August 31, 2015

Submitted electronically

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-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; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System

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 welcomes the opportunity to submit comments in response to the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule for calendar year (CY) 2016.

Proposed Changes to the Inpatient Only List
The Centers for Medicare & Medicaid Services (CMS) is proposing to remove CPT code 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue); and CPT code 54417 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue) from the Inpatient Only list for CY 2016.
The AUA has long advocated having these procedures removed from the Inpatient Only list, since it is not always medically necessary or practical to perform these procedures in an inpatient hospital facility. This proposed change, which is of great importance to the AUA, would ensure that Medicare beneficiaries continue to have access to high quality urologic health care services while still protecting their safety and avoiding the unnecessary cost of an inpatient hospital stay. The AUA applauds CMS for recognizing that CPT codes 54411 and 54417 meet the safety criteria required for performance in a hospital outpatient setting.

ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2016
While we are encouraged by CMS taking the initial step to ensure that seniors have access to a broader range of health care services in the outpatient setting, we are opposed to the proposal to exclude these services from the ASC list of covered surgical procedures for CY 2016. The AUA met with CMS officials on March 11, 2015, where we provided clinical evidence to support the safety of these procedures in an ASC. The proposal to maintain the ASC exclusion is a clear indication that the information provided was misconstrued.

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, since they have been safely performed on numerous non-Medicare patients on an ambulatory basis. Furthermore, we disagree that patients who undergo this procedure would require post-operative medical monitoring overnight. This exclusion will ultimately deny physicians the needed flexibility to offer services in a location and facility that best meets the needs of their patients. The AUA recommends that CMS approve coverage of all locations in which CPT codes 54411 and 54417 are safely performed to ensure comprehensive availability of these services. To fully understand why CMS still believes that these procedures should not be covered in an ASC, we would appreciate written clarification in the CY 2016 final rule of the specific significant health care risks that these services pose to Medicare beneficiaries.

Proposed Additions to the List of ASC Covered Surgical Procedures
In addition, CMS is proposing to add CPT code 57310 (Closure of urethrovaginal fistula) to the ASC list of covered procedures. The AUA supports CMS’ decision to qualify payment for this service in the ASC setting.

Proposed OPPS Ambulatory Payment Classification (APC) Group Policies - Urology and Related Services Procedures
CMS is proposing to restructure nine existing APC clinical families based on the following principals: improved clinical homogeneity, improved resource homogeneity, reduced resource overlap in APCs with clinical family, and greater simplicity and improved understanding of the structure of APCs. In addition to restructuring the APCs, CMS is
proposing to renumber the APC levels for improved identification and understanding of the groupings. If implemented, these changes would reduce the current number of Urology and Related Services APCs from 16 to seven.

In CY 2015, CMS implemented a four-level APC grouping for all Cystourethroscopy and Other Genitourinary Procedures. According to CMS, the regrouping was based on a review and evaluation of the procedures assigned to the APCs and the latest hospital outpatient claims data. The modifications resulted in assignment of CPT code 53850 to an inappropriate APC due to the inclusion of low value charge and cost data reported by a hospital, which skewed the geometric mean cost of the services in that payment group. This resulted in a more than 50 percent reduction in pay rate. The AUA urged CMS to move the procedure to the higher paying APC consistent with the cost of the procedure. Despite our concerns, CMS failed to reassign the service to a more adequate APC placement in the CY 2015 final rule.

The AUA recognizes the importance of greater granularity in resource and clinical characteristics to improve rate-setting under the hospital OPPS. However, now that CMS is proposing to restructure all urology and related services APCs, we have even greater concerns that the hospital cost data that CMS is using to establish the new APC rates may not truly represent the associated resource use and clinical expenses for every procedure. If implemented, the pay rates for several urology and related services will shift dramatically. Such drastic changes signal that some procedures may not be assigned to the proper APC, or that the hospital charge and cost data for which the CY 2016 APC rates are derived may again include inaccurate information. Clinical homogeneity within urology means therapeutic procedures that treat the same disease process. No APC should have more than 150 diverse procedures like APC 5374 and then be labeled as “homogeneous.” CMS should reconsider its urology groupings to more accurately achieve its stated goals of homogeneity, simplification, and understandability.

The AUA notes that while the pay rates will increase for some services, hospitals will be severely under paid for other services, particularly, for CPT code 51741 (Complex uroflowmetry (eg, calibrated electronic equipment)). The proposed restructure would cut the payment rate for this service by 18 percent in a single year. Payment for CPT codes 55700 (Biopsy, prostate; needle or punch, single or multiple, any approach) and 52000 (Cystourethroscopy (separate procedure)) would also be cut by eight and five percent, respectively.

In order for hospitals to be able to forecast for the future and invest in technologies that are essential for providing high quality care, they need stable and predictable payment rates. Instability in payment rates may hinder a facility's ability to effectively negotiate with manufacturers and suppliers on the purchase price of certain devices and services.
Furthermore, substantial payment reductions may result in site-of-service shifts, thereby compromising the ability of physicians to continue to perform certain services in a hospital outpatient setting. **The AUA urges CMS to thoroughly review the charge and cost data used to recalculate the proposed CY 2016 Urology and Related Services APCs prior to finalization of the restructure to ensure the difference in resource utilization is accurate.**

Typically, there is a two-year time lag in the data that CMS uses to set payment rates under the OPPS. Hospitals are still assessing the impact of the CY 2015 four-level APC reclassification of all Cystourethroscopy and Other Genitourinary Procedures. Yet, CMS is proposing to implement another rate schedule change for urology related APCs in CY 2016 before the impact of this year’s changes can be evaluated. **The AUA urges CMS to defer restructuring of the services and procedures that were in the Cystourethroscopy and Other Genitourinary Procedures APCs that were regrouped in CY 2015 and for other urology related APCs where a reduction would occur in CY 2016 until additional claims data can be collected and analyzed to prevent hospitals from incurring substantial costs that could potentially result in a loss of services.**

**Two-Midnight Rule**
In the proposed rule, CMS is proposing to modify the existing “rare and unusual” exceptions policy for hospital inpatient admissions to also allow exceptions to the two-midnight benchmark. The modification would allow hospital inpatient admissions expected to be less than two consecutive midnights to be determined on a case-by-case basis by the physician responsible for the care of the beneficiary, subject to medical review. **The AUA supports this proposal and we are pleased that the proposed modification would take into account that a hospital short-stay inpatient admission of fewer than two midnights may be acceptable based on the physician’s judgment rather than a retrospective review of a Recovery Audit Contractor.**

**Conclusion**
The AUA appreciates the opportunity to comment on the CY 2016 OPPS/ASC proposed rule. If you have any questions please contact Lisa Miller-Jones at (410) 689-3772 or lmiller@auanet.org.

Sincerely,

David Penson, MD, MPH
Chair, Public Policy Council