical labor activity across different pathology services."

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This clinical labor task is unique to immunohistochemistry services as the label instructs the immunohistochemical staining robot which stain to run and which concentration of reagent to use, a task significantly more complicated than performance of a hematoxylin and eosin stained section in the traditional histology laboratory..
The CAP urges the Agency that the clinical labor task "Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer" be finalized for CY 2018 as 5 minutes of histotechnologist time, as recommended by the RUC.

The Agency proposes for CPT code 88361 to remove the 1 minute of clinical labor time from "Performing instrument calibration, instrument qc and start up and shutdown" and a minute of clinical labor time for histotechnologist to "Gate areas to be counted by the machine". Accurate calibration and quality control are key to accurately measuring the cells. "Gating areas" refers to circling 7 areas of cancer cells to exclude the normal cells and tumor necrosis. **The CAP urges the Agency to accept the RUC recommended 1 minute for the clinical labor task of "Performing instrument calibration, instrument qc and start up and shutdown" and 1 minute for the clinical labor task "Gate areas to be counted by the machine" and to finalize these times for CPT code 88361 as recommended by the RUC.**

The Agency proposes to remove the clinical labor time for "Clean room/equipment following procedure" for CPT codes 88360 and 88361, as the CMS believes that this clinical labor is duplicative of the 4 minutes of clinical labor assigned to "Clean equipment and work station in histology lab". The histology laboratory prepares the tissue for sectioning by embedding the tissue into blocks while the immunohistochemistry laboratory (image cytometry lab) is , typically in a separate and distinct work area. **The CAP urges the Agency to retain 1 minute in codes 88360 and 88361 for the clinical labor time for "Clean room/equipment following procedure".**

CMS is proposing refinement of the time associated with the clinical labor task; "Verify results and complete work load recording logs" CMS would like to reduce this time from 1 minute to 0.
The clinical labor task of "Verify results and completing work load recording logs" is the task that describes the technologist recording the work performed in the laboratory record and releasing the slides and/or machine results to the pathologist for interpretation. There is no CMS or RUC standard time for this task and there should not be. The time associated with this clinical task is a direct expense, not an indirect cost input, and is allocable to a specific patient. **The CAP urges the CMS to accept the RUC recommended clinical labor time of 1 minute for "Verify results and completing work load recording logs" for CPT codes 88360 and 88361.**

CMS is proposing refinement of the time associated with the clinical labor task; "Recycle xylene from tissue processor and stainer" from 1 minute to 0. CMS believes that this is an indirect, not a direct practice expense input. Recycling xylene is a common task performed by laboratory technicians. One minute is necessary for this task and this service.. **The CAP urges the CMS to accept the RUC recommended 1 minute for this clinical labor task for CPT codes 88360 and 88361, and not to classify the clinical labor task "Recycle xylene from tissue processor and stainer" as an indirect expense, as this expense was not captured in the last Physician Practice Information Survey (PPIS), and is a direct and variable cost input.**

The CMS is proposing to refine the equipment time for the "Benchmark ULTRA auto slide prep & EBar Label system" (EP112) from 18 minutes to 16 minutes for both CPT codes 88360 and 88361. Within CMS' 2016 Final PFS Ruling, page 70982, equipment items EP112 and EP113 EBar II Barcode Slide Label System were reclassified as a single item, which will use equipment code EP112 with the equipment minutes remaining unchanged. Because of this ruling the equipment

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minutes of both items should have been added together for all codes within CMS' database with EP112 and EP113. These CPT codes include 88342, 88341, 88344, 88360, and 88361.
The RUC recommendations for April 2014 and April 2016 reflect both equipment items. These recommendations were reviewed by the RUC and accepted by CMS.

The CAP recommends the following additions in equipment time by CPT code:

CPT Code	EP112 Minutes	EP113 Minutes	Total time reclassified as EP112
88341	15	1	**16**
88342	15	3	**18**
88344	30	3	**33**
88360	15	3	**18**
88361	15	3	**18**

The CAP urges the CMS to correct the addition error made when equipment items EP112 and EP113 were combined by adding back lost minutes from EP113. The total times for EP112 for 88342, 88341, 88344, 88360, and 88361 is shown above. In addition, the CAP recommends the description of EP112 be renamed in CMS' database to "Benchmark ULTRA auto slide prep & EBar Label system".

The CMS considered refining the equipment time for the DNA/"digital" image analyzer (EP001) from 30 minutes to 5 minutes based on equipment literature that specifies "the machine can run 50 slides per hour". The literature does provide throughput information for 20x and 40x (50 slides/hr. @ 20x and 20 slides/hr. @ 40x). However, the CAP maintains that running 50 slides per hour does not represent the typical patient scenario. This is just the initial step in the analytical process of obtaining an image of the tissue stained for the appropriate antigen. There are a number of additional steps of analyses that resulted in the RUC recommending 30 minutes.

- performing instrument calibration and instrument quality control during start up and shutdown of the imaging instrument
- Transferring, or accessing, the photographed digital image into the quantitative cellular imaging program (which is a separate function from line 14 of the RUC recommendation spreadsheet "Verify order and accession immunohistochemical stain order in laboratory information system").
- The technologist uses the instrument to gate, or circle, 7 areas of cancer cells to be analyzed (excluding the non-cancer areas) in the image and then the run is initiated.
- In many cases, the technician will take the recut slide back to the original pathologist and ask for the tumor to be identified on the slide.
- After the machine counts the stained cells and measures their intensity of staining, the histotechnologist needs to review the machine's work for accuracy, unload it, and meticulously clean it and the lab.
- Each case requires at least 30 minutes where the DNA/"digital" image analyzer (EP001) program cannot be used for any other purpose or patient case.

The CAP urges the agency to accept the RUC recommended 30 minutes for CPT code 88361, DNA/"digital" image analyzer (EP001).

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The CAP also recommends that this equipment item be renamed to "DNA/digital image analyzer" rather than "DNA image analyzer" as the new name more accurately describes equipment item EP001.

2) Standardization of Clinical Labor Tasks, Pathology Clinical Labor Tasks

a) Preservice Clinical Labor for 0-Day and 10-Day Global Issues

CMS notes that the RUC PE Subcommittee reviewed the preservice clinical labor times for CPT codes with 0-day and 10-day global periods. The RUC concluded that these codes are assumed to have no pre-service clinical staff time unless the specialty can provide evidence that preservice time is appropriate. For CY 2018, the Agency notes that 41 of the 53 reviewed codes with 0-day or 10-day global periods includes preservice clinical labor of some kind which suggests that it is typical for clinical staff to make preparations prior to the arrival of the patient. The Agency is concerned that so many of the codes for CY 2018 deviate from the "standard" of 0 minutes of preservice time and is requesting comments on whether or not they should apply the "standard" of 0 preservice time for all 0-day and 10-day global period codes in future rulemaking.

The CAP agrees with the conclusion of the RUC PE Subcommittee that while it is generally true that the assumption should be that 0-day and 10-day global period codes should have 0 preservice work, in some instances circumstances may dictate otherwise. Thus, the RUC allows specialties to present evidence to justify preservice work for these services when it is warranted. **The CAP strongly believes that each CPT code is a separate and unique patient service and discourage CMS from adopting any blanket standard preservice time for 0-day and 10-day global period codes**.

b) Obtain Vital Signs Clinical Labor

CMS has expressed concern in the CY 2018 NPRM regarding the increasing amount of time spent obtaining patient vital signs. The Agency notes that they have traditionally assigned a clinical labor time of 3 minutes to obtain vital signs based on the amount of time typically required to take a patient's vital signs. However, over time the agency has noted an upward trend in the recommended time associated with this task and for 2018 many of the codes that were reviewed allocate 5 minutes to obtain vital signs associated with the addition of obtaining the patient's weight and height. While the Agency acknowledges that review standards for obtaining vital signs may have changed over time, they remain concerned that this additional time is detrimental to relativity among PFS services. However, the CAP would argue that this upward trend does not necessarily imply that a standard time should be assigned to this clinical labor activity. **The CAP disagrees with this assertion and would reiterate that each CPT code service is separate and distinct and that the RUC carefully scrutinizes each recommendation for typicality, particularly when the time associated with any clinical labor task is increased. We urge CMS to evaluate each CPT code independently based on what is typical for that service and <u>not</u> to assign additional time to any service without specific physician input.**

3) Updates to Prices for Existing Direct PE Inputs

The CAP agrees with the Agency's proposal to update the price of the thirteen supplies and one equipment item listed on Table 14: Invoices Received for Existing Direct PE Inputs. The CAP recommends that the updated prices on Table 14 be finalized for CY 2018.

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In addition, in response to the Agency's request for additional updated pricing information for other equipment items, the CAP provides as an attachment to this comment letter current valid invoices for the following equipment items: EQ072, EQ084, EQ206, and EP001. The CAP recommends these invoiced prices to update CMS' database prices of these equipment items and that they be finalized for CY2018.

4) Adjustment to Allocation of Indirect PE for Some Office-Based Services

CMS is proposing to set minimum non-facility indirect PE RVUs for approximately 50 CPT code that describe face-to-face services that have work RVUs greater than zero, and are priced in both the facility and non-facility setting. The Agency recognizes that this change to PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services and estimate that at least $40 million dollars, or approximately 0.04 percent of the total PFS allowed charges would shift within the PE methodology for each during a four year transition starting in 2018. **The CAP is very concerned that the Agency is moving toward a significant shift in the allocation of PE resources with limited stakeholder input resulting in a "significant impact on the allocation of indirect PE RVUs". Given that this is a PE methodology issue, the CAP recommends that the agency not go forward with this proposal until this proposal is discussed through the RUC process. In addition, these codes should be placed on the potentially misvalued code list.**

5) Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

CMS had previously finalized PQRS criteria for the 2016 reporting period that Eligible Professionals (EPs) would have to meet in order to avoid penalties in 2018. This included reporting on a minimum of nine measures covering at least three National Quality Strategy (NQS) domains. **CMS is proposing to lower these previously finalized requirements to reporting six measures with no NQS domain requirements associated with these measures. The CAP encourages CMS to finalize this proposal.** We believe this new reporting criteria will be simpler and more consistent with the CMS goals for the Merit-Based Incentive Payment System (MIPS). CMS recognized the difficulty of the reporting requirements and lack of applicable measures by reducing the requirements in MIPS to six measures and eliminating the domain and cross-cutting measure requirements.

The CAP has heard from many pathologists who tried to successfully report PQRS 2016, but were unable to find nine measures that were applicable and meaningful for their practice. **And while the new CMS proposal will ease the reporting burden, we recommend that CMS create a hardship exemption that would allow physicians who successfully reported on any number of PQRS measures in 2016 to avoid the two percent penalty in 2018.**

6) Value Based Modifier and Physician Feedback Program

The CAP appreciates the CMS proposal to reduce penalties for the 2018 Value-Based Modifier (VBM). Specifically, CMS is proposing to reduce the automatic penalty for not meeting minimum PQRS reporting requirements from negative four percent to negative two percent for groups of ten or more EPs and from negative two percent to negative one percent for solo practitioners and groups of two to nine EPs. Further, CMS is proposing to hold harmless all ECs who meet minimum PQRS

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reporting requirements. The CAP asks that CMS finalize these proposals as they will protect EPs from additional penalties of up to four percent under the VBM.

The CAP believes that the above CMS proposals recognize the existing challenges EPs face under PQRS and VBM and are consistent with the direction CMS is taking with the Quality Payment Program in efforts to reduce burden on clinicians.

7) Protecting Access to Medicare (PAMA)

The CAP appreciates CMS's solicitation of public comments on Medicare's Clinical Diagnostic Laboratory Tests (CDLTs) system initial data collection and reporting period. To assist CMS in better understanding applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first CDLT data collection and reporting periods, the CAP provides general and then more specific feedback regarding our members' experiences.

Overall, reporting under Section 216 of the Protecting Access to Medicare Act (PAMA) has proven administratively burdensome and operationally cumbersome under the best cases, and exceedingly disruptive in the worst. Despite these extensive and costly efforts to collect and report the required applicable information, pathologists and laboratories have expressed significant concern with the accuracy and integrity of data under the new system yielding the accurate market-based rates intended under PAMA to establish a valid clinical laboratory fee schedule (CLFS) beginning in 2018. As a result, they have repeatedly requested a delay so that PAMA implementation conforms to congressional intent and does not result in diminution of access to medically necessary services that are essential to diagnosis and integral to the prevention and treatment of disease and other conditions.

More specifically, in response to CMS's questions, the CAP offers the following:
1. *The data reporting system* – The system was not consistently easy to use. Interestingly, particular difficulty was noted in the registration and set-up phases of systems use. Those offering the most favorable input were the larger, more established pathology practices and laboratories. The submission of information was even more difficult for practices and laboratories with less experience gathering large amounts of data and submitting *en masse*. Since the gathering and submitting of the required applicable information was without precedent, the initial data submission under PAMA presented a challenge to submitters with whom we interacted. Exacerbating the challenges was timing of the release of additional information regarding the submission process during the submission period. While the tools the agency provided contained helpful information, their utility to applicable laboratories would have been greater if released prior to the opening of the reporting period in some cases or in others as data collection needed to occur.

2. *Help Desk or CLFS Inquiries Mailbox* - At the very outset of the process, the help desk was sometimes accessed to confirm which CMS portal was to be used for PAMA reporting purposes as opposed to other existing CMS portal access for different purposes with different passwords. Enrolling as a certifier and submitter proved challenging resulting sometimes in the need to contact the help desk. Other contacts with the help desk were necessary due to inconsistencies in the documentation related to the file format available for upload resulting in the inability to remove data when errors arose in a number of accounts due to this issue. The help desk in these instances was able to resolve the issue. Regarding the CLFS Inquiries mailbox, a response to inquiry took longer than expected at about eight calendar days and included an apology for the delay given a large volume of inquiries. The initial response, which required clarification, was received more expeditiously.

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3. *Availability of Applicable Information in Records Systems* - In addition the information applicable laboratories were required to report was not always readily available in records systems. Since the submission of applicable information on CDLTs to CMS was without precedent, applicable laboratories had not historically stored the information in their systems for purposes of extraction, aggregation and submission. Some of the larger laboratories conveyed the applicable information was available in their systems, but the report to abstract the information from the systems was not available. As a result, in some instances, vendors had to build custom reports that required validation and updates to improve the accuracy of data submitted. In other instances, laboratories had to custom build reporting entirely for purposes of fulfilling the required data submission.

4. *Manual Reporting* - In some instances, applicable information had to be pulled manually during the data collection process. Even laboratories with more advanced systems capabilities reported use of a semi-manual process to comply with reporting requirements in part because they do not receive all remittances electronically. These laboratories report at least 20% of revenue posted manually. Other laboratories reported a much higher percent of manual reporting.

5. *Number of Hours To Assemble and Report* – The number of hours required to assemble and report applicable information to CMS was significant. Between billing office leadership, information systems representative and vendor resources, even those laboratories with solid systems in place reported at least 240 hours to assemble, validate, and report applicable information to CMS.

6. *Other Information to Inform CMS About the First Data Collection and Reporting Period* – The requirements to enroll in the system to submit applicable information were very time consuming and the level of security required to submit the data extreme. Delays in defining and clarifying requirements for submission did not afford laboratories time to implement procedures prior to the reported period that would have supported and made for an easier reporting process.

As you know, the reporting of private payor rates is a complex matter that was not initially addressed with much specificity by the agency in the proposed rule. While the agency subsequently provided additional detail on what constituted applicable information, the timing of this information was much closer to the data collection period and required some pathology practices and laboratories to alter their data collection processes to enable their reporting. Reporting final payment from private payors, for example, presented unique challenges as the payors' reconsideration and appeals processes can be lengthy. Identifying when the payment is in final disposition versus still in reconsideration or appeal at any one of available levels is not simple and straightforward. It can also be resource intensive and affect integrity of data reported particularly when the practice finds final payment not readily discernable. In addition, a lag may exist in confirming the copayment and coinsurance that can affect reporting final payment.

The CAP and other clinical laboratory stakeholder organizations continue to have significant concerns about the implementation of the Medicare clinical laboratory reform under PAMA. Under current regulatory requirements, the new CLFS will not reflect accurate and representative private market rates for clinical laboratory services as required by PAMA. In addition, as shown above, the reporting requirement and mechanism is entirely new for applicable laboratories and imposes not only administrative burden, but also ultimately potential civil monetary penalties. To help address these concerns, the CAP urges delaying implementation for at least a year to resolve significant substantive and operational issues. A delay would enable reassessment of the current regulatory definition of applicable laboratory and afford time for applicable laboratories to be able to fulfill CMS data collection requirements and for CMS data collection systems to function at adequate capacity to accurately capture private payer data and disclose its progress on this data capture.

8) Request for Information on CMS Flexibilities and Efficiencies

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In the CY 2018 PFS Proposed Rule, CMS has included a Request for Information to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. The Agency also seeks to reduce burdens for hospitals, physicians, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. The CAP shares these desires with the Agency. **The CAP is pleased to provide the following recommended actions the Agency can make toward our joint goals for our healthcare system.**

Recommendations for CMS Flexibilities and Efficiencies:

1. Local Coverage Determination (LCD) Reform – The CAP seeks improvement in the LCD process through transparency and consistency in the use of medical and scientific evidence in coverage determinations. The recommendations toward a reformed LCD process are:

- **Open Meetings** – *Require that Medicare Administrative Contractor (MAC) Carrier Advisory Committee (CAC) representative meetings, which are currently closed meetings, be open, public, and on the record, with minutes taken and posted to the MAC's website for public inspection*. Open meetings increase transparency and MAC accountability, which are essential when any decisions are made to limit or deny Medicare coverage of services. Such open, on the record processes also ensure effective information exchange between MACs and interested stakeholders.

- **Upfront Disclosure** – *Require MACs to include, at the outset of the process, a statement of the rationale for a proposed LCD and of any evidence they are relying on to limit or deny coverage*. When this information is not provided until the final LCD is issued, the MAC's decision to limit or deny coverage becomes a *fait accompli* without meaningful opportunity for stakeholder analysis and comment.

- **Meaningful Reconsideration and Options for Appeal** – *Create a process for providers and suppliers to appeal a MAC's decision to deny reconsideration to CMS,* rather than limiting it to the MAC that authored the LCD. Under current Medicare rules, without new evidence, LCDs are essentially unreviewable once they become final, so failure of a MAC properly to consider evidence initially effectively renders it unavailable for reconsideration on appeal.

- **Ombudsman Assistance** – *Create an ombudsman position as part of the LCD reconsideration appeals process* to:
    - provide administrative and technical assistance to providers and suppliers in filing appeals
    - make publicly available information about the number of appeals filed with the MACs and with CMS each year, the actions taken by the MACs and by CMS with respect to appeals filed, including the responsiveness of the MACs, and the number of times the Secretary took action in response to appeals filed with HHS.
    - recommend improvements in the efficiency of the appeals process to the Secretary.

- **Stop the Use of the LCD Process as a Backdoor to NCDs:** *Prohibit a MAC from replicating LCD determinations on a nationwide basis without following in form and in substance the specified process for LCD development, assessment and implementation*. The widespread adoption of replicated LCDs by MACs constitutes, in practical terms, an

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evasion of the requirements of the more rigorous NCD process, to produce a de facto national coverage policy.

Reform of the LCD process will ensure the most credible and compelling evidence available is used consistently to determine the most appropriate coverage. To fulfill the letter and spirit of the LCD program, the process must be transparent, with stakeholder input secured and fully considered by each MAC. MAC determinations must also be reviewable without a new evidence requirement, which undermines the opportunity to correct erroneous decision-making. The current box-checking exercises, void of meaningful exchange within the LCD development process, must be reformed to achieve sound Medicare beneficiary coverage and access.

2. Misvalued Code Initiative: Secretarial Discretion - *Use the discretion contained in statute establishing the misvalued code initiative to ensure physician input is not removed from the Medicare physician fee schedule relative value review process.*

- *Exercise discretion by continuing to utilize the work of the American Medical Association/Specialty Society RVS Committee (RUC).* Independent contractors' valuation of physician work and practice expense relative value units (RVUs) cannot provide the unique and specific insights of actual American medical practitioners, and the fact that what is developed through the RUC's work is a **relative** valuation which ensures that each group of practitioners is vigilant in ensuring accurate and appropriate representations of value.

- *Exercise discretion to limit use of alternative approaches to establishing practice expense values to those circumstances which cannot be addressed by the established processes above.*

- *Use generally accepted cost accounting principles* to recognize all expenses in the practice expense RVU methodology and consult with organizations representing physicians regarding methodology and data used to develop and maintain the Medicare physician fee schedule.

The AMA RUC has a highly credible, transparent mechanism that utilizes the expertise of the entire house of medicine to examine in detail the physician work and practice expenses that most accurately values every physician service on the Medicare Physician Fee Schedule. The use of independent contractors compromises the long and successful history of physician involvement in providing valuation and methodological recommendations to the CMS for the Medicare program.

Engaging contractors to create conceptual models for the value of physician services also moves CMS away from the resource based methodology. Paying independent contractors, who know less about the actual practice of medicine than those already participating in the established RUC mechanisms, does not improve the process of valuing physician services.

In addition, the use of alternative approaches to establish practice expense values is a significant and troubling departure from the current well-established resource based methodology (a formal notice and comment rulemaking, a predictable processes and timeframes for reevaluation of misvalued codes, or physician involvement in collecting data to determine physician relative values) that must not be utilized.

3. Protecting Access to Medicare Act (PAMA) *–To help address these concerns about the implementation of the Medicare Clinical Laboratory Fee Schedule (CLFS) reform under Section 216 of PAMA, we urge the following*:

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- *Delay implementation* for at least one year to resolve significant substantive and operational issues,
- *Reassess and redefine the current regulatory definition of "applicable laboratory"* (those laboratories subject to the reporting requirement) so that private payer rates upon which the CLFS will be based are fully representative of all practice types and reflective of the market,

The CAP and other clinical laboratory stakeholder organizations continue to have significant concerns about the implementation of the Medicare CLFS reform under PAMA. Under current regulatory requirements, the new CLFS will not fully reflect and represent private market rates for clinical laboratory services as intended under PAMA. The reporting requirement and mechanism is entirely new for applicable laboratories and imposes not only administrative burden, but also potential civil monetary liabilities.

3. Delivery System and Payment Reform Models – While supportive of pursing innovative health care payment and delivery models, *the CAP seeks to ensure that physicians, especially specialty physicians as represented by societies participating in and affected by new payment models, have input into their development* whether through the physician-focused payment model (PFPM) process or through the Center for Medicare and Medicaid Innovation (CMMI) models.

- **CMMI Model Development** - *Require CMMI to consult with physician societies impacted by the models it is contemplating prior to model development and implementation.* In carrying out its mission, CMMI is required to consult clinical and analytical experts with expertise in medicine and health care management. These experts do not expressly include specialties impacted in primary or supporting roles by models prior to testing. As part of its model development protocol, CMMI should reach out to and secure input from physician societies representing those specialties affected by its models.

- **Physician-Focused Payment Models (PFPMs)** - *Require model submitters to consult participating and affected specialties prior to submission to the PFPM Technical Advisory Committee (PTAC).* The CAP is supportive of the PTAC's role in the review and recommendation of models developed by physicians, particularly specialists and those who have not had the opportunity to participate in existing models to the HHS Secretary. Under the current process, however, model submitters are not required to consult specialties affected by their proposed models. At least three of the models submitted to the PTAC to date specifically included pathology services. The CAP, the largest organization representing board-certified pathologists, was not consulted by the submitters. We only learned that these models encompassed pathology services upon posting for public comment. Model submitters should be required to contact the specialties their model affects prior to submission and to attest to such outreach.

Physician input and buy-in is critical to effective delivery system reform. While not expressly stated, it cannot be doubted that CMMI was intended to include affected physicians among the experts it consults during model development. Not to include physicians impairs CMMI's ability optimally to formulate models and leaves CMMI's broad authority unchecked. Similarly, for PFPMs to ensure meaningful collaboration and to preserve, and ideally improve, the care of patients, impacted specialties must be consulted. When physicians are included in models submitted to the PTAC, but are not aware of this, they cannot provide the necessary input to optimize care coordination for patients or meaningful physician participation.

4. The Medicare Access and CHIP Reauthorization Act: Quality Payment Program (QPP) – Adopt the following solutions t*o more appropriately measure providers such as pathologists, who typically do not furnish services that involve face-to-face interaction with patients:*

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- **Defining Non-Patient Facing Eligible Clinicians (ECs) –** *Use a hybrid approach to define non-patient facing ECs, using the PECOS code for those specialties where nearly 100% of ECs are non-patient facing.* The current regulatory standard defines non-patient facing ECs by the number of evaluation and management services performed. If entire specialties are nearly entirely non-patient facing, categorize them by specialty rather than by counting visit codes. For those specialties where a larger fraction of ECs may be patient-facing, CMS can use the current approach. This should also serve to minimize administrative burden for CMS and non-patient facing specialists.
- **Reweighting Merit-Based Incentive Payment System (MIPS) Categories** – *Do not reweight MIPS categories for ECs who cannot be scored in all categories.* Pathologists can currently participate only in two MIPS categories, while many other ECs can participate in four categories. These categories differ substantially in required performance characteristics and expected baseline levels, so to ensure a fair comparison *we request that a median score in the Advancing Care Improvement (ACI) and Resource Use (RU) categories be utilized rather than a reweighting among categories for those who cannot be measured in all categories using the current methodology.* This is similar to CMS' approach with the cost category under the Value-Based Payment Modifier program. Unfair scoring of MIPS categories for those eligible clinicians who cannot be scored in all categories (particularly ACI and RU) will be further exacerbated if the list of activities under the Clinical Practice Improvement Activities category remains primarily focused on specialties primarily involved in office visit practices.
- **Scoring Topped Out Measures** – *Use an absolute percentage to score topped out measures rather than retiring these measures*. Retention of measures is critical where continued maintenance of performance at the current level remains an appropriate measure of quality even when those measures currently reflect good performance in important care characteristics – what is no longer measured tends to degrade.

In order for the QPP to make Medicare better, helping physicians focus on care quality and keeping patients healthier, one size cannot fit all specialties. In order for pathologists to successfully participate in the QPP, they need to be readily able to identify themselves as non-patient-facing with less burden placed on both them and the agency than is currently required. Scoring should create a more level playing field for all physicians rather than penalizing those who are unable to participate in certain MIPS categories. Finally, maintaining consistent and accurate performance, which is a core competency for pathologists in directing laboratories, should not be punished, but rewarded through the QPP measurement system.

5. Cytology Proficiency Testing – *Replace the current punitive and outdated cytology proficiency testing (PT) program with an education program* that:

- Ensures all individuals involved in screening and interpreting cytological preparations participate annually in an approved CME program in gynecologic cytology that provides each participant with gynecology cytologic preparations designed to improve locator, recognition, and interpretive skills,
- Requires the laboratory to maintain a record of annually
- Requires the laboratory director to:
    a. utilize results from the annual CME testing, along with other CLIA required metrics, to assess individual performance and if necessary, to take appropriate action in terms of remedial training or further continuing medical education;
    b. share individual CME testing results with the laboratory's accrediting organization on an ongoing basis, including review of CME results by the accrediting organization as part of the conducting laboratory inspections and accreditation under CLIA; and

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c. transmit assessment results and improvement to the accrediting body of the laboratory for quality assurance.

The current regulations for cytology PT rely on government driven testing scheme that attempts to "grade" individuals using a 1992 model that is neither meaningful nor reflective of Pap test practice today. An educational approach will foster a willingness to be challenged with difficult cases and learn through constructive feedback. It will also accommodate new science and technology without having to change a regulation. The House of Representatives twice passed legislation to repeal the current cytology PT testing standards and replace them with continuing CME requirements. The legislation amended the Public Health Service Act to require the Secretary of Health and Human Services to revise national quality assurance standards to assure consistent performance by laboratories of valid and reliable cytology services to include the requirements outlined above for each clinical laboratory. The legislation was supported by the Cytology Proficiency Improvement Coalition that represented more than 60 groups including patient advocates such as the National Cervical Cancer Coalition, Prevent Cancer Foundation and the Society for Women's Health Research.

6. Medicare Administrative Contractors (MACs) "Unlisted" Code Reporting Requirement - Prevent *MACs from requiring the use of non-HIPPA compliant codes (e.g. McKesson Z codes) and/or "unlisted" codes when a specific CPT code exists. HCPCS and CPT-4 are the current HIPAA-specified medical data code set standards adopted for use in Medicare health care claims transactions for physician and other health care services and only used.*

- *Prevent MACs from directing providers to use non-HIPAA compliant codes (e.g. McKesson Z codes).* MACs are directing providers to use the "McKesson Z codes" as a "Code Set.". However per page 41075 of CMS' PAMA Final Ruling, (Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, (42 CFS Part 414, (CMS-1621-F), RIN 0938-AS33)) CMS states: "We believe our current HCPCS coding processes will sufficiently meet our coding needs under section 1834A(e)(3) of the Act. We also note that, as of this final rule, the McKesson Z codes are not a HIPAA-compliant code set; HCPCS and CPT-4 are the current medical data code set standards adopted for use in health care claims transactions for physician and other health care services, such as CDLTs (see 42 CFR 162.1000 and 162.1002)."
- *Prevent MACs from directing physicians/providers to report "unlisted" codes when a specific CPT code exists.* When MACs direct providers to report "unlisted CPT codes" in combination with "Z codes" for services reported for Medicare beneficiaries (when CPT codes for these services already exist), physicians are required adhere to the burdensome and non-HIPAA-compliant process of reporting/billing the same test/service different ways depending upon the particular payer.

The CAP believes the MACs are providing direction that is non-compliant with the Health Insurance Portability and Accountability Act (HIPAA), and MACs should require only HIPAA compliant code sets/codes when specific CPT codes are available for reporting services provided to Medicare beneficiaries. The CAP believes that Federal contractors should not require use of "non-HIPAA" codes.

The "unlisted" code reporting requirement is also burdensome for physicians because physicians are required to report/bill the same test different ways depending upon the payer. MACs should discontinue directing physicians/providers to report "unlisted" codes when specific CPT codes exist. "Unlisted" codes should not be required by the MACs and established HCPCS/CPT codes should (per statute and regulation) be considered sufficient for coverage and payment.

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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 for questions related to practice expense inputs, potentially misvalued codes and proposed valuation of specific codes; Loveleen Singh (202) 354-7133/lsingh@cap.org for questions related to PQRS/VBM; or Todd Klemp (202) 354-7105 / tklemp@cap.org related to CMS Flexibilities and Efficiencies and PAMA.

Attachments

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