



COLLEGE of AMERICAN PATHOLOGISTS

September 6, 2016

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

Attention: CMS-1654-P

Subject: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. Proposed Rule. Vol. 81 No. 136 Fed. Reg. (July 15, 2016); CMS-1654-P; RIN 0938-AS81

Dear Acting Administrator Slavitt:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1631-P entitled "Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule." 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.

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

- 1) Valuation of Specific Codes, CY2017 Proposed Codes that Were Also CY 2016 Proposed Codes:
 - a) Immunohistochemistry (CPT Codes 88341, 88342, 88344, and 88350)
 - b) Practice Expense Inputs – (CPT codes 88341, 88342, 88344, 88360, and 88361)
 - c) Morphometric Analysis (CPT Codes 88364, 88365, 88367, 88368, 88369, and 88373)
 - d) Flow Cytometry Code Interpretation (CPT codes 88184, 88185, 88187, 88188, and 88189)
 - e) Flow Cytometry Interpretation – CPT Coding
 - f) Flow Cytometry Practice Expense Inputs (CPT codes 88184 and 88185)
 - g) Microslide Consultation (CPT codes 88321, 88323, and 88325)
 - h) Prostate Biopsy, Any Method (HCPCS Code G0416)
 - i) Practice Expense Medical Supplies for Eosin
 - j) Cytopathology fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)
 - k) Updates to Prices for Existing Direct PE Inputs
- 2) Standardization of Clinical Labor Tasks, Pathology Clinical Labor Tasks
- 3) Technical Corrections to the Direct PE Input Database for CY 2016

- 1) Valuation of Specific Codes, CY2017 Proposed Codes that Were Also CY 2016 Proposed Codes:**



a) Immunohistochemistry and Immunofluorescence (CPT Codes 88341, 88342, 88344, and 88350)

88341 and 88350

For CY 2017, the CMS is proposing physician work values of 0.56 for 88341 and 0.59 for 88350. Although these values represent an increase to the current CY 2016 physician work RVUs they still do not reflect the appropriate work involved compared to the base codes 88342 and 88346. While the CAP appreciates these increases that come closer to the RUC recommended values, they still do not represent the proper work RVUs for the work involved and present a rank order anomaly with respect to other services. The CMS proposes these values in relation to their corresponding base codes in a similar manner to two add-on intravascular ultrasound evaluation services, 37252 and 37253. These ultrasound services are add-on services involving the introduction of an ultrasound catheter over a guide wire to a noncoronary vessel for imaging, evaluation, and/or with therapeutic intervention. 37252 and 37253 involve an array of different components within a hospital surgical suite setting that are much different than work of pathology. **The two intravascular procedures are not comparable medical services to CPT codes 88342 and 88341 as well as CPT codes 88346 and 88350.**

The physician work of 88342, 88341, 88346, and 88350 involves the pathologists' verification of staining, examination of controls, evaluation of the presence and patterns of specimen specific staining, and interpretation the such staining patterns, histologic locations, and intensities to determine their histopathological and clinical significance. The pathologist then composes and dictates a report. This physician work is quite different from what is required for intravascular ultrasound procedures.

There are RUC surveys that evaluate physician work differentials between the base codes and the add-on codes for pathology services. Examples are CPT codes 88333 and 88334, and codes 88331 and 88332. These survey-documented differentials and the subsequent RUC recommended values reflect the accurate physician work differential and rank order with respect to other pathology services. In other RUC surveys for base and add-on codes, the physician work differentials are not apparent and therefore specialty society and RUC expert opinion appropriately valued the services. These examples illustrate that the RUC process works and indeed worked well with the recently valued immunohistochemistry, immunofluorescence studies, and morphometric analyses services. Despite this, the CMS did not accept the RUC recommended values.

Although in some medical procedures and services there may be efficiencies present through the lack of specific pre, intra, or post service physician work or intensities and complexities between base and add-on services, this is not the case for 88342, 88341, 88346, and 88350. Each of these pathology services is unique and distinct from all other medical services within and outside the domain of the specialty of pathology. There are differences in the components of each of the services and in their individual intensities and complexities that terminally compromise any attempt at rational comparison of the physician work of intravascular ultrasound services to pathology services.

Specifically, for additional immunohistochemistry services represented by add-on CPT code 88341 and immunofluorescence services by code 88350, each antibody is evaluated independently as part of a separate stain procedure on different slides. Each antibody has a specific staining pattern for true positivity as opposed to non-specific staining and the pattern of cytoplasmic versus nuclear versus membrane and heterogeneous versus homogenous staining must be individually evaluated for each stain. Each antibody provides specific additional information for the pathologist to interpret in order to arrive at a diagnosis for the specimen. Thus, each additional service is separate and distinct.



We remind the CMS that the RUC carefully reviewed the survey data to ensure the relativity of CPT code 88341 to other services on the physician fee schedule. The RUC reviewed the survey results from 206 pathologists for CPT code 88341 and determined that the survey 25th percentile work RVU of 0.65 appropriately accounts for the work required to perform this service. The RUC noted that although the work is slightly less for the additional single antibody procedure, this add-on service requires the same time as the base code 88342. The physician work difference between base code 88342 and 88341 is miniscule.

In addition, the CMS should also be aware that the most recent CAP physician work survey of 88346 and 88350 received over 50 respondents each. The median physician time differed by only one minute (24 and 23 minutes, respectively). In the typical case, one base code and three add-on codes would be reported. The pathologist would never be reviewing multiple cases simultaneously. The RUC noted that 88350 requires only one minute less to perform than base code 88346 and the survey respondents have placed these services in the proper rank order. The physician work difference between base code 88346 and 88350 is again, miniscule. The RUC's approach of evaluating the actual work associated with each unique base and each unique add-on service is far more accurate, rational, and responsive to the specific circumstances than holding codes equal to a fixed discount from the base code. Applying ratio comparisons and fixed discounts to arrive at a work relative value will continue to create intra-specialty rank order anomalies of physician work RVUs. **The CAP respectfully urges the Agency to accept the RUC recommended work values for 88341 and 88350 of 0.65 and 0.70.**

b) Practice Expense – (CPT codes 88341, 88342, 88344, 88360, and 88361)

In the CY 2017 proposed rule, the CMS states a stakeholder suggested “that an error was made in the implementation of direct PE inputs for code 88341 and several other related codes”. The “stakeholder stated that when the CMS reclassified equipment code EP112 (Benchmark ULTRA automated slide preparation system) and EP113 (EBar II Barcode Slide Label System) into a single equipment item, with a price of \$150,000 using equipment code EP112, the equipment minutes assigned to the E-Bar II Barcode Slide Label System should have been added into the new EP112 equipment time. The stakeholder requested that these minutes should be added into the EP112 equipment time; for example, 1 additional minute should be added to CPT code 88341 for a total of 16 minutes.”

The CMS seeks comment “whether it would be appropriate to add the former EP113 minutes to EP112”. The commenter’s suggestion is accurate and consistent with the RUC’s most recent recommendations provided to the Agency. **The CAP agrees with the stakeholder and requests finalization of the equipment minutes of EP113 being combined and added into the new EP112 equipment time for CPT codes 88341, 88342, 88344, 88360, and 88361. The CAP urges the Agency to correct the current CY 2016 PE RVUs and PE input data files to reflect this edit to the equipment PE files in the CMS’ next quarterly update.**

**c) Morphometric Analysis (CPT Codes 88364, 88365, 88367, 88368, 88369, and 88373)
88364 and 88369**

For CY 2017, the CMS is proposing a physician work value of 0.70 for 88364 and 88369. These values represent an increase to the current CY 2016 physician values. Although the CAP appreciates these increases that come closer to the RUC recommended values, they still do not represent the proper work RVUs for the work involved and present rank order anomalies with similar services. These work RVUs represent 20% discounts from their base code work RVUs of 0.88 for 88365 and 88368. Again, as mentioned above concerning immunohistochemistry and immunofluorescence studies, the CMS’ theoretical comparison of these codes to 37252 and 37253 is inappropriate. These are not comparable medical services to CPT codes 88364 and 88369. We



maintain that there can be no rational comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any other pathology service.

There are RUC surveys that indicate physician work differentials between the base codes and the add-on codes for pathology services. Examples are CPT codes 88333 and 88334, as well as codes 88331 and 88332. These surveys demonstrate differentials and the RUC recommended values reflect the accurate differential and rank order with respect to other pathology services. In other RUC surveys for base and add-on codes, the physician work differentials are not apparent and therefore specialty society and RUC expert opinion appropriately values the services. The point is that the RUC process works and it did work well with the recently valued immunohistochemistry, immunofluorescence studies, and morphometric analyses services; however the CMS did not accept the RUC recommended values.

Although in some medical procedures and services there may be efficiencies present through the lack of specific pre, intra, or post service physician work or intensities and complexities between base and add-on services, this is not the case for 88364 and 88369. Each pathology service is unique and distinct from all other medical services within and outside the scope and specialty of pathology. There are several differences in the components of each of the services and in their individual intensities and complexities that preclude any rational comparison of the physician work of intravascular ultrasound services to pathology services.

No pathology add-on service can be presumed to have a discount in physician work from the base service, which is one of the reasons the RUC surveys the base codes as well as the add on codes.. For add-on codes 88364 and 88369 the pathologist is looking at a unique and distinct second probe with an entirely different signal than that of its base coded physician service. In the case of ISH add-on services, there is no corresponding interpretive diagnosis previously established when pathologists begin work on the additional single probe stain procedure. When the RUC reviewed these codes they determined that the base codes and the add-on codes require the same time and intensities as their add-on codes; in other words, designation of the second and subsequent services as "add-on's", represents a coding convention, and does not represent an underlying difference in the characteristics of the initial ("base") and subsequent services.

As you recall, the RUC carefully reviewed the physician work survey data to determine relativity of these services and this family. Specifically, the RUC reviewed the survey results for CPT code 88364 and 88369 determined that a work RVU of 0.88, the same as the recommended work RVUs for CPT code 88365 and 88368, appropriately accounts for the work required to perform these add-on services. These two services should be valued the same as their base codes.

The CAP urges the Agency to accept the RUC recommendations for CPT codes 88364 and 88369 with physician work values of 0.88.

88373

For CY 2017, the CMS is proposing a physician work value of 0.58 for CPT code 88373. This work RVU represents a 20% discount from its base code work RVU of 0.88 for 88367. The CMS used a theoretical comparison of this code to 37252 and 37253 as discussed above. We maintain, as discussed above, that there can be no rational comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any other pathology service.

For pathology services, it is irrational to assume that second and subsequent services designated by convention as "add-on" services require a reduction in resources relative to the corresponding initial (by convention, "base") service. It is clear that when pathologists perform in situ hybridization add-on services there is no corresponding interpretive diagnosis previously established when their work begins on additional single probe stain procedures, as demonstrated by the RUC process.



The RUC carefully reviewed the survey data to determine the relativity of this service and this family of services. The RUC agreed that “using computer-assisted technology,” as included in the descriptor, does not replace physician work. Computer-assisted technology refers to the computer selecting the images for the pathologist to review. The computer does not establish the distinction between cancer and non-cancer cells. Specifically, the RUC reviewed the survey results for CPT code 88373 and determined that a work RVU of 0.86, the same as the recommended work RVU for CPT code 88367, appropriately accounts for the work required to perform this service. The RUC compared 88373 to 88369 and noted that CPT code 88369 is manual and requires slightly more physician work and time because the physician is scanning the slide on the fluorescent microscope to find the cells of interest that will potentially be evaluated. In code 88373, the images that the physician evaluates are selected by the computer; however the images still requires the physician to analyze them and make decisions. **The CAP urges that the CMS adopt the RUC recommended work RVU of 0.86 for CPT code 88373.**

d) Flow Cytometry Code Interpretation (CPT codes 88184, 88185, 88187, 88188, and 88189)

For CY 2017, the CMS proposes the RUC recommended work RVUs of 0.74 for CPT code 88187, and the RUC recommended work RVU of 1.70 for CPT code 88189. **The CAP agrees with the Agency that these work values be finalized.** In the meantime, the CMS proposes a cross-walked value of 1.20 for CPT code 88188 rather than the RUC recommended value of 1.40. The CAP disagrees with the cross-walked value for several reasons. First, the CMS states that the value was arrived at “by noticing that there were no comparable codes with no global period in the RUC database with intra-service time and total time of 30 minutes that had a work RVU higher than 1.20.” This statement is not supported by information found in the RUC database as there are at least 10 such codes, valued over 1.20 RVUs in the 2016 v2 RUC database (1 XXX and 9 ZZZ global codes, ZZZ codes that are add-on codes to XXX codes). These 10 codes range in work value from 1.38 to 2.40 RVUs, with a median of 1.67. Therefore, based on this data, CPT code 88188 could be fairly valued 1.67 RVUs. However, a work RVU of 1.67 for 88188 would disrupt the service’s work RVU rank order with CPT codes 88187 and 88189, and such a value would be contrary to the expert opinions of the house of medicine voiced through the RUC deliberative processes.

The Agency should realize that the establishment of physician work values that are higher than others on the fee schedule is not unprecedented. New and revised medical services and procedures are constantly being developed, refined, and should be recognized by the Agency. The establishment of new physician work values reflects the resources utilized to provide them. The CAP disagrees with the logic that led to the Agency’s proposed cross-walk of CPT code 88188 to CPT code 88120. Further, it should be recognized that the physician work of CPT code 88120 is much different than that of CPT code 88188. The step by step physician work efforts are completely different, as are their intensities and complexities.

The physician work and complexity of the interpretation of flow cytometric analyses for 9-15 markers is substantially greater than that associated with the service the CMS has proposed, CPT 88120 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual). 88120 typically only involves identifying and quantifying a limited subset molecular probes (e.g., FISH probes for chromosomes 3, 7, 17 and 9p21 loss), using two to four color signal enumeration to detect aneuploidy staining of nuclei on slides from isolated cell preparations, usually from morphologically well-characterized specimens. In contrast, with 88188 the pathologist is required to integrate multi-parameter diagnostic information on different cell populations (both abnormal and normal), by assessing cell scatter (size and shape) along with signal intensity and pattern of staining of cell surface markers with antibody reagents using four to six (or more) color fluorescent antibody probes. Typically, to characterize 9 to 15



markers in the evaluation of a patient with lymphadenopathy and lymphoma, this means the pathologist will be reviewing and performing comparisons and correlations of between 14 and 24 antibody probes in five or more stained cell preparations (tubes) derived from a single primary patient specimen. The pathologist must perform successive, iterative analyses of 2- and 3-dimensional plots and histograms and re-gating of identified cell populations (based on size, shape, relative staining patterns, signal intensity, etc.) to characterize cell lineage and render a final diagnosis and interpretation.

In addition, the CMS reviewed the work RVU increments between the flow cytometry services from the 25th percentile survey results and that of the cross-walked code value. While attending the RUC meeting, the Agency should recall that the specialty originally recommended work values had almost identical increments between the three services (0.60 between 88187 and 88188, and 0.63 between 88188 and 88189); however the median survey results indicated a much greater physician work increment between 88188 and 88189. The final RUC recommendations were based on the physician expertise represented in the RUC process during which the work increments between 88187 and 88188 became more obvious (0.74) than the difference between 88188 and 88189 (0.30). The 25th percentile work RVUs also reflected a more pronounced work increment between 88187 and 88188 (0.40) in relation to the work increment between 88188 and 88189 (0.30). The RUC agreed with this relationship and agreed with the cross-walk of CPT code 88346 to code 88187. In addition, if the median survey increment between 88187 and 88188 (0.60) was added to the final value of 88187 the work RVU would be 1.34. However, the 25th percentile survey results and the RUC's opinion that there should be a more pronounced increment of work between 88187 and 88188 than for 88188 and 88189 presents validation of the RUC recommended work value of 1.40 for CPT code 88188.

Lastly, when the RUC reviewed the physician work of the flow cytometry services they recognized that, over the last decade, flow cytometric analyses have changed through technological advances that have allowed for an increased interpretative sophistication. It is now typical for the physician to analyze substantially more data than in the past. With the advent of 5, 6, 8, and 10 color flow cytometry, the intensity and complexity of these services have significantly increased. This increased intensity and complexity is reflected in the RUC recommendation for this service, based on additional physician work associated with technological changes, time, and intensity. The RUC recommended work RVU for 88188 is based on survey results from 82 practicing pathologists from a random survey. The RUC recognized the difference in physician time from the initial work survey performed 12 years ago and understood that technological advances had reduced the physician time and work for these services. The RUC agreed with the specialty's survey effort, comparisons of the key reference services and the recommendation of the 25th percentile survey results which reflected a 17% decrease in the physician work value from its current value. **The CAP urges the Agency to accept the RUC recommended physician work value of 1.40 for CPT code 88188.**

e) Flow Cytometry Interpretation– CPT Coding

In the proposed rule discussion on CPT codes 88184 and 88185 which describes the technical component of flow cytometry services, the agency states that the coding for these two procedures may inhibit accurate valuation as CPT code 88184 describes the first marker for flow cytometry, while CPT code 88185 is an add-on code that describes each additional marker. The CMS further indicates that it may be more accurate to have a single CPT code that describes the technical component of flow cytometry on a per-patient case basis.

The CAP understands that there are stakeholder concerns with the undervaluation of these services. To that end the CAP remains engaged with stakeholders in discussions and reviewing all coding solutions for flow cytometry. The current structure allows for the capturing of the increased



cost of each additional marker. We are concerned that the current technical component valuation as proposed by the CMS in this rule does not accurately reflect costs associated with these services (see 1.f below), and therefore we are additionally concerned that a coding structure change may exacerbate the undervaluation of these services. The RUC has reviewed these services twice in the last two years, which, when combined with practice expense edits made by the CMS, has resulted in substantial decreases in the practice expense relative values. Those reviews together with further reductions made by the CMS have resulted in substantial decreases in the practice expense relative values. Any additional change revaluation or coding change would be premature and potentially disruptive to the marketplace. When and if a revised coding structure is deemed appropriate, the CAP and other stakeholders will proceed to work with the AMA CPT processes as appropriate. At this time, the CAP remains engaged with other stakeholders in reviewing this issue.

f) Flow Cytometry Practice Expense Inputs (CPT codes 88184 and 88185)

On pages 46251-2 and again on Table 25 starting on page 46354 of this proposed ruling, the CMS discusses a number of refinements to the direct practice expense inputs of CPT codes 88184 and 88185 from what the specialty societies and the AMA RUC recommended. The CAP specifically comments on each of these refinements below:

- **Code 88184:** The CMS proposes to refine the time for the printer, dye sublimation (photo, color) from 5 minutes recommended by the RUC to 2.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: For flow cytometry services the dedicated equipment time for the printer, dye sublimation (photo, color) (ED031) printing is 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 exactly 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 88184:** The CMS proposes to refine the time for the lab technician (L033A) to enter data into the laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation from 4 minutes recommended by the RUC to 0.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: These tasks are the standard of care for reporting the results into the laboratory information system (LIS) of this service and assistance to the physician regarding quality assurance. 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. The laboratory technician carefully reviews, and checks the information, then enters the reporting results into the LIS 4 minutes for this task is very typical.
- **Code 88184:** The CMS proposes to refine 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.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: 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 any patient case carryover. Waste management after the procedure is the responsibility of the laboratory technologist as well. The equipment instruments and work areas are also cleaned at the end of the shift and throughout the day.

- **Code 88184:** The CMS proposes to refine the time for the 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.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: These services are more complex than 88182. 88182 is a different patient service than flow cytometry immunophenotyping services captured by CPT codes 88184-88189. Comparison to 88182 is not appropriate as 88184 uses 4-6 color channel instruments, while 88182 uses 1-2 channels. The time it takes for data capture, data modeling, data acquisition, and computational analysis is substantially longer for 88184 than for 88182. Time here is also associated with flow cytometry analytics software. 10 additional minutes for 88184 and 2 additional minutes for 88185 are necessary for the cytotechnologists' use of this software. 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.
- **Code 88184:** The CMS proposes to refine the time for the Cytotechnologist (L045A) to Print out histograms, assemble materials with paperwork to pathologists from 5 minutes recommended by the RUC to 2.
CAP Comment: We agree with the proposal: If the time it takes the cytotechnologist to determine which histograms to print is subtracted, then we can agree on 2 minutes.
- **Code 88184:** The CMS proposes to refine the time for the Cytotechnologist (L045A) to Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling from 15 minutes recommended by the RUC to 13.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: Comparison to 88182 is not appropriate, which uses older/simpler technology. 88184 uses 4-6 or more color channels, while 88182 uses 1-2 channels. CMS lowered the time for this task by comparing it to this other pathology service, but these tasks are unique to this service. 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. Standardizations were applied incorrectly as this service uses different kinds of equipment and therefore the time is longer.
- **Code 88184:** The CMS proposes to refine the quantity of medical supply SL186 antibody, flow cytometry (each test) from 1.6 recommended by the RUC to 1.0.
CAP Comment: We disagree with the proposal: It is standard of practice to use a single antibody (such as CD45 or CD19) multiple times during the flow analysis, however, each antibody or marker can only be billed once per analysis. The use of a single antibody is needed multiple times for gating and comparative expression analyses to other markers analyzed and is integral to the process. Multiple use of such antibodies are not reportable or billable, but are essential to the overall analysis and interpretation of results and, as such, are necessarily part of the total cost for each 88184 procedure performed. Consultation with numerous stakeholders indicate 1.6 aliquots of antibody reagent are typically used for each reported and billed marker. The quantity of 1.6 antibodies per billed marker was derived from 2015 data from a survey of experts performing these services at multiple facilities, laboratories, and with different protocols [based on a typical flow cytometry panel consisting of 24 markers].



- **88184-88185:** We thank the CMS for adopting the RUC's recommendation to include use of flow cytometry analytics software as a dedicated practice expense for this procedure. **We urge the CMS to finalize its proposal.**
- **Code 88185:** The CMS proposes to refine the time for the printer, dye sublimation (photo, color) from 5 minutes recommended by the RUC to 2.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: For flow cytometry services the dedicated equipment time for the printer, dye sublimation (photo, color) (ED031) printing is 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 proposes to refine 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.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended time: These tasks are the standard of care for reporting the results into the laboratory information system (LIS) of this service and assistance to the physician regarding quality assurance. These tasks must be performed for each individual patient case. The results are manually entered in most facilities, as there is typically no interface capable to perform this function. The laboratory technician carefully reviews, double checks the information, and enters the reporting results into the LIS. 1 minute for this task very typical for 88185.
- **Code 88185:** The CMS proposes to refine the medical supply SL089 Lysing reagent (FACS) from the RUC recommended 3 ml to 2 ml.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended quantity: The CMS proposed to maintain the quantity of the "lysing reagent" supply (SL089) at 2 ml for CPT Code 88185, which it derived from the allocation of 50-55 ml across 24 markers. Based on a high level review, the CAP acknowledges that the current Medicare data shows that a patient case of 24 markers is typical, but this result ignores certain deeper and relevant pieces of information. First, an analysis of the 2014 Medicare 5% Sample Carrier Database showed that over 50% of individual providers typically bill fewer markers per patient case. These providers are generally smaller and see fewer annual cases than the larger flow cytometry laboratories that typically analyze and bill more than 20 markers per case. A patient case of fewer than 20 markers and 50ml of lysing reagent would require more than 2ml per marker. Therefore, reducing the ml of lysing reagent from 3ml to 2ml would harm more than half of all providers that perform flow cytometry, and drive these providers to consider ceasing their flow cytometry services. Second, the CAP posits that when the flow TC codes (88184, 88185) are performed by a reference lab and the PC interpretation (88187, 88188, and 88189) are performed by a pathologist, it is often billed as part of either Inpatient DRG, Hospital OPPIs, or client billed. This additional data will have an effect on the typical number of markers billed per case that should be taken into account.



- **Code 88185:** The CMS proposes to refine the quantity of medical supply SL186 antibody, flow cytometry (each test) from 1.6 recommended by the RUC to 1.0.
CAP Comment: We disagree with the proposal and urge the Agency to accept the RUC recommended quantity: It is standard of care to use a single antibody multiple times for gating and comparative expression analyses of different antibodies. The use of these antibodies multiple times are currently not reported or allowed as billable. The research studies indicate 1.6 aliquots of antibody reagent are typically used for each reported and billed marker. The quantity of 1.6 antibodies per marker was derived from 2015 data from a survey of experts performing these services at multiple facilities, laboratories, and with different protocols.

g) Microslide Consultation (CPT codes 88321, 88323, and 88325)

On Table 23 – Proposed CY 2017 Work RVUs for New, Revised and Potentially Misvalued Codes, the CMS proposes to accept the RUC recommendations for physician work for microslide consultation codes 88321, 88323, and 88325. **The CAP agrees and requests that the Agency finalize the RUC recommended physician work values for these codes.**

On page 46254, the CMS states that in “the CY 2016 PFS final rule with comment period, we finalized our proposal to remove any of the inputs for clinical labor, supplies, and equipment for CPT code 88325. ... After further discussion with pathologists and consideration of comments received, we have been persuaded that slide preparation does take place in conjunction with the service described by CPT code 88325. In the RUC recommended direct PE inputs from the January 2016 meeting, the lab or, supplies, and equipment inputs related to slide preparation were added once again to CPT code 88325”. The Agency proposes to accept these restorations related to slide preparation without refinement. **The CAP agrees with the Agency and requests that these direct inputs be finalized for CY 2017. In addition, the CAP urges the Agency to correct the current CY 2016 PE RVUs and PE input data files to reflect this edit in the current CY 2016 PE RVUs and PE inputs data files in CMS’ next quarterly update.**

The CMS proposes on table 25, page 46357, to refine the time for assembling and delivering slides with paperwork to the pathologists. The CMS states that this clinical labor task is redundant with another clinical labor task. This is not the case for 88321, this is a necessary step in providing this service. This was accidentally left off of the April 2014 RUC recommendation for 88321. The CMS had added a minute for 88321 into the direct inputs and now have proposed to take it out. This is not a redundant task and what the CMS claims it is redundant with is not explained in the proposed ruling. If this task is eliminated, the CAP recommends 1 minute for "Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist." **The CAP urges the CMS not to refine the clinical labor time for 88321 for assembling and delivering slides with paperwork to the pathologists.**

Please see the attached practice expense refinement spreadsheet for additional CAP comments.

h) Prostate Biopsy, Any Method (HCPCS Code G0416)

For CY 2017, the CMS proposes a physician work value for HCPCS code G0416 of 3.60 based on a “intra-service time ratio between HCPCS code G0416 and CPT code 88305”. The math is as follows: $((120/25) \times 0.75) = 3.60$. As further support, the Agency also lists using the intra-service work per unit of time of CPT code 88305 multiplied the cross-walked 120 minutes from CPT code 88305 (120



X 0.03) = 3.60. **The CAP does not agree with the CMS formulaic approach of multiplying time by intensity to arrive at a value for this code.**

The RUC valued HCPCS code G0416 through agreement of the presented cross-walk methodology and compelling evidence. The CAP would also like to remind the Agency that the RUC agreed with the compelling evidence presented by the specialties and that the work of G0416 may involve the examination of 20-60 or even more specimens. The CAP urges the Agency to discard its formulaic approaches to value the physician work and adopt the proven RUC's methodologies of physician surveys, expert panel opinions, cross-walks, and magnitude estimation. **The CAP urges the CMS to accept the RUC recommended physician work value of 4.00 for HCPCS code G0416.**

i) Practice Expense Medical Supplies for Eosin

The CAP acknowledges that Eosin used in histology labs is now typically purchased as a premade solution and measured in milliliters. Eosin is no longer typically mixed in the lab from powder.

j) Cytopathology fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)

The CMS proposes to refine the clinical labor time for 1) ordering, restocking, and distributing specimen containers, slides, and requisition forms, and 2) recycling xylene from the stainer equipment, for codes 88104-88162 to zero from the RUC recommended times. The proposal lists that these are considered forms of indirect practice expense. Indirect practice expense costs are identified from indirect practice expense surveys that were conducted by the AMA several years ago. The CMS does not list the question on the survey where these costs are captured in the CMS' methodology. These costs are differentiated by pathology service type as they are unique. The CAP maintains that these tasks are direct expenses as they are variable based on the volume of these services. The RUC recommended times were calculated from directly attributable time based on the quantity of specimens typically provided from a typical laboratory. **The CAP urges the CMS not to refine the time for these two clinical labor tasks but to accept the RUC recommended times of 1) 0.5 minutes for ordering, restocking, and distributing specimen containers, slides, and requisition forms, and 2) recycling xylene from the stainer equipment for CPT codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162.**

The CMS proposes to refine the equipment time for EP038 – solvent recycling system from 2 minutes to 0. The time for recycling xylene is a variable direct expense based on the volume of these services. This is a calculated time directly attributable to the quantity of specimens typically provided from a typical laboratory and was not captured in the indirect practice expense cost survey to our knowledge. The CMS does not list the question on the indirect expense survey that captures these costs. **The CAP urges the CMS not to refine the time for EP038 and urges the Agency to accept the RUC's recommended time of 2 minutes for CPT codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162.**

Due to comments clarifying batch size for codes 88108 and 88112, the CMS proposes to restore the quantity of 0.2 for the gloves (SB022), gowns (SB027), and eye shields (SM016) associated with these services. **The CAP agrees with these changes to the quantities of these supplies which are consistent with the most recent RUC recommendations for these services. The CAP requests the Agency to finalize these specific practice expense supply edits for codes 88108 and 88112 for CY 2017.**



Please see the attached practice expense refinement spreadsheet for additional CAP comments.

k) Updates to Prices for Existing Direct PE Inputs

In CY 2017, the CMS is proposing to update the price of the Antibody Estrogen Receptor monoclonal (SL493). Specifically, the CMS received information including three invoices regarding the SL493 supply. Based on this new information, The CMS is proposing to price this item at \$14.00 per test which is the average price of the invoices that were received. **The CAP supports the CMS proposal to price supply SL493 at \$14.00 per test. The CAP urges the CMS to finalize this pricing in the Final Rule.**

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

As the CMS and the AMA RUC continue to increase the transparency of the information used to set PE RVUs, the CAP has several concerns about the standardization of pathology clinical labor tasks and the use of the clinical labor time in the assignment of equipment minutes. Although the CAP agrees that there may be some instances where it would make sense to compare clinical labor times for activities associated with services across the PFS, it would not make sense in many other situations. For pathology services and other services and procedures paid under the PFS, the standardization of clinical labor tasks across services and across specialties presents significant challenges. For example, the process and time required to clean a room or workspace for a standard evaluation and management service, a partial ostectomy, a colonoscopy, or nerve teasing preparations are vastly different and the standardization of these tasks is unrealistic. Blanket standardizations such as these will disrupt the relativity of the direct PE inputs on the PFS. Standardization of clinical labor tasks within specialties can be easy for some and still be challenging for others. Within the specialty of pathology, the CAP is concerned that the CMS still has neglected to consider issues such as the inherent nature and processes of the particular specialized service, the block, the batch size, or add-on service status that determines the accurate resources required for the PFS resource based PE methodology to properly function.

Each pathology service has its own unique processes that utilize specialized medical supplies and equipment. **Generally speaking, clinical labor tasks with the same description may or may not be comparable across different pathology procedures.** The CAP maintains that standardization of clinical labor tasks for pathology services across all services is inappropriate and will result in rank order anomalies in the PE inputs unless careful consideration is made through specialty society input and RUC review. Therefore, the six standardized times of pathology clinical labor tasks on Table 6 (page 46176), **that have not been** specifically addressed with specialty input and RUC reviewed should be eliminated across all pathology services. The RUC's deliberative process agreed upon clinical labor task times for all of the codes containing those tasks on Table 6. These clinical labor times should be applied to the direct PE inputs for CY 2016 and beyond. **The CAP urges the Agency to remove the standard times for clinical labor tasks associated with pathology services on Table 6 on page 46176, and revert the times for these tasks to the RUC recommended times.**

3) Technical Corrections to the Direct PE Input Database for CY 2016

The CAP lists the following possible errors in the existing CY 2016 direct PE input files. The CAP believes that in the following instances, the CMS standardized specific clinical labor tasks within the PE direct inputs in error based on proposed, not finalized, clinical labor standardizations that were listed on Table 6 - Standard Times for Clinical Labor Tasks Associated with Pathology Services on



page 41698. In its PFS final rule for CY 2017, the CMS finalized 6 out of 11 proposed pathology clinical labor tasks. These errors may have occurred early in the rule making process, and were not corrected for the final ruling. **The CAP urges the Agency to revert these errors in clinical labor time back to the RUC recommended time as soon as possible for the next CY 2016 quarter update to the physician fee schedule and direct practice expense input files.**

1. CPT code 88329 – RUC Reviewed April 2014, the RUC recommended 10 minutes for Assist pathologist with gross specimen examination. CY 2016 direct PE input files indicate 3 minutes for this task. In addition, the current direct PE input files indicate a staff type of cardiovascular technician rather than the RUC recommended histotechnologist (L037B).
2. CPT code 88331 – RUC Reviewed April 2014, the RUC recommended 10 minutes for “Assist pathologist with gross specimen examination. The CY 2016 direct PE input files indicate 3 minutes for this task.
3. CPT codes 88360 and 88361 – RUC Reviewed April 2014, the RUC recommended 5 minutes for “Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer”. The CY 2016 direct PE input files indicate 1 minute for this task.

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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 either; Maurine Dennis (202) 354-7136 / mdennis@cap.org or Todd Klemp (202) 354-7105 / tklemp@cap.org.

Sent via Electronic Submission to <http://www.regulations.gov>