January 27, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS–1600–FC
Mail Stop C4–26–05,
7500 Security Boulevard
Baltimore, MD 21244–1850

Attention: CMS–1600–FC

Subject: CMS–1600–FC: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule; (December 10, 2013)

Dear Administrator Tavenner:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the final rule CMS–1600–FC entitled “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014.” The CAP is a national medical specialty society representing more than 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 proposed rule:
1. Immunohistochemistry Services;
2. Using OPPS and ASC rates in developing PE RVUs;
3. Optical Endomicroscopy (CPT code 88375);
4. Payment for molecular pathology services;
5. Prostate biopsy HCPCS code descriptor changes;
6. Cell enumeration services;

**Immunohistochemistry Services (CPT codes 88342 and 88343)**
We oppose CMS’ rejection of the new and revised CPT codes for immunohistochemistry services (CPT codes 88342 and 88343) and decision to establish G codes (G0461 and G0462) to report these services. The RUC’s Relativity Assessment Workgroup and CMS both identified CPT code 88342 for revaluation. The College of American Pathologists requested a code change proposal to better define a small minority of immunohistochemical/immunocytochemical services where more than one separately identifiable antibody can be used on a single microscopic slide. We felt that by establishing a base and an add-on code, the base code would be reported once for the first separately identifiable antibody per slide and the add-on service would be used to report an additional separately identifiable antibody on the same
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The new and revised CPT code language was put forward to allow for accurate valuation by the RUC and CMS. Mapping of RUC recommended CPT valuation of a second or subsequent stain on a single slide, to the add-on G code for all stains subsequent to the first on an entire specimen, would not be valid based on either the valuation process or the actual (infrequent) utilization of multiple versus single stains per slide. The RUC valuation is based on additional stains per slide, while the G codes are based on additional stains per specimen. This difference corresponds to an entirely different service with different physician work and different practice expense. The markedly decreased reimbursement if the valuation determined by the RUC for additional stains per slide were applied to all staining after the initial stain on a specimen (as G0462 does) threatens patient access. The RUC recommendations cannot be directly crosswalked to the new G codes.

The College of American Pathologists understands from discussions with the Agency that there is a significant concern about the current and potential future frequency of immunohistochemical procedures that include multiple separately identifiable antibodies on the same histologic slide (ie, “multiplex antibody stain procedure”). We acknowledge that the vast majority of these procedures are currently used in the evaluation of prostate needle biopsies performed for the detection of carcinoma. We collected data from a small yet diverse group (n=8) of our membership to identify the incidence of multiplex IHC (differentiating 88342 claims by ICD-9) and found a range of 0% to 6.5% (average 2.2%), confirming the rarity of this multiplex IHC procedure. Further, we utilized a major pathology billing company who queried 114 pathology groups and found the average of all cases to be 2.9%. In addition, the average of all practice cases using multiplex staining was 3.6% and in labs using multiplex staining the median percent of slides that involve multiplex staining was 1.5%. At this time, we are unaware of evolving technologies that would suggest that significant changes to the clinical utilization of these services will emerge in the foreseeable future. Hence the G code language will result in inappropriate reimbursement for immunohistochemistry, because approximately 96% of services that are currently billed use single antibodies on separate slides and only roughly 4% of services use multiplex antibody stain procedures. With the G codes, only the first antibody per specimen will be billed as G0461. This causes a significant undervaluing of the G0462 in a vast majority of cases when subsequent separate antibodies are applied to a different slide.

Furthermore, the use of the G0462 correctly is not administratively feasible. There is no way for a pathology group or billing company to successfully crosswalk between CPT and the corresponding G-codes.

We have carefully reviewed the concerns of CMS and, for the reasons stated below, suggests that modifications be made to both G0461 and G0462. We suggest these codes be reworded as:

G0461 Immunohistochemistry or immunocytochemistry, per specimen; each single antibody stain procedure
G0462 each multiplex antibody stain procedure

(Use either one unit of G0461 or G0462 for each separately identifiable antibody stain procedure per histologic, cytologic or hematologic specimen)

This proposed structure would eliminate the misaligned and misvalued add-on designation of G0462. To clarify the use of these codes we would suggest the consideration of a parenthetical “(Do not use more than one unit of G0461 or G0462 for each separately identifiable antibody stain procedure per histologic, cytologic or hematologic specimen)”, which clearly defines the unit of service as the specimen, reflecting the significant concern espoused by CMS.
The modified G-code structure will provide a mechanism for differentiating the additional work and practice expense of this minority of immunohistochemical procedures, limit the potential migration of additional units of service of the add-on code, and provide a mechanism that will allow a crosswalk from the existing corresponding CPT codes. Further, it could be used as a template for in situ hybridization procedures, should the agency have similar concerns with these studies.

We propose that the valuation of G0461 remain crosswalked to the recently revalued 88342. G046X would include both the 88342 service plus the 88343 service, and hence the crosswalk would be to the work and PE RVU's for one unit of 88342 plus the work and PE RVU's for one unit of 88343.

We would welcome the opportunity to address any questions and concerns that CMS may have in this regard.

**CMS' PE input decisions for G0461 and G0462**

CMS made several refinements to the practice expense inputs of G0461 and G0462. These refinements were made based upon “CMS clinical review” and CMS stance on what is included as indirect costs and methodology. We oppose all these reductions in the medical supplies and equipment time for these two services as the RUC’s practice expense subcommittee thoroughly reviewed and agreed with these inputs.

In addition, we have identified to two significant errors in the costing of two different supplies.

1) **Supply item SL483 - Hematoxylin II (Ventana 790-2208)** was priced by CMS for CY 2014 at $0.02256 per ml. This price is inaccurate as it is not priced correctly per milliliter per the invoice. Supply item SL483 has a quantity of 25 milliliters, and therefore the price per milliliter should be $22.58 according to the invoices submitted to the RUC. CMS' practice expense supplies data inputs indicate the correct quantity at an incorrect price.

2) **Supply item SL486 - 250 Test Prep Kit # 78 (Ventana 786-3034)** has been priced by CMS at the per test level, whereas the RUC recommendation was listed at the per item level and then quantified to the per test level. To correct this error we recommend the quantity be changed from 0.004 to 1.00.

Please also note that the equipment time for the ER041 and ER043 are dependent upon the clinical labor tasks on lines 17, 18, and 19 on the RUC recommendations spreadsheet. During these tasks, both of these equipment items are in use, and cannot be utilized for any other purpose.

Furthermore, the equipment item EP112 Benchmark ULTRA automated slide preparation system had been RUC recommended having 15 minutes of use for 88342 and 33 minutes for 88343. CMS, after its clinical review of 88343, reduced the time for EP112 from 33 minutes to 15. CAP acknowledges an error made in our calculations whereas the incubation time (15 minutes) associated with the equipment’s use in 88342 was not subtracted from the 33 minutes in the add-on service. Therefore, we recommend the time for EP112 for CPT code 88343 be changed to 18 minutes rather than 33. This recommendation also applies to G0462, as CMS has crosswalked these direct inputs. **We urge CMS to make these important practice expense edits for CPT codes 88342, 88343 and HCPCS codes G0461 and G0462.**

**Using OPPS and ASC Rates in Developing PE RVUs**

While we are pleased that CMS decided not to finalize its proposal to cap payments to services performed in the non-facility setting when those payments are greater than what is paid when the same service is performed in either the hospital outpatient or ASC facility setting, we remain concerned because CMS continues to pursue this proposal. As stated in our comments to the 2014 NPRM, the proposed policy fails to take into consideration the technical costs associated with specific individual codes and fails to recognize the distinct costs of physician services, which are required by law to be
based on the resources required to perform the service. Large discrepancies between the technical component in the hospital outpatient setting and physician office setting may be a useful screening tool to identify misvalued codes, however any suggestion of a change in the relativity amongst services on the physician fee schedule should be vetted through the established processes of the American Medical Association/Specialty Society RVS Update Committee (RUC). Arbitrarily accepting hospital outpatient rates in lieu of the carefully reviewed inputs by the RUC is a step backwards towards improving the relativity of the physician fee schedule. CAP supports the existing RUC process for valuing physician service codes and welcomes the opportunity to continue to provide guidance to the agency to improve the accuracy of its data. This process involves many stakeholders across the payer community, government, and medicine, including CAP. The AMA-RUC has shown itself to be the most accurate and fair expert medical professional body available for valuing physician services. We fundamentally disagree that the correct measurement to identify potentially misvalued services in the non-facility setting should be to compare the costs generated by two vastly different payment systems. Therefore, we urge CMS not finalize this proposal or any other proposal that derives its methodology from the comparison of these separate payment systems. Please refer to CAP’s 2014 proposed ruling comment letter filed with CMS on September 6, 2013.

Optical Endomicroscopy (CPT code 88375)
CMS assigned a Medicare Status of I (not valid for Medicare purposes) to CPT code 88375 with a rationale that payment for this code would represent double counting of the work done in other endoscopic procedures. In the event that this service is provided, CMS also stated that they “would expect the pathologist to report other codes more appropriate to the service (e.g. CPT code 88392)” (which we interpret as referring to 88329) Pathology consultation during surgery). We disagree with this conclusion. CPT code 88375, Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session, was established to distinguish between the work done by a physician interpreting referred images by the endoscopist and work performed by the endoscopist for optical endomicroscopy. We disagree with CMS’ suggestion that physicians use a different CPT code to bill for these services as CPT code 88375 was developed to precisely describe this unique service which is separate and distinct from 88329, pathology consultation during surgery. In addition, the parenthetical clearly states that the physician performing the endomicroscopy cannot also bill the 88375 code. The RUC reviewed CPT code 88375 together with two new endoscopic procedure codes to carefully review the work and practice expense of each separate service. We urge CMS to reverse its decision and utilize the RUC’s recommendations to establish Medicare payment for CPT code 88375. We recommend a Medicare Status of A and the immediate publication of all of the relative value units for this service.

Molecular Pathology Professional Interpretation
We note that CMS finalized interim value of G0452-26 Molecular pathology procedure; physician interpretation and report. While we do agree with the need for a mechanism for reimbursing pathologists for these physician services provided to Medicare beneficiaries, pathologists are still experiencing difficulty receiving reimbursement under this HCPCS II code at the MAC level. We encourage the CMS to instruct the carriers to provide providers detail as to why the physician services are not being reimbursed, whether because of administrative errors or due to another rationale as appropriate.

Practice Expense Refinement - Cytopathology Service 88112
CMS states on one page of its Final Ruling that they accepted the PE inputs refinement edit on page 74347 table 28, then lists refinements on page 74372 table 29. On table 29, CMS refined the inputs based on their “clinical review,” extracting all of the cytotechnologist time (12 minutes) and a half a
minute of lab technician time. The RUC’s practice expense subcommittee thoroughly reviewed and agreed with these inputs, which were subsequently unanimously recommended by the RUC.

We oppose this substantial reduction in clinical labor and support the total time recommendation approved by the RUC of 38.5 minutes.

Prostate Biopsy HCPCS Code Descriptor Changes

On page 74320 of CMS’ final ruling, the Agency states that they “continue to receive feedback regarding the appropriate coding and code descriptors for surgical pathology for the prostate needle biopsy services”. And that the Agency believes that revising the code descriptors (for codes G0416 - G0419) would clarify these services. The Agency changed the code descriptors by deleting the phrase “saturation biopsy sampling” and replacing it with “biopsies, any method”. We recommend that substantive changes of this type be thoroughly vetted through the existing processes of a proposed rule that includes a comment period. We recommend the Agency postpone this change to allow appropriate comment period by providers performing these services.

RUC Recommendations of Cell Enumeration Services - 86153

The College appreciates CMS’ finalization of the RUC’s physician work relative value for CPT code 86153 - Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required. However, we disagree with CMS’ decision to not accept the RUC recommended direct PE inputs for CPT code 86153. The RUC recommended typical PE inputs for this service in April 2012. There remains consensus among recognized experts in the field that for cases in which a physician provides the interpretation, the technician must collate the images, and physician and the technician typically must discuss the case and review images together in order to properly classify difficult-to-interpret cells and to decide whether to count additional cells. These interactions can take from two to 20 minutes, but are typically 5 minutes. Physician involvement in interpretation occurs infrequently, and only when it is necessary for interpretation of the images produced by the instrument. In the majority of cases code 86152 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood) will be submitted for payment without an accompanying 86153 code.

For code 86153, the RUC and CAP believe that five minutes for the technician to collate the images and review them with the pathologist is the typical practice and assures optimal care for Medicare beneficiaries. The CELL SEARCH System and the laboratory information system are utilized by the technician and physician for viewing cells, interpreting the study results, making important decisions on the subsequent course of patient care, and generating the interpretive report. We urge CMS to accept the RUC’s PE input recommendations for CPT code 86153.

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 (847) 832-7403 (tklemp@cap.org)