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September 3, 2013

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

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals [CMS-1601-P] RIN 0938-AR54

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 proposed rule. 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. We appreciate your attention to the concerns of America's urologists. Our comments will address the areas of the proposed rule that are of most concern to our members.

PROPOSED ESTABLISHMENT OF COMPREHENSIVE APCs

In 2014, CMS proposes to convert 29 device-dependent APCs into comprehensive APCs. The proposal represents a sweeping change in the way APC payment structures are currently developed, as it would greatly expand hospital outpatient department (OPD) packaging policies to incorporate costs for all adjunctive services billed with the primary service.

The AUA is concerned that CMS has not provided detailed information regarding the impact the proposal will have on the adjunctive services included in the APCs. It is challenging to effectively study the effect of the proposal and provide meaningful comments on the appropriateness of the package services without having access to the utilization assumptions and mean costs that CMS used to determine payment rates for the comprehensive APCs.

The lack of detailed information makes it difficult to ensure that the proposed payment rates adequately reflect the cumulative costs and the full range of services that may be furnished during an outpatient encounter.

The CMS Advisory Panel on Hospital Outpatient Payment (HOP Panel) met recently to review the packaging proposals in the CY 2014 OPPS/ASC proposed rule. The HOP Panel recommended that CMS delay implementation of proposal to establish comprehensive APCs and other proposals to package drugs and supplies, clinic visits and emergency department services, and implement new cost centers for CT and MRI procedures, until data can be reviewed at the Spring 2014 meeting. At that time, the HOP Panel will look at the interaction between all of the proposals and the potential cumulative impact. **The AUA supports the HOP Panel recommendation for delayed implementation of CMS' packaging proposals and urges the agency to cooperate with the request to disseminate the data needed to analyze the full implications of the proposed changes.**

PROPOSED NEW PACKAGING POLICIES FOR CY 2014

Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure

In 2013, Cysview® HCPCS code C9275 was unconditionally packaged as a contrast agent with related cystoscopy APCs. CMS now concludes that Cysview is not a contrast agent, but rather a drug that "functions as a supply when used in a diagnostic test or procedure to detect bladder cancer." In 2014, CMS is proposing to change the packaging policy for drugs, biologicals, and radiopharmaceuticals to unconditionally package drugs that function as supplies as part of a more encompassing diagnostic service or procedure. **The AUA agrees with CMS' reclassification of Cysview as a drug rather than a contrast agent; however, we disagree with the notion that it is a supply and the basis upon which CMS is relying to justify unconditional packaging in 2014.**

Cysview is a drug and should not be incorrectly categorized as a supply because of its adjunctive characteristic. In fact, Cysview is used as part of first-line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors, after the disease has been diagnosed through a previous cystoscopy. As such, it should be reimbursed like other cancer drugs that exceed the packaging cost threshold.

Cysview is a revolutionary technology that has extended the lives of many patients suffering from bladder cancer. The photodynamic blue light allows urologists to see and treat more cancerous lesions, thereby reducing the probability of recurrence and progression of the disease. CMS' decision to packaging Cysview in 2013 has deterred hospitals from offering it as a treatment option. Access to Cysview treatment is already limited in the United States because it is currently performed in only a few dozen hospitals. We are concerned that continued packaging will lead to significantly reduced payment and compromise the ability of hospitals to

cover cost for this technology. Rather than reduce costs to the Medicare program, continued packaging will increase cost by forcing physicians and hospitals to use less effective methods of treatment, which will lead to ongoing recurrences of bladder cancer and multiple cystoscopy procedures.

It appears as though CMS did not consider the effect that packaging Cysview would have on patient access to advanced bladder cancer treatment. **The AUA urges CMS to withdraw its proposal for unconditional packaging and reimburse Cysview in the same manner as other cancer drugs so that it is feasible for physicians and hospitals to provide this treatment option to bladder cancer patients.**

PROPOSED PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES

Proposed Changes to the Inpatient List

CMS has proposed to not remove any procedures from the inpatient list for CY 2014 and to maintain the requirements used to assess whether procedures potentially could be removed from the list. The established criteria upon which CMS makes such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the inpatient list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

We would like to point out that many hospitals use the McKesson Medical-Surgical InterQual criteria to determine the appropriate facility site for approved surgical procedures. CMS' Quality Improvement Organizations (QIOs) and Medicare Administrative Contractors (MACs) also use InterQual's criteria to support utilization review and enforce auditing programs. Private third-party payers also align with Medicare requirements for approved facility settings. Consequently, if a procedure is included on Medicare's inpatient list, it will not be reimbursed if performed in any other facility setting. Therefore, any data available on procedures "being

performed in numerous hospitals on an outpatient basis" will be limited. **For this reason, the AUA recommends that CMS remove the fourth criterion to determine whether codes potentially could be removed from the inpatient list, because it will be difficult, if not impossible to meet this requirement.**

The AUA has repeatedly requested that certain procedures be removed from the inpatient list. It is especially important to the AUA that safety concerns for patients receiving urologic services are met, particularly seniors that receive care through the Medicare program. To that end, the AUA's Quality Improvement and Patient Safety (QIPS) Committee comprised of clinical experts reviews urological procedures and determines whether or not they would pose a significant health care risk to a Medicare beneficiary when performed in a different facility settings including the hospital outpatient and ASC setting.

The QUIPs Committee uses CMS' exclusion criteria to make their decision and has determined that the following procedures do not require or involve active medical monitoring and care at midnight following the procedure, extensive blood loss, major or prolonged invasion of body cavities, major blood vessels, emergency or life-threatening care, or systemic thrombolytic therapy.

Based on our understanding of CMS' safety criteria, we have concluded that patients would not be at a higher risk for adverse outcomes if the procedures were performed in a hospital outpatient or ASC setting. Therefore, AUA hereby requests that the following procedures be removed from the inpatient list:

- 54411 Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session

- 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

PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM

Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

The AUA has requested on several occasions for CMS to add certain codes to the ASC list of covered surgical procedures. We are disappointed that CMS is not proposing additions to the list of ASC covered surgical procedures for CY 2014. CMS has failed to explain why the following codes have not been added to the list, even though they clearly meet the safety criteria, are assigned to an APC group, and currently paid for under the OPPS.

Again, we respectfully repeat our request for the following codes to be added to the ASC list of approved procedures in 2014:

- 57310 Closure of urethrovaginal fistula

- 54332 One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap

- 54336 One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap

- 54411 Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session

- 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

- 54535 Orchiectomy, radical, for tumor; with abdominal exploration

- 54650 Orchiopexy, abdominal approach, for intra-abdominal testis (e.g.Fowler-Stephens)

If the agency finds the above codes inappropriate for inclusion in the ASC list of approved procedures for 2014, we respectfully request an explanation for the decision.

The AUA is grateful for the opportunity to present our views to CMS on the proposed rule. 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