COLLEGE of AMERICAN PATHOLOGISTS

December 29, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1631-FC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016. Final Rule. Vol. 80 No. 220 Fed. Reg. (November 16, 2015)

Dear Acting Administrator Slavitt:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the final rule CMS-1631-FC entitled "Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule." The CAP is a national medical specialty society representing 18,000 physicians who practice anatomic and/or clinical pathology. 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 final rule:

1) Valuation of Other Codes for CY 2016 - Specific Pathology Services
    a. Immunofluorescent studies (CPT Codes 88346 and 88350)
    b. Immunohistochemistry (CPT codes 88341, 88342, 88344)
    c. In situ hybridization (CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377 88368, and 88369)
2) Standard Tasks and Minutes for Clinical Labor Tasks – Pathology Clinical Labor Tasks
3) Direct PE Input-Only Recommendations
    a. Morphometric Analysis, Tumor Immunohistochemistry (CPT Codes 88360 and 88361)
    b. Flow Cytometry Cytoplasmic Cell Surface (CPT Codes 88184, 88185)

4) Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT codes 88104, 88106, 88108, 88112, 88160, and 88162) Direct Practice Expense Edits (88112, 88104, 88106, 88108, 88160-2) **– See attached spreadsheet.**

1) Valuation of Other Codes for CY 2016 - Specific Pathology Services
a. Immunofluorescent studies (CPT codes 88346 and 88350)

Physician Work

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The CAP disagrees with the CMS' decision to alter and/or not accept the RUC's physician work recommendation for CPT code 88350. Specifically the CAP strongly disagrees with the comparison of immunofluorescent services (codes 88346 and 88350) to the intravascular ultrasound codes (codes 37250 and 37251) through its inappropriate physician time ratio calculations. The CMS had proposed to value this immunofluorescence add-on service in relation to the corresponding base code in a similar manner to two add-on (ZZZ global) ultrasound evaluation services, 37250 and 37251. The CMS valued the difference between a base pathology service (XXX global) and its add-on service (ZZZ global) using the difference in relative values of two highly intense and complex add-on codes (ZZZ global). As we noted in our proposed rule comments, these ultrasound services are both add-on services involving the initial and additional vessels. They are completely different services that necessitate completely different physician resources and their valuations were obtained through vastly different assumptions and survey information. Unlike CPT codes 88346 and 88350 which involve the work related to initial and additional single antibody stain procedures, 37250 and 37251 are highly intense and complex services that are three times the intensity and complexity of 88346 and 88350. The comparison of two add-on services of high complexity and intensity, performed during a diagnostic evaluation and/or therapeutic intervention, to one pathology base code and one add-on service is an unprecedented valuation methodology contrary to statute Sec. 1848. [42 U.S.C. 1395w–4] (a) (i), which states: "The Secretary shall determine a number of work relative value units for the service based on the relative resources incorporating physician time and intensity required in furnishing the service."

There is no history of correlation between these services nor logical reasoning understood by the CAP or stated by CMS that there should be a correlation in physician time, intensity, and complexity between two ZZZ codes and an XXX base code and one ZZZ code. Additionally, the CAP reiterates that these two ultrasound codes were valued once by the RUC in August 1995 using a sample size of 49 with 29 respondents. The sample size alone would indicate these services were not surveyed using a random sample but likely were target surveyed 20 years ago under substantially different RUC guidelines and rules. Both 37250 and 37251 have been recently deleted from CPT and there should be no comparison of these codes to the immunofluorescent studies codes. The CAP does not agree with the arbitrary calculation that has led to the incorrect valuations of these codes and rank order anomalies across a wide range of services.

In contrast to the ultrasound surveys, the recent RUC physician work survey of 88346 and 88350 received over 50 respondents each, making the results robust and much more reliable. The median physician time differed by only one minute (24 and 23 minutes, respectively). The RUC agreed with the survey respondents, who reported that 23 minutes of intra-service time is appropriate relative to other similar services. 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 arbitrary ratio comparisons and fixed discounts to arrive at a work relative value will continue to create inter-specialty and intra-specialty rank order anomalies. **The CAP urges the agency to**

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discard its inappropriate physician time ratio comparisons and accept the relative resources reflected in the RUC values derived from survey data and magnitude estimation for 88350 with a work RVU of 0.70 with 23 minutes of intra-service and total time, reflecting the RUC survey 25th percentile results. Any different valuation would create rank order anomalies throughout the physician fee schedule.

b. Immunohistochemistry (CPT codes 88341, 88342, 88344)

Physician Work
For CY 2015, the CMS accepted the RUC recommended values for the base code 88342 (0.70 RVUs) and for the multiplex service 88344 (0.77 RVUs), but implemented a value for the add-on service **88341** equal to 40% of the base code (0.42 RVUs). The CAP disagreed and explained to the agency that each antibody is evaluated separately on different slides, that it is inappropriate to apply a 40% reduction, and that it is reductive to categorize all pathology add-on services as requiring the same resources. In addition, the CAP also demonstrated that the difference in physician work from the base code to the add-on service is diminutive for most pathology services. This was reflected in the RUC survey for 88341.

Specifically, as we noted in our proposed rule comments, each antibody is evaluated separately on different slides for immunohistochemistry services represented by new CPT code 88341. Each antibody has a specific staining pattern for true positivity as opposed to non-specific staining and the pattern of cytoplasmic, versus nuclear, 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. Therefore, **each additional service is separate and distinct**.

For CY 2016, the CMS proposed, without explicitly stating in the ruling but only in the proposed fee schedule RVU tables, that the add-on service 88341 be valued at 0.53 RVUs. The CMS had no stated rationale. The CAP assumed the rationale would be the same as the rationale the CMS stated in the rule for its proposed reduction to the new add-on code for immunofluorescent studies code 88350, which would include a 24% discount from the base code as mentioned above. Again, we reiterate that there should be no comparison of intravascular ultrasound services to immunohistochemistry, immunofluorescence, or any pathology service for the reasons previously stated. The CAP does not agree with these arbitrary physician time ratio calculations as discussed above regarding CMS' valuation of 88350.

The CAP appreciates the fact that CMS has acknowledged that it inadvertently omitted discussion about the rationale for the increased work RVU for CPT code 88341 in the proposed rule. In light of this CMS will maintain the current interim value in 2016 while seeking comment during the Final rule comment period.

However, the CAP reiterates its previous comments that the RUC carefully reviewed the survey data to ensure the relativity of CMS code 88341 to other services on the physician

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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 this add-on service requires the same time as the base code 88342, the work is slightly less for the additional single antibody procedure. Based on the relativity established by the RUC through its review of this service, as well as the above explanation for why pathology add-on services cannot all be presumed to have any fixed discount in physician work from their respective base services, there is no rationale for a 24% reduction. **Therefore, the CAP urges the agency to discard its inappropriate physician time ratio comparisons and accept the relative resources reflected in the RUC values derived from the RUC survey data and magnitude estimation for 88341 with a work RVU of 0.65 and with both 25 minutes of intra-service and total time, reflecting the RUC survey 25th percentile results. Any different valuation would create rank order anomalies throughout the physician fee schedule.**

c. In situ hybridization (CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377 88368, and 88369)

Physician Work
88364
For CY 2016, the CMS had proposed, without explicitly stating any rationale in the ruling but only in the proposed fee schedule RVU tables, that the add-on service for FISH (**88364**) and manual HER2 (**88369**) be valued at 0.67. The CAP assumed the rationale would be the same as the rationale that the CMS stated in the rule for its proposed reduction to the new add-on code for immunofluorescent studies code 88350, which reflects a 24% discount from its base code. There should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any pathology service. Again, the CAP does not agree with these arbitrary inappropriate physician time ratio comparison calculations. These comparisons are not relative resource based and are contrary to statute as discussed above concerning CPT code 88350.

The RUC carefully reviewed the physician work survey data to determine relativity of the physician resources of these services and this family. Specifically, the RUC reviewed the survey results for CPT code 88364 and determined that a work RVU of 0.88, the same as the recommended work RVU for CPT code 88365 and 88368, appropriately accounts for the physician work required to perform this service. The RUC also noted that the pathologist is looking at a second probe with an entirely different signal than the base code 88365. The RUC also pointed out that the recommended work RVU is lower than the survey 25th percentile work RVU of 0.95. The RUC determined that since 88365 and the add-on code 88364 require identical time and intensity, these two services should be valued with the same work RVU.

Based on the resource based relativity established by the RUC through its review of this service, as well as the above explanation for why pathology add-on services cannot all be presumed to have any fixed discount in physician work from their respective base services,

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there is no rationale for a 24% reduction. **The CAP urges the agency to discard its inappropriate physician time ratio comparisons and accept the RUC process of utilizing the relative resources reflected in the RUC values derived from the RUC survey data and magnitude estimation for 88364 with a work RVU of 0.88**. **Any different valuation would create rank order anomalies throughout the physician fee schedule.**

88369
As the CAP discussed in our proposed rule comments, the RUC carefully reviewed the physician work survey data to determine relativity of this service and this family. Specifically, the RUC reviewed the survey results for CPT code 88369 and determined that a work RVU of 0.88 — the same as the recommended work RVU for CPT code 88365 and 88368 — appropriately accounts for the work required to perform this service. The same numbers of cells are evaluated by the pathologist when rendering a diagnosis for CPT code 88369 as in CPT code 88368. 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 fluoroscopic microscope to find the cells of interest that will be counted.

The agency has acknowledged that the discussion about the rationale for the increased work RVU was inadvertently omitted from the proposed rule. Therefore, it will maintain the interim final status of the work RVU of 0.76 for CPT codes 88464 and 88369 for CY 2016 and seek comment on these work RVUs during the comment period for this final rule. **The CAP urges the agency to discard its inappropriate physician time ratio comparisons and accept the relative resources reflected in the RUC values derived from the RUC survey data and magnitude estimation for 88369 with a work RVU of 0.88**. **Any different valuation would create rank order anomalies throughout the physician fee schedule.**

88367
In this final ruling, the CMS has maintained its interim work value on its physician fee schedule for CY 2016 for CPT code **88367**. The CAP disagrees with this decision and recommends that the CMS adopt the RUC recommended value for 88367. The agency had noted that CPT code 88367 is the computer assisted version of morphometric analysis, analogous to 88368, which is the manual version. The CMS accepted the RUC recommended work RVU of 0.88 and time of 30 minutes for 88368, but the agency did not recognize that the RUC recommended work RVU of 0.86 for 88367 adequately reflected 25 minutes of intra-service time. The CMS used the ratio of intra-service time for the two codes to discount the work RVU of 88367 by 15%, resulting in a value of 0.73 RVUs and ignored the RUC's resource based relativity assessment of the intensity, complexity, and magnitude estimation for this service. The CAP disagrees with the manipulation of work RVUs based on speculation rather than through the accuracy of the RUC process of valuation using survey data and magnitude estimation. When reviewed, the RUC concluded that the 0.86 work RVU appropriately accounts for the work required to perform this service and compared this code together with its code family including CPT code 88368 for relativity. In

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addition, it was noted that the same numbers of cells are evaluated by the pathologist when rendering a diagnosis for CPT code 88367 as in CPT code 88368. The RUC compared 88367 to 88368 and noted that CPT code 88368 is manual and requires slightly more physician work and time because the physician is moving among the images from the fluorescent microscope to find the cells of interest that will be counted. In code 88367, the images that the physician evaluates are selected by the computer. CPT code 88367 still requires the physician to independently view, analyze and make decisions on each separate image, and calculate a ratio for each service. **The CAP urges the agency to discard its inappropriate physician time ratio comparisons and accept physician resources reflected in the RUC's value derived from survey data and magnitude estimation for a work RVU of 0.86 for CPT code 88367.**

88373
In this final ruling, the CMS has maintained its interim work value on its physician fee schedule for CY 2016 for CPT code **88373.** For CY 2016, the CMS had proposed a work RVU for 88373 of 0.43 which represents a 50% discount from the RUC recommendation of 0.86.

Again, the RUC carefully reviewed the survey data to determine relativity of this service and this family. The RUC firmly 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. 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 fluoroscopic microscope to find the cells of interest that will be counted. In code 88373, the images that the physician evaluates are selected by the computer. CPT code 88373 still requires the physician to analyze and make decisions as to whether the computer correctly selected the cells to be evaluated. **The CAP urges that the CMS adopt the RUC recommended work RVU of 0.86 for CPT code 88373**. **Any different valuation would create rank order anomalies throughout the physician fee schedule.**

88374
In this final ruling, the CMS maintained its interim work value on its physician fee schedule for CY 2016 for CPT code for **88374*.*** The CMS reduced the RUC recommended work RVU for CPT code 88374, because the code is a computer-assisted version of CPT code 88377. The agency inappropriately applied a ratio of the RUC surveyed time of 88374 to 88377 (30 minutes/45 minutes) to the work RVU value for 88374 to assign an interim work RVU of 0.93 for 88374. The CMS ignored the RUC's resource based relativity assessment of the intensity, complexity, and magnitude estimation for this service. It is clear to the RUC that "using computer-assisted technology" for 88374, as included in the descriptor**, does not replace physician work**. Computer-assisted technology refers to the computer-aided

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selection of images for the pathologist to review, but the computer does not establish the distinction between cancer and non-cancer cells. In addition, the American Society of Clinical Oncology (ASCO) guidelines indicate that a minimum of 40 neoplastic cells need to be examined for signal intensity for Her2 evaluation by FISH (fluoresecent in situ hybridization). The RUC compared 88374 to 88377 and noted that CPT code 88377 is manual and requires slightly more physician work and time because the physician is scanning the fluoroscopic microscope slide to find the cells of interest that will be counted. In code 88374, the images that the physician evaluates are selected by the computer. CPT code 88374 still requires the physician to analyze and make decisions on each selected cell. In addition, when rendering an interpretation for CPT code 88374, as in CPT code 88377, the pathologist evaluates the same number of cells. The RUC concluded that, based on the survey's 25th percentile work RVU, a value of 1.04 appropriately accounts for the work required performing this service. **The CAP urges the CMS to discard its inappropriate physician time ratio comparisons and accept physician resources reflected in the RUC's value derived from survey data and magnitude estimation for a work RVU of 1.04 for CPT code 88374. Any different valuation would create rank order anomalies throughout the physician fee schedule.**

2) Standard Tasks and Minutes for Clinical Labor Tasks – Pathology Clinical Labor Tasks

As stated in our comments in response to the proposed rule, the CAP does not support the standardization of clinical labor activities across all pathology services, because each pathology service encompasses distinct and unique clinical labor tasks. Furthermore, the CAP does not feel that the standards finalized by the CMS are unaffected by batch and block size, as the agency has stated. The clinical labor time for tasks such as "Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste" is certainly influenced by the number of specimens and/or blocks. Additionally, if there are more specimens chemicals, or other waste in one procedure than another, it holds that it would take longer to dispose of those items. This concept is supported by the surgical pathology family, in which 88309 *Level VI Surgical Pathology* (18 blocks) has a higher clinical labor time for the task "Dispose of remaining chemicals" at 2 minutes than 88305 *Level IV Surgical Pathology* (2 blocks) at 1 minute. The other five tasks standardized by the CMS face similar problems. **The CAP urges the CMS not to standardize any clinical labor activities at this time and to return all of the clinical labor time standardized in the CY 2016 rulemaking process to previous levels for the first quarterly update of the physician fee schedule.**

The CAP also disagrees with CMS' decision to zero out the time for separate labor tasks that the CMS likely believes is overlapping with a standardized labor task. For instance, the CMS reduced the time for the task "Prepare, pack and transport cedar oiled glass slides and records for in-house special storage (need to be stored flat)" in the code 88362 *Nerve teasing preparations* from 10 minutes to 0 minutes while also reducing the time for the task "Prepare, pack and transport specimens and records for in-house storage and external

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storage (where applicable)" from 2 minutes to 1 minute. There is not overlapping work involved in these tasks, because they are distinct, unique, and both necessary for the completion of the service. **The CAP urges the CMS revert this and all similar changes, and return the time of the clinical labor tasks to the original values as recommended by the RUC.**

The CAP is also perplexed by the CMS' decision to keep the reductions in clinical labor time for the standardized tasks that were not finalized. When the CMS did not finalize the standard times for the remaining 11 tasks, it removed "Refined time to standard time for this clinical labor task" as a viable reason to change the times for these tasks. If CMS continues to believe that "clinical labor tasks with the same description are comparable across different pathology CPT codes" and "refinements to clinical labor time ensure the most accurate values for these activities, based on a comparison with other pathology codes that share these same clinical labor activities", then the CAP believes that the CMS must withdraw these edits for CY2016 and re-present them in a different rulemaking process under a more appropriate edit comment, such as "Refined to conform with identical labor activity in other codes in the family" or other. **The CAP requests that CMS restore the original clinical labor times for all codes containing the 11 non-finalized tasks as recommended by the RUC.**

For all the reasons stated above, the CAP disagrees with the standardization of clinical labor tasks as currently constructed, and urges the CMS to undo the edits made to any codes in the process of standardization. The CAP does acknowledge that there are possibilities to standardize pathology codes, but requests that the CMS allows the CAP to work with the RUC and other stakeholders to develop more fitting and sensible standards. The CAP appreciates CMS' acknowledgment that batch size and block number affects the labor time of clinical staff. The CAP supports submission of detailed information regarding batch size and number of blocks as part of the RUC's PE submission for pathology services, which the CAP has already started to do where possible. The CAP will continue to work with the RUC to expand upon that information in the future. The CAP also requests that, when the CMS receives information from public comment on batch and block size, the CMS encourages those parties to work with the CAP to improve the information provided to the RUC. As stated elsewhere in this comment letter, a single data point does not imply typicality better than the current process developed through the RUC. The CAP welcomes the opportunity to improve the quality of its data, and hopes to continue to work with the CMS and other stakeholders to accomplish this goal.

3) Direct PE Input-Only Recommendations

a) Morphometric Analysis, Tumor Immunohistochemistry (CPT Codes 88360 and 88361)

In this final ruling, the CMS welcomed the submission of updated pricing information regarding SL493 monoclonal antibody estrogen receptor. In response to the CMS' original proposal and continuing requests for updated pricing information, the CAP continues to

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disagree with the CMS' price for Antibody Estrogen Receptor monoclonal supply (SL493). Pathologists are constantly looking for products or methods that will improve workflow and efficiency while simultaneously enhancing quality and maintaining costs. In this instance, the CMS states that they have "identified numerous monoclonal antibody estrogen receptors that appear to be consistent with those recommended by the specialty society, at publicly available lower prices, which we believe are more likely to be typical since we assume that the typical practitioner would seek the best price available to the public." While there may be other monoclonal antibody estrogen receptors found in the marketplace used for a variety of purposes, only specific, human use, monoclonal antibody estrogen receptors should be used for CPT code 88360 and 88361. When a supply or equipment item is identified as being lower priced than what is in CMS's databases, it should first be confirmed to be the correct item. It should then, carrying equal weight, be evaluated for typicality of use amongst providers. A lower priced item may be inappropriate for the service provided and may produce suboptimal results what could threaten the quality of patient care. The CAP believes that specialty society submitted invoices provide CMS with the most valuable and accurate information available. Specialty societies have the access to a wide variety of providers and practice information and therefore can more accurately identify the correct item for the service and the typical provider from which to obtain an invoice. The CMS should use the invoices submitted to the RUC as the typical product or equipment item to set the typical price.

The lower priced example the CMS provided, Estrogen Receptor Antibody (h-151) [DyLight 405], **is not an immunohistochemical reagent, but rather an immunoflorescent antibody, an estrogen receptor antibody conjugated with an immunofluorescence marker which is excited at 400 – 421 nm by a laser. <u>This item is not an alternate reagent for CPT codes 88360 and 88361</u>**, and would not be used for these services. Providers who care for the most complicated Medicare beneficiaries would not cover their operating costs on every breast cancer case if this reagent were priced so incorrectly low. The CAP supports the originally submitted invoice <u>generated recently</u> from a hospital's purchasing department computer system as it represents the typical hospital purchasing supplies rather than a large integrated health system. **(Please see attached CAP invoices). In addition, we are supplying an older (and difficult to read) invoice for the same product with a slightly lower price that should be used as a reference only. The CAP supports using the originally submitted typical hospital's invoice.**

b) Flow Cytometry Cytoplasmic Cell Surface (CPT Codes 88184, and 88185)
The agency identified 88185 as potentially misvalued and the CAP believes both 88184 and 88185 are potentially misvalued and should be re-evaluated through the RUC process as soon as possible. **The CAP looks forward to this review and urges the agency to implement the results when received into the physician fee schedule's next quarterly update.**

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c) Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT codes 88104, 88106, 88108, 88112, 88160, and 88162) Direct Practice Expense Edits (88112, 88104, 88106, 88108, 88160-2)

The CAP appreciates CMS' effort to maintain appropriate relativity among PE and work components of PFS payment and in some cases the CAP agrees with the refinement of direct PE inputs listed in Table 16. However, there are many instances where the CAP disagrees with the refinements. Please see a list of the *CY 2016 Interim Final Codes with Direct PE Input Recommendations Accepted With Refinements* with the CAP's comments in the attached table **(*see CAP Comments – CY2016-CMS FR PE Refinements.xlsx*).**

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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 regarding these and other issues related to this ruling to Todd Klemp at (202) 354-7105 (tklemp@cap.org).

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