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Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical
Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

The American Urological Association (AUA) is a globally-engaged organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy. The AUA welcomes the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services' (CMS) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule for calendar year (CY) 2018. Our comments are limited to the sections of the proposed rule that are most applicable to AUA members.

Proposed Complexity Adjustment for Blue Light Cystoscopy Procedures
CMS proposes to apply a complexity adjustment to the reimbursement rate for cystoscopy with blue light, referred to as Cysview (C9275), by creating a new HCPCS C-code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)). Current CPT coding for cystoscopy procedures does not distinguish white light from blue light.

As CMS is aware, one year ago in April 2016, the Guideline for Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer, jointly published by the American Urological Association ("AUA") and the Society for Urologic Oncology ("SUO") was amended to include Blue Light Cystoscopy with Cysview. Yet, as we have commented in the past, CMS since 2013 has chosen

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to treat this procedure as it treats standard “white light” cystoscopy and to “package” Cysview into the procedure payment. We have repeatedly objected to that approach in our prior comments.

We were pleased to note CMS’s acknowledgment that its packaging policies have impeded patient access to care, and we have taken note of the Agency’s proposed solution of applying a “complexity adjustment” to the Blue Light Cystoscopy with Cysview procedure to accommodate the extra costs and resources when the treatment is required for bladder cancer patients. Unfortunately, the method by which CMS intends to apply the adjustment will exclude approximately 70% of the procedures, making the proposal incomplete, at best. We understand that this is because CMS will apply several “tests” in order to trigger the complexity adjustment, and will only apply it if: (1) the procedure is reimbursed through a Comprehensive APC; (2) there are a minimum of 25 claims in the procedure code; and (3) the procedure would trigger the “two times rule.”

In our view, drugs like Cysview should never be packaged into procedure payments; as such packaging both harms patient access to care and even if done properly harms access in ambulatory surgery centers. However, if CMS insists on using the “complexity adjustment” concept, it must do so without limitation to all “paired claims” for Blue Light Cystoscopy with Cysview. Only by doing so will CMS prevent the very harm it has acknowledged its packaging concept has caused on patient access to care. **Thus, if the Agency is unwilling to abandon packaging drugs into procedure payments, we recommend that CMS eliminate any utilization thresholds (either claims volume or two times rule requirements) in applying the complexity adjustment and ensure access to the procedure in ambulatory surgical centers (“ASCs”) by applying a methodology conceptually similar to the “device intensive” adjustment.**

Brachytherapy Insertion Procedures

CMS proposes to delete composite APC 8001 for low dose rate (LDR) prostate brachytherapy and assign HCPCS code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to composite APC 5375 (Level 5 Urology and Related Services) to status indicator J1 and to provide payment for this procedure through the C-APC payment methodology. Specifically, when CPT code 55875 is the primary service reported on a hospital outpatient claim, all adjunctive services would be packaged into the payment. CMS proposes to assign HCPCS code 55875 to C-APC 5375 (Level 5 Urology and Related Services). **We agree that this proposed change is appropriate and recommend that CMS finalize this policy as proposed.** However, in support of ongoing accurate valuation of services and access to care, we request that CMS examine data as they become available to ensure that payments for the set of services included in the C-APC remain appropriate and reasonably cover the costs of providing care.



Aquablation

CMS proposes to assign Aquablation procedures (Category III code 0421T) to APC 5374 (Level 4 Urology and Related Services). The Aquablation procedure is a new and novel form of treatment for benign prostatic hypertrophy. It has levels of complexity that are similar to cryoablation of the prostate and high intensity focused ultrasound (HIFU) of the prostate, both of which are cancer procedures. The complexity of instrumentation is paramount in this procedure. Similar to treating the prostate with cryoablation and HIFU, Aquablation requires trans-rectal ultrasound preplanning and live monitoring during treatment. The Level 4 APC coding does not take into account the cost for the device and the overhead relative to comparable procedures. More complex services with 5376 (Level 6 Urology and Related Services) designation such as HIFU, Cryoablation and Interstitial seed implantation all need more sophisticated equipment to perform the procedure and appropriately trained personnel to help manage and run the computerized machinery, all of which are also necessary for Aquablation. It would not be possible for the physician to perform these tasks alone during the Aquablation procedure. Unlike level 4 designated procedures, the required equipment for this procedure is not reusable. Even transurethral resection of the prostate and laser ablation of the prostate are level 5 designated procedures because of the complexity of the equipment and time involved for completing the procedure. **Therefore, the AUA strongly encourages CMS to revisit the APC designation for Aquablation and consider a Level 6 (5376) designation.**

Changes to the Inpatient Only List

CMS proposes to remove CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed) from the Inpatient Only List and assign it to Comprehensive APC (C-APC) 5362 (Level 2 Laparoscopy & Related Services) with status indicator J1. **We agree that most outpatient departments are equipped to provide this service to the Medicare population and that this procedure may be performed safely in most outpatient departments. As such, we support CMS' proposal to remove CPT code 55866 from the Inpatient Only List.**

Proposed New Ambulatory Surgical Center Quality Reporting Program Quality Measure (ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures)

For ambulatory surgical centers (ASCs), CMS proposes to adopt a new ASC measure (ASC-18) to assess hospital visits after urology ambulatory surgical center procedures beginning the 2020 payment determination year. The AUA supports delay of the measure, since it has not been endorsed by the National Quality Forum (NQF) or approved by the Measure Applications Partnership (MAP) yet. **While we believe the measure could potentially be used to drive urologists towards performing better in terms of reducing risk of readmission, we are concerned about risk attribution as the measure would not capture the nuances of urologic surgery (factors that cause some of our patients to**



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return to the emergency room). Thus, we suggest CMS pilot test the measure before implementation.

Conclusion

The AUA appreciates the opportunity to comment on the CY 2018 OPPS/ASC proposed rule. If you have any questions please contact Lisa Miller-Jones at (202) 403-8501 or lmiller@auanet.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris M. Gonzalez".

Chris M. Gonzalez, MD, MBA
Chair, Public Policy Council

A handwritten signature in black ink, appearing to read "J. Stuart Wolf, Jr.".

J. Stuart Wolf, Jr., MD
Chair, Science & Quality Council