September 6, 2016

Submitted electronically via:
http://www.regulations.gov

Andrew M. Slavitt
Acting Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program, Proposed rule

Dear Acting Administrator Slavitt:

The American Urological Association (AUA) is a leading advocate for the specialty of urology, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy. On behalf of our nearly 15,000 members in the United States, the AUA appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule for calendar year (CY) 2017.

Transprostatic Urethral Implant Procedure
For CY 2017, CMS is proposing to reassign HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) from APC 1565 (New Technology - Level 28) with a current payment rate of $5,250 to APC 5376 (Level 6 - Urology and Related Services), which has geometric mean cost of approximately $7,723.

HCPCS code C9740 is one of two procedure codes used to report the UroLift System for treatment of patients diagnosed with benign prostatic hyperplasia (BPH).

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We agree that the proposed reassignment for C9740 from APC 1565 to APC 5376 is appropriate and will allow a payment rate to be set that more accurately reflects the charge for this procedure. **The AUA recommends that CMS finalize the proposal to reassign C9740 from APC 1565 to APC 5376 for CY 2017.** We also agree with the J8 ASC status for this procedure, as it would allow for accurate payment rate in the ASC setting for this device intensive procedure.

**Device Intensive Status for C9739**

HCPCS code C9739 ([Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants]) also is associated with the UroLift System. We agree with the proposed device intensive status for C9739, as the claims data analysis supports this designation. We also agree with assigning J8 ASC status for C9739, as it would allow for transprostatic implant procedures of less than four implants to be conducted in the ASC with a more appropriate facility payment. **The AUA supports CMS’ proposal to assign a J8 ASC status indicator for C9739 for CY 2017.**

**Proposed Additions to the List of ASC Covered Surgical Procedures**

The AUA is deeply disappointed in CMS’ decision to continue to ignore requests to add CPT code 54411 ([Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue]) and CPT code 54417 ([Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue]) to the list of ASC covered surgical procedures, or provide an explanation as to why these services are ineligible for ASC coverage.

These procedures have been safely performed on numerous non-Medicare patients on an ambulatory basis. In 2015, the AUA met with CMS and provided clinical evidence to support the safety of these procedures in a hospital outpatient and ASC setting. CMS removed these codes from the Inpatient Only list (IPO), but did not add them to the ASC list of covered surgical procedures. The proposal to maintain the ASC exclusion for CY 2017 is unclear.

As stated during the meeting and in previous comment letters to CMS, we have no evidence that either of these services would pose a “significant risk to beneficiary safety” in an ASC. Furthermore, patients who undergo this procedure would not require post-operative medical monitoring overnight. This exclusion, if maintained, will continue to deny physicians the needed flexibility to offer services in a location and facility that best meets the needs of their patients. **The AUA once again requests that CMS approve coverage of CPT codes 54411 and 54417 in the ASC, or at least, provide clarification as to why CMS believes that these services are ineligible for ASC coverage.**
Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider
As CMS works to implement section 603 of the Bipartisan Budget Act of 2015, we urge the agency to consider the following modifications to its proposals:

- The MPFS non-facility rate applicable to physician practices should be deemed the only “applicable payment system” for nonexcepted, off-campus provider-based departments (PBDs) and not merely for a “transitional” period in 2017.
- An excepted off-campus PBD should only be permitted to seek payment under the OPPS for specific items and services that the excepted off-campus PBD actually furnished and billed prior to November 2, 2015 (as opposed to CMS’s current proposal, which would except an entire clinical family of services based on an excepted PBD having furnished and billed for a single item or service within that clinical family prior to November 2, 2015).
- Excepted off-campus PBDs should only be permitted to seek payment under the OPPS for those items and services that were billed by the excepted off-campus PBD at some point during the 12 months prior to November 2, 2015 (as opposed to CMS’s current proposal that does not provide a specific timeframe during which the billing had to occur).
- Excepted off-campus PBDs should only be permitted to seek payment under the OPPS for items and services furnished by physicians and other health care professionals who had furnished services through the off-campus PBD prior to November 2, 2015.
- Any relocation exception that CMS announces in the Final Rule should be defined as narrowly as possible, using the existing objective standards defined in statute for the Secretary to declare a public health emergency.

Conclusion
The AUA appreciates the opportunity to comment on the CY 2017 OPPS/ASC proposed rule. If you have any questions please contact Lisa Miller Jones at (410) 689-3772 or lmiller@auanet.org.

Sincerely,

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

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