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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-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]

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 proposed revisions to payment policies under the Medicare Physician Fee Schedule (MPFS) and other Part B revisions for calendar year (CY) 2017.

II. Provisions of the Proposed Rule for PFS

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)

Equipment Recommendations for Scope Systems

In the proposed rule, CMS states that unexplained inconsistencies involving the use of scopes and the video systems associated with them have been found during routine reviews of direct PE input recommendations. Therefore, CMS is proposing to apply standalone prices for each scope (monitor, processor, a form of digital capture, cart, and printer) and the video systems involving endoscopes.

American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) mentioned that a workgroup is being convened to review practice expense of endoscopy codes and believes that specialty societies would then be involved to determine the appropriate scope and video system particular to each endoscopy code. Each specialty society also would be able to submit invoices for the endoscopy and video systems involved.

C. Medicare Telehealth Services

Adding Services to the List of Medicare Telehealth Services

For CY 2017, CMS proposes to add new services to the list of Medicare-covered telehealth services to include critical care consultation services GTTT1 (*Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial))* and GTTT2 (*Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent))*. CMS acknowledges the potential benefits of critical care consultation services furnished remotely and the need to distinguish such services from telehealth consultations for other hospital patients. We believe the creation of new codes for consultations of critically ill patients via telehealth would allow CMS to adequately identify resource cost, time and intensity involved in furnishing these services remotely. **The AUA recommends that CMS finalize the proposal to create and pay for new codes for critical care consultations furnished via telehealth.**

Place of Service (POS) Code for Telehealth Services

In response to several requests to establish a Place of Service (POS) code specifically for telehealth services furnished from a distant site, CMS also proposes to create a new POS code under the MPFS. If created, physicians and practitioners would be required to report the POS code as early as 2017. CMS further proposes to use facility PE relative value units (RVUs) to reimburse for the telehealth services reported. Currently, there is not a POS code specific for telehealth services. Instead, CMS instructs providers furnishing telehealth services to report the POS code that would have been reported had the service been furnished in person.

Basing the POS rate on the facility PE RVU is consistent with most providers that report the facility POS when currently billing for telehealth services. CMS notes that the process for establishing POS codes is managed by the POS Workgroup within CMS, is available for use by all payers, and is not contingent upon Medicare PFS rulemaking. Additionally, CMS suggested that POS code usage for the originating site remain unchanged, and that originating sites should continue to bill for the facility fee and continue to use the POS Code applicable to the patient's location to receive the correct reimbursement rate.

While we commend CMS for promoting use of telehealth services by continuing to expand the list of covered Medicare services, we urge CMS to work with the AMA Current Procedural Terminology (CPT) Editorial Panel Telehealth Services Workgroup. The Telehealth Services Workgroup was established in September 2015 to recommend solutions for reporting of current non-telehealth services when using remote telehealth technology, address the accuracy of telehealth data, recommend whether any other telehealth service codes should be developed based upon services currently being provided, and develop new introductory language or modify existing introductory language to guide coding of telehealth services. **The AUA strongly recommends that CMS work closely with the AMA CPT Telehealth Services Workgroup to develop the new HCPCS codes for telehealth critical care consultations and with the RUC in reviewing the facility PE RVUs for the distant site POS code.**

0-day Global Services that are Typically Billed with an Evaluation and Management (E/M) Service with Modifier 25

In the proposed rule, CMS used a review screen to identify CPT codes with a 0-day global period that are typically billed with an E/M code 50 percent of the time or more, on the same day of service, for the same patient, by the same physician, that have not been reviewed in the last five years, and with Medicare utilization greater than 20,000.

The RUC also conducted a separate review of the same codes using the same criteria identified by CMS, and concluded that 38 of the 83 services flagged for review are invalid because they were either reviewed in the last 5 years and/or are not typically reported with an E/M service. Three urologic procedures were identified by CMS (Table 7). The codes were recently surveyed and reviewed at the January 2016 RUC meeting. During the RUC review, consideration was given to services billed with an E/M service, and therefore, duplicative physician work and time were reduced. **Based on the RUC research findings and latest review, the AUA respectfully requests that CMS remove CPT codes 51701, 51702 and 51703 from the list of potentially misvalued services since they clearly do not meet the criteria for review specified by CMS.**

Table 7: 0-day Global Services that are Typically Reported with an E/M Service with Modifier 25

AUA requests to remove the following:

CPT	Long Descriptor	Total with E/M	Most Recent RUC Survey	CPT Year	RUC Comment to NPRM for 2017

51701	Insertion of non-indwelling bladder catheter (eg, straight catheterization for residual urine)	85%	Jan. 2016	2017	Does not meet screen criteria; surveyed within the last 5 years and RUC rationale specifically noted "Code 51701 is typically reported with an Evaluation and Management service. The specialty society indicated and the RUC agreed that the pre-service time of 14 minutes does not overlap with an E/M service."
51702	Insertion of temporary indwelling bladder catheter; simple (eg, Foley)	52%	Jan. 2016	2017	Does not meet screen criteria, surveyed within the last 5 years
51703	Insertion of temporary indwelling bladder catheter; complicated (eg, altered anatomy, fractured catheter/balloon)	49%	Jan. 2016	2017	Does not meet screen criteria; surveyed within the last 5 years and not typically reported with an E/M

Insertion and Removal of Drug Delivery Implants - CPT Codes 11981 and 11983

Stakeholders have urged CMS to create new coding describing the insertion and removal of drug delivery implants for buprenorphine hydrochloride for the treatment of opioid addiction based on the assumption that current coding describing insertion and removal of drug delivery implants is too broad, and new coding is needed to account for specific additional resource costs associated with particular treatment. CMS, therefore, has identified CPT codes 11981 (*Insertion, non-biodegradable drug delivery implant*), 11982 (*Removal, non-biodegradable drug delivery implant*), and 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*) as potentially misvalued. These codes were developed to report the implantation, removal and replacement of a non-biodegradable drug delivery for a prostate cancer implant, Viadur. We disagree with the assumption that these codes may be misvalued, as the physician work and practice expense has not changed. The drug delivery implants for buprenorphine hydrochloride for the treatment of opioid addiction is for multiple implants whereas CPT codes 11981, 11982 and 11983 are for single implants. The CPT Editorial Panel has stated its intentions to address this issue in a future meeting. **Until such time as there has been a thorough review, we respectfully request that CMS remove CPT codes 11981, 11982 and 11983 from the list of potentially misvalued codes.**

Collecting Data on Resources Used in Furnishing Global Services

In the 2015 Medicare Physician Fee Schedule final rule, CMS finalized a policy to transition all services with a 10- and 90-day global period to a 0-day global period. Subsequently, Section 523 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 prohibited CMS from implementing this policy. Instead, MACRA directed CMS to collect data, starting January 1, 2017, on the number and level of visits furnished during the global period from a *representative sample* of practitioners.

However, in the 2017 Medicare Physician Fee Schedule proposed rule, CMS proposed a policy to collect data on all 10- and 90-day global services from all physicians who perform them. With this proposal, CMS would use newly created G codes differentiated by typical, complex or critical level of service, to collect claims data in10 minute interval per visit for both physician and staff activities. In addition, CMS is considering whether to impose a 5 percent penalty on physicians who fail to participate in the claims-based reporting process.

The AUA is adamantly opposed to this proposal, at least in its currently proposed form, for the following reasons:

1. The G-codes do not represent or capture various levels of service or consider medical decision making by the physician during a postoperative surgical visit. While there are descriptions of what "typical" activities in a postoperative visit consist of in Table 10 of the propose rule, these activities are not inclusive. The definition of "complex" visits consists of activities more than typical but not considered "critical." These definitions are unclear.
2. The G-codes do not align with clinical workflow. Tracking the entire time a patient is being seen is onerous and will likely result in under reporting.
3. The G-codes lack validation and physicians are used to reporting existing E/M services. The G-codes are not comparable to existing E/M services assumed to be bundled into the current global package.
4. The reporting of potentially multiple G-codes on one day and over an entire global period puts an undue burden on physicians and practices. Multiple codes will need to be submitted. Physicians should not be incentivized to focus on their stopwatches rather than patient care.
5. Practices will likely have to hire more employees merely for submission of these study codes. Since CMS has not provided additional funding to comply with the proposed data collection, the burden once again falls solely on physicians and their practices.
6. This does not align with the Congressional request for a representative sample.

If data needs to be collected, we propose:

1. A representative subset of CPT codes should be identified as first definable data points, not requiring all codes to be reported.
    a. Examples may be: Medicare volume of at least 10,000 and/or $10 million in allowable charges, and that at least 100 physicians performed the procedures in 2014.
2. A selected representative sample of providers should be identified to include geographic settings, practice types, practice sizes, and specialties to collect data on these codes.
3. There should be support or funding from CMS for the study sites to help offset costs incurred by practices
4. For accurate data collection, there were suggestions of using existing CPT codes and CMS felt that the current E/M codes may not adequately capture the greater complexity in the post-operative visit. It was suggested that physicians report the current CPT code 99024 Post-operative follow-up visits, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure.

The AUA supports the use of CPT code 99204 to report post-operative visits. However, we do not feel that creating modifiers corresponding to the proposed G-codes are appropriate, as these codes are unfamiliar to practitioners and will not accurately capture the work performed during the post-operative period. This CPT code will determine that there was, in fact, a post-operative visit during the global period.

The AUA also supports a follow-up survey conducted by RAND on the level of service performed during the post-operative period to gather firsthand accounts of the work that goes into the surgical global period for a subset of CPT codes.

In response to CMS' data collection proposal, in early August, the American College of Surgeons conducted a nationwide survey across 25 medical specialties in multiple practice settings, to assess the impact of the proposal. Thirty percent of more than 6,000 survey respondents indicated that it would cost more than $100,000 to integrate the new global survey G-codes and data collection process into their practice by 2017. More than 80 percent of survey respondents anticipate the need to develop new processes to collect, track and distinguish between Medicare and private insurer pre- and post-operative visit information, as well as modify EHR and billing systems, and spend additional time performing tracking activities beyond the amount of time that is currently dedicated to documenting medical services.

In light of the survey results, the AUA strongly recommends that CMS' withdraw the proposal to collect data on resources used in furnishing global services until after careful consideration has been given to the methodology and administrative burden of the process has been assessed. While we recognize the Congressional mandate to collect data, the legislation requires that a process be put in place by January 1, 2017; it does not confine the collection process to claims reporting. Furthermore, any process proposed to collect data of this magnitude should be performed in a manner that is consistent with CMS' longstanding intent to reduce the paperwork and regulatory burdens on practitioners, especially when the regulation may unintentionally direct care away from patients. More importantly, the proposal should adhere to the intent of the MACRA directive to collect data on the level and number of visits performed during the post-operative period of a surgical procedure from a representative sample of practitioners.

L. Valuation of Specific Codes

Genitourinary Procedures (CPT codes 50606, 50705, and 50706)
While the AUA appreciates CMS' proposals to finalize the RUC recommended physician work values for CPT codes 50606 (*Endoluminal biopsy of ureter and/or renal pelvis, non-endoscopic, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation), 50705 (Ureteral embolization or occlusion, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation*) and 50706 (*Balloon dilation, ureteral stricture, includingimaging guidance (eg, ultrasound and/or fluoroscopy*) and all associated radiological supervision and interpretation), we strongly oppose the proposed action of CMS regarding the direct PE inputs for these CPT codes.

CMS is proposing to remove the angiography room from these three procedures and add in its place the component equipment that make up the room. Because CMS currently lacks pricing information for these components they are proposing to include each of these components in the direct PE input database at a price of $0.00 and are soliciting invoices from the public for their costs to be able to price these items for use in developing final PE RVUs for CY 2017.

As CMS is aware, it is difficult for specialty societies to obtain paid invoices. CMS also is statutorily obligated to develop payment for the PE of CPT codes based on the resource costs of the codes. Clearly the resource costs of the individual components of the angiography room are not $0.00, and if CMS were to implement this proposal they would be shirking their obligation. Furthermore the practice of assigning $0.00 to supplies and equipment due to lack of accurate pricing information has become a common practice of CMS over recent rulemaking periods. The AUA considers this proposal completely inappropriate, as well as extremely punitive. **We urge CMS to withdraw this proposal and maintain the resource cost for the equipment rooms as they currently exist**.

Laparoscopic Radical Prostatectomy (CPT Code 55866)

The AUA continues to disagree with CMS' misinterpretation of the similarities between *Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed* (CPT Code 55866) and a *Prostatectomy, retropubic radical, with or without nerve sparing*; (CPT code 55840). CPT code 55866 should not be cross-walked to CPT code 55840 which is a totally different procedure. The RUC reviewed code 55866 in 2015 and determined that the RVU should be 26.80; the RUC moved to accept the survey 25th percentile for physician work with which the AUA agreed. There was no debate at the RUC about the value as the RUC agreed the value was appropriate. After careful consideration of the RUC survey results and review of intensity, skill and mental effort and psychological stress of a Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed (CPT Code 55866) it should be clear that 55866 is higher than the open radical prostatectomy procedure.

We agree with CMS that the code descriptor might have caused confusion by the RUC survey respondents and are encouraged by CMS' comments that the valuation might be improved if the CPT Editorial Panel were to consider further revisions to this code to describe a laparoscopic radical prostatectomy with and without robotic assistance. AUA looks for a very strong statement from CMS urging the CPT Editorial Panel to create two unique codes: one for laparoscopic radical prostatectomy and one for robotic radical prostatectomy. The AUA will pursue this effort at the upcoming October 2016 RUC meeting once again to urge separate CPT codes.

The AUA was very disappointed that CMS did not accept the Refinement Panel recommendations for a physician work value of 26.80, which is in line with the RUC's recommendations. Even with the new evidence presented at the Refinement Panel, and accepted by the Refinement Panel, CMS did not adjust their decision. We welcome the opportunity to discuss the results of the study presented during the Refinement Panel deliberations. We have attached a copy of the study presented during the Refinement Panel and will continue to work with CMS to determine the times included in this study are more accurate than the time reflected in the RUC survey. *(See Addendum A - Robot-assisted Versus Open Radical Prostatectomy: A Contemporary Analysis of an All-payer Discharge Database).*

In addition, the AUA is currently working with CMS representatives to explain the study presented in the Refinement Panel review to provide more data to support the RUC and Refinement Panel recommendation of 26.80 physician work value. Additional comments will be provided directly to CMS separately for consideration. *(See Addendum B)*

Electromyography Studies (CPT codes 51784 and 51785)
CMS also identified CPT code 51784 (*Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique*) as potentially misvalued through a screen of high expenditures by specialty. This family also includes CPT code 51785 (*Needle electromyography studies (EMG) of anal or urethral sphincter, any technique*) but this code was not included in the review screen. Both codes currently have 0-day global periods. CMS reviewed the RUC recommendation for CPT code 51784 and accepted the work RVU. However, CMS indicated that CPT code 51784 should have a XXX global period instead of a 0-day global period. Assuming the global period change, CMS is proposing to also add 51785 to the list of potentially misvalued codes to update the value of the service to maintain consistency with CPT code 51784.

We would like to point out that there is no difference in the work value of CPT code 51784 whether it has a 0-day global period versus an XXX global period, and should not be considered as misvalued. The RUC has stated in writing that CPT codes 51784 and 51785 will be added to the next Level of Interest (LOI) form if CMS finalizes this proposal. **The AUA supports the RUC's intentions and the request for CMS to indicate any global period changes and requests for codes as part of the family when initially nominating a code or reviewing the RUC LOI prior to distribution.**

Cystourethroscopy (CPT code 52000)
CMS noted that the RUC recommended work RVUs of 1.75 for CPT code 52000 (Cystourethroscopy (separate procedure)) is larger than the work RVUs for all 0-day global codes with 10 minutes of intra-service time, and it does not believe that the overall intensity of this service is greater than all of the other codes. CMS believes the overall work for CPT code 52000 compares favorably to CPT code 58100 (*Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure*), and has identical intra-service time and similar total time. The RUC recently reviewed this code and despite the RUC-recommended work RVU of 1.75, CMS is proposing a work RVU of 1.53 based on a crosswalk to CPT code 58100 (*Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)*), which also has a work RVU of 1.53. Therefore, CMS is proposing a direct crosswalk to CPT code 58100 and a work RVU of 1.53 for CPT code 52000.

The AUA urges CMS to accept the valid survey of 162 physicians for the 25th percentile work RVU of 1.75. The RUC recommendation was bracketed by the two key reference services and is relative to the physician work, time and intensity and complexity measures. The top key reference service was CPT code 52005 (*Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service);* (work RVU = 2.37 and 30 minutes intra-service time)) and the RUC noted that the physician time, work and intensity and complexity required to perform CPT

code 52005 is much greater, thus the recommended RVU is appropriate. The RUC compared the surveyed code to the second key reference service CPT code 57420 [*Colposcopy of the entire vagina, with cervix if present;* (work RVU = 1.60 and 19 minutes intra-service time)], and noted the physician time is slightly higher, but the survey respondents indicated that CPT code 52000 is slightly more intense and complex to perform for all measures (mental effort, technical skill and psychological stress), and thus is appropriately valued slightly higher than 57420. **The AUA urges CMS to accept the RUC-recommended work RVU of 1.75 for CPT code 52000. The AUA also requests Refinement Panel review of CPT code 52000.**

Biopsy of Prostate (CPT code 55700)

The RUC also recently reviewed CPT code 55700 (Biopsy, prostate; needle or punch, single or multiple, any approach) for physician work and PE, and recommended a work RVU of 2.50 based on the 25th percentile of the survey. CMS believes the RUC recommended work RVU overestimates the work involved in furnishing 55700 given the reduction in total service time; specifically, the reduction in pre-service and post-service times. Instead of accepting the RUC-recommended work RVU of 2.50, CMS is proposing a work RVU of 2.06 based on a crosswalk to CPT code 69801 (*Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal*). CMS states in the rule that the RUC overestimated the work involved in prostate biopsy given that the total service time; specifically, the reduction in pre- and post-service times. CMS further noted that that the RUC recommendation also appears overvalued when compared to similar 0-day global services with 15 minutes of intra-service time and comparable total times, and proposes to crosswalk the work RVUs for CPT code 55700 to CPT code 69801 *Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal*, noting similar levels of intensity, similar total times, and identical intra-service times. Therefore, CMS is proposing a work RVU of 2.06 for CPT code 55700.

The RUC compared CPT code 55700 to other 0-day global services with 15 minutes of intra-service time and determined that the intensity (0.1416 IWPUT) was appropriate relative to the physician work required. The RUC also compared the surveyed code to similar services (CPT code 93503 *Insertion and placement of flow directed catheter (eg, Swan-Ganz) for monitoring purposes* (work RVU = 2.91, intra-service time of 15 minutes and 0.1659 IWPUT) and CPT code 36556 *Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older* (work RVU = 2.50, intra-service time of 15 minutes and 0.1192 IWPUT), and the RUC determined that these services required the same intra-service time, comparable physician work and intensity. **Based on the RUC analysis, we urge CMS to accept the work RVU of 2.50 for CPT code 55700. The AUA also requests Refinement Panel review of CPT code 55700.**

The RUC recommended inclusion of new equipment, a biopsy guide for CPT code 55700. The AUA is submitting manufacturer invoices provided by urology practices to ensure accurate pricing when determining practice expense inputs. (*See Addendum C*)

Prostate Biopsy, Any Method (HCPCS code G0416)
For CY 2017, CMS is proposing a physician work value for HCPCS code G0416 (*Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method*) of 3.60 based on an intra-service time ratio between HCPCs code G0416 and CPT code 88305 (Level IV - Surgical pathology, gross and microscopic examination). CMS also used the intra-service work per unit of time of CPT code 88305 multiplied the cross-walked 120 minutes from CPT code 88305. The AUA disagrees with the proposed outdated building block approach to valuing physician work values.

The RUC valued HCPCS code G0416 through agreement of the presented cross-walk methodology and solid compelling evidence. As CMS is aware, the RUC process has transitioned from building block methodologies being used as the sole determinant of a physician work value because of the numerous mathematical arguments one can make. Building block methodologies, based on any array of assumptions, produce vastly different results, and again, this is why the RUC has moved away from the building block approach as the sole determinant of a physician work value. The AUA would also like to remind CMS that the RUC agreed with the compelling evidence presented by the specialties and that the work of G0416 may involve the examination of 20-60 or even more specimens. **We recommend that CMS accept the RUC-recommended physician work value of 4.00 for HCPCS code G0416 and discontinue its building block methodologies to value physician work ,and adopt the proven RUC's methodologies of physician surveys, expert panel opinions, cross-walks, and magnitude estimation.**

Telehealth Consultation for a Patient Requiring Critical Care Services (HCPCS codes GTTT1 and GTTT2)
To evaluate the proposed new HCPCS codes to report telehealth consultations for a patient requiring critical care services, CMS is proposing to assign a work RVU of 4.0 to GTTT1 and a work RVU of 3.86 to GTTT2.

As stated in Section II.C of this comment letter, the AUA concurs with the creation of new HCPCS codes to report initial and subsequent telehealth consultations for patients requiring critical care services. We also support the work RVUs as proposed.

III. Other Provisions of the Proposed Rule for PFS

Appropriate Use Criteria for Advanced Diagnostic Imaging Services
The Protecting Access to Medicare Act of 2014 (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The basis of the new Medicare AUC Program was established in the 2016 MPFS final rule. The remaining PAMA requirements for AUC requires CMS to establish mechanisms for consultation with AUC by April 1, 2016, AUC consultation by ordering

professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and identification of outlier professionals, which will facilitate a prior authorization requirement, beginning January 1, 2020.

In the proposed rule, CMS acknowledges that the second phase for consultation mechanisms was not identified by April 1, 2016 and the list of qualified clinical decision support mechanisms (CDSMs) will not be available by January 1, 2017 as required by PAMA. Therefore, ordering professionals will not be required to consult CDSMs and furnishing professionals will not be able to report information on the consultation by that date. Instead, CMS puts forth proposals to revise the definition for CDSMs, requirements and processes for qualified CDSMs, an initial list of priority clinical areas, and exceptions for ordering professionals for whom consultation with AUC would pose a significant hardship.

CDSM Definition, Qualifications and Requirements

Specifically, CMS proposes to define CDSM as "an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition." CMS further specifies that CDSM may be a module within or available through certified EHR technology (CEHRT) or independent from CERHT. Additional qualification requirements would direct CDSMs to make available specified supporting information, certification or documentation including a unique consultation identifier, electronically report applicable AUC to the consulting professionals, and issue aggregate feedback in the form of an electronic report annually. The proposals also would require that CDSMs update AUC content at least every 12 months, comply with privacy and security standards, maintain electronic storage of information related to the consults for a minimum of six years, and comply with any new requirements or modifications within 12 months of the effective date of the modification.

The AUA has no objections to the proposed definition of a CDSM, but is concerned with the onerous requirements and processes that CDSMs must comply with to become qualified. We urge CMS to be mindful of the unintended but potential consequences of rushing implementation of an overly burdensome process. CMS notes, the first qualified CDSMs will not be specified before June 30, 2017, at the earliest, and expects to implement the AUC consultation and reporting requirements on January 1, 2018. The problem, in part, is the timeline, as it will not provide sufficient time for physicians to align with a qualified CDSM and prepare themselves to begin reporting on that date. CDSMs are yet another component of health information technology (IT) that physicians must purchase and work with their health IT vendors to integrate with other information systems. We believe that CMS is overestimating the level of interoperability that will be achieved when AUC requirements go into effect. With value-based payment required under MACRA, CMS must be careful not to pile on additional requirements that are not tied specifically to value. **The AUA**

appreciates the delay in implementation of the AUC consultation provisions for ordering physicians, however, we urge CMS go a step further and delay the provision until 2019 to align use of AUC with the forthcoming Quality Payment Program.

Priority Clinical Areas

In addition to the CDSM proposals, CMS proposes to establish an initial list of priority clinical areas. The proposed priority clinical areas include: chest pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism), abdominal pain, headache (traumatic and non-traumatic), low back pain, suspected stroke, altered mental status, cancer of the lung (primary or metastatic suspected or diagnosed), and cervical or neck pain. CMS notes that the initial list is comprised of the top eight clinical groupings based on volume of procedures, and accounted for roughly 40 percent of paid Medicare Part B advanced diagnostic imaging services in 2014.

The AUA's Urologic Diagnostic Therapeutic Imaging Committee reviewed the initial list and has no objections to the proposed number of priority clinical areas that CMS believes reflects both the significance and the high prevalence of some of the most disruptive diseases in the Medicare population, or the methodology used to derive at the clinical categories for AUC for advanced imaging services.

Consultation by Ordering Professional

CMS' proposed timeline would cram through onerous new consultation requirements for ordering physicians. Required completion of modules and computerized form filling has already become unmanageable for many physicians. We are concerned that AUC requirements for ordering physicians will place further burden on specialists and add another unnecessary level of complexity to the already convoluted Medicare reporting system. If AUC consultation is required each time the physician orders a test, the physician will be forced to see fewer patients. Urologists are already well trained and educated in the care of patients with urologic medical conditions. Implementing further roadblocks in an untimely and haphazard manner may interfere with treatment and many patients may be unable to be seen by qualified board certified urologists who can offer them the best care. Evidence-based AUC is intended to assist physicians in selecting imaging studies that will most likely improve health outcomes for patients. Even highly sophisticated cognitive computing algorithms have difficulty with negating decision-making when multiple comorbid conditions exist. This is why it is the physician's clinical judgment that ultimately determines if an imaging study is appropriate, and therefore, should be allowed to outweigh recommendations from consulted AUC. **We urge CMS to ensure that the AUC consultation requirements will facilitate, not obstruct, the ability for treating physicians to continue to order applicable diagnostic imaging services based on sound clinical judgment.**

Exceptions to Consulting Requirements

For the AUC Medicare Program, CMS proposes three exceptions for the consultation and reporting requirement for imaging services requested by the ordering physician. The proposed exceptions would apply to emergency services when provided to individuals with emergency medical conditions, an inpatient for whom payment is made under Medicare Part A; and ordering physicians granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year.

The AUA supports the proposal that if an ordering physician is exempt from the Medicare EHR Incentive Program payment adjustment, then that ordering physician should also be exempt from the Medicare AUC Program for the same payment year. **As CMS prepares to implement the Quality Payment Program, it is important that reporting exceptions are aligned across all quality related programs.** Furthermore, we believe the exception should be automatic and not require a separate application on behalf of the physician.

Medicare Shared Savings Program

CMS proposes changes to the quality measure set that accountable care organizations (ACOs) are required to report in order to better align the Medicare Share Savings Program (MSSP) with recommendations by the Core Quality Measures Collaborative. Of particular interest to the AUA is CMS' proposal to change the specifications for quality measure ACO #11 (*Percent of PCPs Who Successfully Meet Meaningful Use Requirements*) to align with proposed policies included in the new Quality Payment Program proposed rule. Currently, quality measure ACO #11 is under the Care Coordination/Patient Safety domain and is applicable only to primary care providers within an ACO. CMS notes the significant impact of quality measure ACO #11 on the overall quality scoring for an ACO because it is double-weighted compared to any other measure.

Specifically, CMS proposes to change the title and specifications for quality measure ACO #11 to remove reference to PCPs and assess an ACO on the degree of CEHRT used by all providers and suppliers designated as eligible clinicians (ECs) within an ACO under the Quality Payment Program. For performance years 2017 and 2018, the measure would be a pay-for-reporting measure. Beginning in the 2019 performance year, the measure would be phased in as a pay-for-performance measure starting with the second performance year (PY2) of an ACO's first agreement period and for all performance years of any subsequent agreement periods, assuming no further major changes are made to the measure. Given the double-weight of ACO #11, CMS also is considering whether to finalize a policy that would require the measure to be pay-for-performance in all performance years, including the first year of an ACO's first agreement period, and whether to finalize a policy that would require the measure to remain pay-for-performance, even when a new EHR measure is introduced or there are significant modifications to the specifications for the measure.

In the 2015 MPFS proposed rule, CMS solicited comments on how ACO #11 might evolve in the future to ensure the Agency is incentivizing and rewarding providers for continuing to adopt and use more advanced health information technology. In response to the 2015 MPFS proposed rule, we expressed appreciation for CMS' willingness to consider changes to the MSSP so that ACOs may acknowledge patient care coordination activities successfully performed by specialists as well as primary care providers. **The AUA, therefore, encourages CMS to finalize the proposal to change the title and specifications of quality measure ACO #11 to assess the degree of CEHRT use by all providers and suppliers designated as ECs under the Quality Payment Program proposed rule, rather than narrowly focusing on the degree of CEHRT used only by primary care physicians participating in an ACO.**

Incorporating Beneficiary Preference into ACO Assignment

The Center for Medicare & Medicaid Innovation (CMMI) began testing patient attestation, referred to as voluntary alignment for the 2015 performance year. CMS now is proposing to implement an automated approach that would allow patients to determine which healthcare provider they believe is responsible for coordinating their overall care so that ACOs, ACO participants, or ACO professionals do not have to directly obtain this information from patients and then communicate it to CMS. CMS believes an automated approach would be more efficient for all parties involved. This proposal, if finalized, would start in early 2017. CMS proposes to start incorporating patient attestation into the assignment methodology for the MSSP effective for assignment for the 2018 performance year, regardless if the final process is automatic or manual.

The AUA has long advocated for patients to have a say in physician assignment and supports the proposed process to allow patients to voluntarily align with an ACO provider that they believe is responsible for their overall care. **We encourage CMS to finalize the proposal to allow voluntary patient attestation, as we believe the process will ensure that patients are appropriately aligned with the physicians that care for them, and physicians are not held accountable for resource use based on medical services they did not provide.**

Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments

CMS solicits input on whether to allow physicians to review manufacturer reports prior to submission to CMS, among other issues related to the Open Payments Program. Under the Open Payments Review and Dispute period, CMS allows 45 days for physicians and teaching hospitals to analyze financial information submitted on their behalf by manufacturers of medical devices, drugs, and biological and/or group purchasing organizations (GPOs). An additional 15 days is allotted for physicians to file a dispute for resolve before the data is released to the public. If the dispute is unresolved during that timeframe, the data is still posted on the Open Payments website, but flagged as "disputed."

Given the short amount of time to review and dispute any errors or inconsistencies, we believe that physicians reserve the right to preview manufacturer's financial information prior to submission to CMS to ensure accuracy. The data currently lacks validation and cannot be reasonably relied upon to provide accurate information about physician and industry financial interactions. Moreover, CMS' failure to extend the Review and Dispute period has prevented many physicians from reviewing the data and seeking correction. Pre-approval of the information would make the process less burdensome for physicians and manufacturers.

Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

CMS proposes to allow physicians who bill under the Tax Identification Number (TIN) of an ACO participant to report separately for the purposes of the 2018 PQRS payment adjustment, when the ACO fails to successfully report on behalf of the physician. Since the deadline for participating in the PQRS Group Practice Reporting Option (GPRO) was June 30, 2016 for the applicable reporting period, physicians would not need to register for PQRS GPRO for the 2018 PQRS payment adjustment. Instead, CMS proposes to allow physicians to mark the data as group data in their submission.

In addition, CMS is proposing relief for physicians who billed through the TIN of an ACO participant in an ACO that failed to satisfactorily report on behalf of physicians during the 2015 reporting period to avoid the 2017 payment adjustment. Physicians would have the option to use a secondary reporting period (January 1, 2016 through December 31, 2016) to report PQRS data to avoid the 2017 payment adjustment. Physicians also would be able to use 2016 data as a secondary reporting period for the 2017 payment adjustment, for the 2018 payment adjustment, or for both payment adjustments if the ACO failed to satisfactorily report PQRS measures for both years.

We agree that physicians should have the option to report PQRS quality data outside the ACO for purposes of avoiding the PQRS payment adjustment when the ACO does not successfully report on their behalf as required by the MSSP. Physicians that aim to satisfactorily report quality data to avoid the PQRS payment adjustment and a downward adjustment under the Value Modifier should have a safeguard to protect them against unfortunate circumstances beyond their control. **The AUA, therefore, urges CMS to finalize this proposal. We also support a secondary PQRS reporting period for the CY 2017 PQRS payment adjustment that would coincide with the reporting period (January 1, 2016 through December 31, 2016) for the CY 2018 PQRS payment adjustment. However, we recommend that CMS accept all reporting options, and waive the deadline for all eligible professionals and not just those that are part of a group practice participating in the PQRS GPRO.**

Value-Based Payment Modifier and Physician Feedback Program

Due to inconsistency of available PQRS data to calculate the quality composites for individual and group tax identification numbers (TINs), the case-by-case nature of the informal review process, and the condensed timeline to calculate an accurate upward payment adjustment factor, CMS is proposing to update the Value Modifier (VM) informal review policies and establish how the quality and cost composites would be affected if unanticipated issues arise for the 2017 and 2018 payment adjustment periods. In addition, CMS proposes methods to recalculate the cost score for physicians and groups when there are widespread quality data issues or widespread claims data issues.

Historically, when claims or data issues arise as a result with PQRS or the VM informal review process, CMS automatically assigns physicians with a "low" quality composite score an "average" score instead of recalculating the quality composite. Under CMS' proposal, if a physician earns a "low" quality score due to systematic or widespread claims data issues, and also earned a "high" cost composite score, CMS would designate both composite scores as "average." This proposal would alleviate concerns from stakeholders that a physician or group could receive a downward VM adjustment. Given the increased volume of data integrity adversely affecting the VM, we agree that eligible professionals who encounter data issues through no fault of their own should be held harmless, and **thereby support CMS' proposal to assign an "average" score for low quality and high cost to avoid a downward VM payment adjustment.**

In Scenario 4 (*Category 1 TINs with Widespread Claims Data Issues*) of the proposed rule, CMS admits that it will take approximately six weeks to recalculate composites, and notify individual and group eligible professionals about their recalculated VM, if after the release of QRURs, widespread claims data issues are determined. Given that the VM information review process is only 60 days following release of the QRURs, it is unclear why CMS proposes to recalculate composite scores when claims data is involved. CMS has proposed not to perform recalculations when other issues arise, so it is difficult to comprehend why CMS would do so with claims data. **We request that CMS clarify their decision to single out recalculations for this specific problem, or adapt the same policy for Scenario 4 as proposed for Scenarios 1-3.**

Physician Self-referral Updates

Unit-based Compensation

CMS is re-proposing a ban on per-unit compensation for certain space and equipment leases based on the outcome of *Council for Urological Interests v. Burwell.* The current proposal would not permit rental charges for office space or equipment to be determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee for the exceptions at § 411.357(a) and (b) for the rental of office space and equipment, respectively. CMS is

additionally re-proposing the requirement in the exceptions at § 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively.

The AUA is concerned about certain aspects of the discussion of this proposal and any possible unintended impact on unit-based compensation for service arrangements. CMS has noted previously that the provision of certain services "under arrangements" to a hospital may be billed using a unit-based compensation formula. Specifically, in an FAQ issued by CMS, a physician-owned lithotripsy partnership contract with a hospital to provide a lithotripter and skilled technician "under arrangements" may bill the hospital using unit-based compensation. Lithotripsy is not considered a designated health service (DHS) for purposes of the physician self-referral law. If the physician owners of the lithotripsy partnership truly provide lithotripsy services "under arrangements" to a hospital as part of actually furnishing a service to the hospital, (provision of a skilled technician and the use of the lithotripter) and not simply leasing the lithotripter to the hospital, the hospital may compensate the lithotripsy partnership using a unit-based compensation formula, as long as all of the requirements of a relevant exception are satisfied. CMS views this as payment for a services rather than a lease of equipment.

In the current proposal, CMS included additional support for the proposed space and equipment unit-based compensation ban from the OIG. CMS made brief note of two advisory opinions published by the OIG in 2003 and 2010 that express the OIG's concerns with per-unit of service compensation arrangements. The OIG's opinions were based upon concerns of overutilization and per-click fee arrangements that are "inherently reflective of the volume or value of services ordered and provided." Although the advisory opinions expressed some of the same concerns as CMS, it is of note that both advisory opinion addressed *service arrangements* and *not lease of space or equipment* as is CMS' focus in the proposal at issue.

The AUA is seeking confirmation from CMS that unit-based service arrangements are not intended targets of this proposal. The investments by urologists in state of the art equipment and the provision of lithotripsy to hospitals "under arrangement" ensures that beneficiaries are able to receive access to the best and most advanced urologic health care. These longstanding arrangements were developed in a manner intended to comply fully with CMS' guidance while also providing access and high quality care to beneficiaries. If references to problematic service arrangements demonstrate CMS' intention to extend the proposed ban to such arrangements, then we object to such a ban and would request that CMS formally propose such a ban, with related regulatory language proposals, to permit the public to consider such a proposal and submit informed comments addressing the proposal.

American Urological Association

Conclusion

In closing, the AUA appreciates the opportunity to offer our comments on the proposed rule for the Medicare Physician Fee Schedule and other Part B Services for CY 2017. If you have any questions regarding our comments, please contact Lisa Miller Jones at (410) 689-3772 or lmiller@auanet.org.

Sincerely,

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