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January 27, 2014

Marilyn B. Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 [CMS-1600-FC] RIN 0938-AR56

Dear Administrator Tavenner:

The American Urological Association (AUA), representing more than 90 percent of practicing urologists in the United States, welcomes the opportunity to submit comments in response to the above final rule, with comment period. The long-standing mission of the AUA is to promote the highest standards of clinical urological care through education, research, and formulation of health care policy. Our comments will address the areas of the final rule that are of most concern to America's urologists.

RESOURCE-BASED PRACTICE EXPENSE (PE) RELATIVE VALUE UNITS (RVUs)

Using OPPS and ASC Rates in Developing PE RVUs

The AUA commends CMS on the decision not to finalize the proposed policy to use hospital outpatient department and ambulatory surgical center (ASC) rates to develop non-facility practice expense (PE) RVUs. The agency received an unprecedented number of public comments in opposition to the proposed policy, and we agree with several of the points raised by the commenters. The final rule states that CMS will take time to consider more fully the comments received and develop a revised proposal for using hospital outpatient department and ASC rates in developing PE RVUs, which will be proposed through future notice and comment rulemaking. **We urge the agency to convene a meeting with all affected stakeholders to discuss alternative payment methodologies that would accurately account for cost and resource use of services furnished in the non-facility settings, prior to restarting another**

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Ultrasound Equipment Recommendations
In the final rule, CMS adopted the AMA RUC recommendations for new equipment inputs for ultrasound services for CPT code 76942 (*Ultrasonic guidance for needle placement (eg, biopsy aspiration, injection, localization device), imaging supervision and interpretation)*. The AUA agrees with CMS that the change in equipment from *room, ultrasound, general, EL015* to *ultrasound unit, portable, EQ250,* reflects the typical kinds of procedures reported with this image guidance service.

To the contrary, we disagree with the agency's decision to designate 76942 as a potentially misvalued code because of the high frequency with which it is billed with CPT code 20610 (*Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa)*. In the proposed rule, CMS acknowledged that this service is used by many different specialty societies for guidance of needle placement. In our comment letter, we recommended that CMS coordinate review of 76942 with the RUC as part of the misvalued code initiative. Given that the service was scheduled for review at the October 2013 RUC meeting, a coordinated effort would have been the most logical evaluation process.

While we understand CMS' urgency to establish appropriate inputs for 76942, we are strongly opposed to the decision to proceed with review without consideration of recommendations from the RUC. We do not believe that a review based solely on claims information and other unspecified "sources of data" will yield an accurate assessment as to whether the code is inappropriately valued. **Therefore, the AUA wishes to reiterate our recommendation that CMS defer review of 76942 as potentially misvalued and continue to seek input from the RUC and other stakeholders regarding the most accurate valuation of this service.**

MISVALUED CODES

Validating RVUs of Potentially Misvalued Codes
In addition to identifying and reviewing potentially misvalued codes, CMS has entered into a two-year project with the RAND Corporation and the Urban Institute to establish a formal process to validate RVUs under the Physician Fee Schedule. Included in the final rule is a set of CPT codes the two contractors will use to build the validation model to predict the individual time and intensity components, and develop time estimates for the work RVUs.

Research for the project is already underway, yet CMS failed to include in the proposed rule, the complete list of CPT test codes for the study, or mention the process and methodologies used by the RAND Corporation and the Urban Institute. The AUA is deeply disappointed that CMS did not provide an opportunity for public comment on the test codes or the validation process. Given the central role of time in establishing physician work RVUs, we believe it would be more valuable for CMS

to coordinate its efforts with the RUC, and the respective medical specialty societies. Due to the concerns that have been raised about the current time values for the six urology services (CPT codes 52000, 52224, 52281, 52601, 55700, and 55866) being tested for the study, the AUA is eager to work with CMS as a member of the clinical panel that will be convened to review the new time data after the time estimates for the selected services and data analysis are completed. **Only with a more transparent process, subject to RUC and medical specialty society review, will the study serve the end goal of developing accurate validation models for physician work RVUs.**

Pathology and Laboratory: Surgical Pathology (CPT Codes 88300, 88302, 88304, 88305, 88307, 88309)
The AUA would like to call attention to an inconsistency in the short and long code descriptors for prostate biopsy examination HCPCS G codes: G0416–G0419. The HCPCS codes were originally developed for Medicare to cover prostate saturation biopsy sampling specimens. For CY 2014, CMS revised the terminology for pathological examination of prostate biopsy specimens from "saturation biopsy" to "any method". However, the revision does not reflect in the short descriptor in the Medicare RVU spreadsheet (Sat biopsy prostate). **To avoid ambiguity with appropriate selection and application of the HCPCS codes, the AUA requests that CMS update its website and all data files without delay to ensure that the short and long code descriptors are consistent.**

In addition, changes to the new descriptors were not published in the proposed rule, which prevented any comments from stakeholders on the impact of this change. The AUA is very disappointed with the lack of transparency by CMS in the change in the descriptors for HCPCS G codes G0416-G0419 to encompass any method of obtaining prostate biopsy specimens and the subsequent reporting of the examination of the specimens. **We believe that the lack of transparency and the lack of stakeholder comments could provide some unintended consequences and confusion in the reporting of these codes for prostate needle biopsy specimens.**

Contractor Medical Director Identified Potentially Misvalued Codes
From the start of the misvalued code initiative in 2008, CMS has taken an aggressive stance in identifying and addressing inappropriately valued services. To increase this effort, in the CY 2012 final rule, CMS established a process for the public to nominate codes for consideration as potentially misvalued, including input from Medicare Contractor Medical Directors (CMDs). In the CY 2014 proposed rule, several codes were identified by CMDs, including CPT codes 55845, 55866, 64566, and 76942. The AUA submitted an action plan for review of these codes at the October 2013 RUC meeting and in our comments on the proposed rule, we urged CMS to withhold action on these codes until after the RUC review process was

completed. In the final rule, CMS decided to move forward with review of these codes as potentially misvalued, despite the AUA's request and prior to the RUC's scheduled review.

CPT code 55845 will be surveyed for the April 2014 RUC meeting. That being said, we believe review of this code without the RUC's contribution is premature and may prove ultimately to be repetitive. CMS' decision to proceed with review of CPT code 76942 comes on top of revised direct PE inputs for this code in CY 2014. The change from ultrasound "room" to "portable device" combined with the reduction in procedure time from 45 minutes to 10 minutes, and the reduction in clinical labor and equipment time from 58 to 23 minutes, will undoubtedly have a profound impact on reimbursement for this service, which will negatively impact patient access to care, and may have unintended consequences for the Medicare program. When the cost of care exceeds payment, physicians often send patients to the hospital outpatient facility setting, where the cost to furnish service is more expensive. CPT code 76942 also is scheduled for subsequent review of the work RVU at the April 2014 RUC meeting, which may result in further RVU adjustments.

CPT Code 64566 underwent an extensive RUC survey in 2010. Using the results of that survey, the RUC agreed to the physician work time and recommended the current RVU of .60 for physician work to CMS. In addition, CPT code 64566 was compared to other CPT codes to determine relativity by other specialties. After additional RUC review in October 2013, it was determined that the physician work for this procedure has not changed and the RVU of .60 should be maintained. **The AUA supports the RUC's recommendation and do not consider 64566 to be misvalued. If there is to be any future modification of the current valuation, it should be done through the existing RUC process with the participation and support of the appropriate medical specialty societies.**

We fear that such aggressive and overlapping efforts to identify inappropriately valued codes may result in multiple payment reductions that would seriously compromise the ability for physicians to continue to provide these services. **Therefore, we believe it is incumbent upon CMS to withhold review of CPT codes 55845, 55866, 64566 and 76942 until the RUC has completed its review and the contracts with the RAND Corporation and the Urban Institute are completed. Until then, the AUA strongly urges the agency to place a moratorium on any further review of potentially misvalued services that are undergoing separate simultaneous review.**

PHYSICIAN COMPARE WEBSITE

In the final rule, CMS reaffirmed the proposal to provide a 30-day preview period for physicians and other eligible professionals to view all measurement performance data as it will appear on the Physician Compare website in advance of publication.

The AUA does not believe that a 30-day preview period is sufficient time for review and appeal if necessary. At a minimum, participating providers should have 45-days for preview of their data, consistent with the 45-day review period for Open Payments (Physician Payments Sunshine Act). **Unless physicians have sufficient time to review and verify the accuracy of their data, Physician Compare will not be actionable and meaningful for either patients or physicians. We believe a 45-day preview period would better balance this objective.**

Public Reporting of Physician Performance Data

Another concern with Physician Compare is the accuracy of the data currently posted on the website. In CY 2014, CMS will post all PQRS quality measures that groups report through the GRPO web interface and for Accountable Care Organizations (ACOs) that participate in the Medicare Shared Savings Program. Since the inception of the website, there has been a significant increase in the number of physician practices reporting problems with Physician Compare. To date, the website continues to be riddled with errors. Users of the website should be able to trust that the performance data posted is accurate. CMS should consider the potential consequences to a physician's reputation if the information on the website is incorrect or misleading. With such widespread inaccuracy of the data on Physician Compare, we question how CMS can move forward with further expansion of the website prior to ensuring accuracy of the information. **For that reason, we reiterate our request for CMS to delay incorporation of quality reporting program data on the Physician Compare website until ongoing problems have been resolved.**

PHYSICIAN QUALITY REPORTING SYSTEM

Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Registry for Individual Eligible Professionals for the 2014 PQRS Incentive

The AUA commends CMS on decreasing the PQRS reporting threshold through data registries from 80 percent to 50 percent. In general, we believe this change will simplify the reporting process. However, we disagree with CMS' decision to expand the reporting requirement from 3 to 9 measures across at least 3 National Quality Strategy domains beginning in 2014 for individual eligible professionals via claims or a registry. As stated in our comment letter on the proposed rule, we believe the increase in reporting measures is extreme and inappropriate for the 2014 PQRS incentive because urologists, and many other specialists, do not have 9 pertinent measures on which they could report. Instead of easing the burden that physicians bear to satisfactorily meet PQRS, EHR meaningful use, and data registry requirements, the additional reporting measures will increase administrative pressure on physician practices. **The AUA is strongly opposed to CMS' policy to increase the number of required reported measures from 3 to 9 for claims-**

based reporting, and urges CMS to reinstate the number of required reported measures needed to earn an incentive to 3 until more applicable measures are available for all participants.

Proposal Related to Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals

The AUA is pleased that CMS finalized the proposal to add a qualified clinical data registry (QCDR) reporting mechanism to allow individual eligible professionals to report quality measures used by a QCDR instead of those on the PQRS measures list. We believe the QCDR reporting option will allow individual eligible professionals flexibility to report to the registry that is most applicable to their practice. In November 2013, the AUA Board of Directors formally approved the development and launch of the AUA Quality (AQUA) Registry. The AQUA Registry will initially focus on prostate cancer and gradually expand to other urological conditions.

Although the AUA is in the initial stages of registry development, we have serious concerns about mandating public reporting at the individual level. **The AUA believes it is premature for CMS to require public reporting of QCDR data at the individual provider level at the onset of the reporting option. We request that CMS recognize that physician group, rather than individual, is the most appropriate measurement level for QCDR reporting at this time.** We also believe that the requirement for an entity to report, on behalf of its individual eligible professional participants, a minimum of 9 measures, across at least 3 National Quality Strategy domains, as required for participation in conventional PQRS reporting, cannot reasonably be met.

VALUE-BASED PAYMENT MODIFIER AND PHYSICIAN FEEDBACK PROGRAM

Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

CMS finalized its decision to include the Medicare Spending Per Beneficiary (MSPB) measure as an additional measure in the Value-Based Payment Modifier (VBPM) cost composite beginning in 2016, despite opposition to the proposal from the AUA and many other commenters. The measure includes all Medicare Part A and B payments during an MSPB episode, which spans from three days prior to an index admission at a hospital through 30 days post discharge with certain exclusions. We wish to reiterate our concerns expressed previously regarding use of MSPB measure for the VBPM, and emphasize that the measure does not provide a clear link between specialist resource use and patient quality of care. **We are particularly opposed to use of the measure because of the reliability and validity of the group attribution methodology, given that beneficiaries will be identified based on a plurality of primary care services, and that the measure will include hospital costs but will not account for patients who have avoided**

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hospitalization altogether. For these reasons, we urge CMS to reconsider use of the MSPB for the VBPM cost composite.

In conclusion, the AUA appreciates the opportunity to provide our views on the final rule, and we look forward to working with CMS to achieve consensus on these critical issues. If you have any questions or wish to discuss our comments, please contact Lisa Miller-Jones, Regulation Policy Manager at (410) 689-3772 or lmiller@auanet.org.

Sincerely,

David Penson, MD, MPH
Chair, Health Policy Council