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

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

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 appreciates the opportunity to comment on the Physician Fee Schedule proposed rule for calendar year (CY) 2018. We support many of the proposed changes in the rule, and are particularly pleased that the Centers for Medicare & Medicaid Services (CMS) acknowledges the challenges physicians face with the current quality improvement program requirements, and is proposing to use its statutory authority to provide regulatory and penalty relief in 2018.

Equipment Recommendations for Scope Systems

The AUA is supportive of the changes to the scope video system (ES031) to include the LED light rather than a separate light as well as include in the pricing the expense of miscellaneous small equipment associated with the system such as cables, microphones, foot pedals, etc. The AUA encourages CMS to continue to describe scope accessories as justified per each individual procedure. In addition, the AUA has concerns regarding CMS' proposal to create a single scope equipment code for each anatomical application: 1) rigid scope; 2) semi-rigid scope; 3) non-video flexible scope; 4) non-

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channeled flexible video scope; and 5) channeled flexible video scope. Although the changes are to streamline these direct PE inputs for ease of review and pricing via rulemaking, however, this equipment is not always apples to apples across specialties who utilize it. For example, a rigid endoscope used by a gastroenterologist as compared to an otolaryngologist may vary in price significantly. The same scopes - both flexible and rigid - (e.g. with operating/irrigating channels) are used for diagnosis (e.g. looking around) and for a surgical procedure (e.g. removing a stone or tumor). In addition, small flexible ureteroscopes have a shorter useful life than a flexible cystoscope as they are more delicate and are damaged more easily. CMS seems to have some misconceptions about scopes and how they are used. **The AUA supports CMS' changes to the scope video system; however, we urge CMS not to aggregate prices for these five types of scopes across all specialties, but rather, create packages, per specialty, for these five categories of scopes, as applicable.**

Medicare Telehealth Services

CMS is proposing to add several codes to the list of covered Medicare telehealth services for CY 2018. The AUA supports the addition of the services and encourage CMS to continue to expand access to telehealth services under the Medicare program. In addition, we support CMS' proposal to eliminate required use of the telehealth modifier GT (*via interactive audio and video telecommunications systems*) for professional claims. Implementation of the new Place of Service (POS) codes confirm that both the provision and code-specific telehealth requirements have been met, thereby rendering requirement for the distant site practitioner to report the GT modifier unnecessary.

Transurethral Electrosurgical Resection of Prostate (CPT code 52601)

CMS recently identified CPT code 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included) as potentially misvalued codes, and therefore is proposing to reduce the work RVU from 15.26 to 13.16 as recommended by the RUC, but also is considering an alternate crosswalk to CPT code 58541 (Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less) with a lesser work RVU of 12.29.

The AUA disagrees with CMS that CPT code 58541 may potentially be a more accurate crosswalk for CPT code 52601, rather than the RUC-recommended direct crosswalk to CPT code 29828 (Arthroscopy, shoulder, surgical; biceps tenodesis). While the alternate crosswalk has a similar work value, it does not recognize the critical differences in the procedures and unique aspects of work. All patients treated with CPT code 52601 involve the management of a catheter in the immediate postoperative period because of bleeding and blood clots, which still occur in spite of advancements in technology. Each patient also has a bladder irrigation system attached to the catheter in the immediate postoperative period, and this catheter must be managed. Catheter management is not present in the CMS recommended crosswalk CPT code 58541. Furthermore, the intensity required for CPT



52601 is greater than CPT code 58541 and the total time for 52601 is marginally higher by 10 minutes (236 vs 226). Therefore, the appropriate crosswalk for CPT code 52601 is CPT code 29828 with a value of 13.16. **The AUA recommends that CMS finalize the RUC-recommended work RVU of 13.16 for CPT code 52601 as proposed.**

Peri-Prostatic Implantation of Biodegradable Material (CPT code 55X87)

In October 2016, the CPT Editorial Panel deleted CPT Category III code 0438T and created CPT code 55X87, to report transperineal placement of biodegradable material. For CY 2018, CMS is proposing to implement a work RVU of 3.03 for CPT code 55X87, as recommended by the RUC.

However, in the rule, CMS notes the decrease in pre-service time compared to the current time, and is seeking comment on whether its alternative value of 2.68 should be considered given the changes in time reflected in the survey data. The AUA questions why CMS believes there is a decrease in pre-service time (30 minutes) compared to the current pre-service time, given that the current code is a Category III code (0438T), which has not been surveyed. Therefore, there are no current physician time inputs for this service. Perhaps, CMS is referring to the difference between the surveyed pre-time of 55 minutes and the application of the pre-time package times, which reduced the total pre-service time to 25 minutes. We would like to point out that use of pre-time packages is a long-standing RUC policy, and CMS typically accepts and supports this methodology.

The RUC reviewed the survey results from 175 urologists and radiation oncologists and determined that a work RVU recommendation of 3.03 was appropriate and supported by the 25th percentile of the survey. Of the 175 survey respondents, 65 had performed the procedure in the last year which exceeds the survey threshold; these responses were combined with the 110 other respondents who had not performed the procedure in the last year but likely had contributed to the initial clinical trial. The AUA and the American Society for Radiation Oncology (ASTRO) confirmed that the final recommendation of the 25th percentile reflected the combined survey. The specialty societies also clarified that ultrasound is performed continuously throughout the procedure. Furthermore, it was confirmed that the description of intra-service work is correct in that, after the ultrasound probe is placed and anesthesia is conducted, hydrodissection is the initial step in the procedure. Once the hydrodissection is completed, the syringe is removed but the needle is intact; at that time, the biodegradable material is prepped. It is never prepped prior to the procedure but is done after the hydrodissection, which is why it is included in the intra-service time.

The RUC recommended 25 minutes pre-service time, 30 minutes intra-service time, and 15 minutes post-service time (total time 70 minutes). The RUC agreed to add five minutes of positioning time above the standard package to account for positioning the patient in the dorsal lithotomy position. The RUC also compared the surveyed code to the top key reference service CPT code 49411 (*Placement of interstitial device(s) for radiation therapy*



guidance (eg, fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple (work RVU = 3.57, intra-service time of 40 minutes, total time 75 minutes) and noted that both services have similar physician IWPUT (0.074 and 0.071 respectively) with the surveyed code being higher due to the shorter intra-service work time. The RUC further noted that the second key reference service CPT code 55876 (*Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple*, (work RVU = 1.73 and intra-service time of 20 minutes) requires 10 minutes less intra-service time and is less complex and intense, thus the surveyed code is appropriately valued higher.

For additional support, the RUC compared the surveyed code to CPT code 44389 (*Colonoscopy through stoma; with biopsy, single or multiple* (work RVU = 3.02, intra-service time of 30 minutes, total time 65 minutes)) and also considered CPT code 50386 (*Removal (via snare/capture) of internally dwelling ureteral stent via transurethral approach, without use of cystoscopy, including radiological supervision and interpretation* (work RVU = 3.05, intra-service time of 30 minutes, total time 80 minutes)). The RUC recommended a work RVU of 3.03 for CPT code 55X87. **The AUA supports the RUC recommendation and urges CMS to finalize the RUC-recommended valuation of 3.03 RVUs for CPT Code 558X7.**

CMS is also seeking public comments related to whether equipment item EQ250 (portable ultrasound) includes probes, even though the RUC already confirmed that the EQ250 ultrasound unit does not include an intracavitary probe, the probe necessary to perform this procedure. Both the portable unit and the intracavitary probe should be recognized as direct practice expense inputs for CPT Code 558X7. CMS also commented on pricing information regarding two new supply items: “endocavity balloon” and “biodegradable material kit – periprosthetic” included in the PE spreadsheet. The correct unit price for the new supply item “endocavity balloon” is \$39.90. **The AUA requests that CMS finalize the direct practice expense inputs for CPT Code 558X7 as recommended by the RUC.**

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The AUA generally supports use of AUC, as we believe clinical decision support mechanisms (CDSMs) can play a valuable role in ensuring appropriate use of advanced diagnostic imaging services. In light of recent policy changes, specifically implementation of MIPS, we now urge CMS to reconsider whether it is necessary and appropriate to implement the AUC program as a stand-alone program for use of advanced diagnostic imaging, since both programs hold clinicians accountable for quality and patient outcomes, as well as for resource use, including the use of tests and procedures.

CMS tested the ability of AUC to reduce inappropriate ordering and utilization of computed tomography, magnetic resonance imaging, and positron emission tomography from October 2011 through September 2013, long before enactment of the Medicare Access and



CHIP Reauthorization Act of 2015 (MACRA) that established MIPS under the Quality Payment Program. We understand that CMS is mandated by the Protecting Access to Medicare Act of 2014 (PAMA) to promote use of a new program for AUC, however, this mandate also was enacted before MACRA. Although federal law requires CMS to implement an AUC program for all advanced diagnostic imaging testing, CMS has already missed some of the statutory deadlines in rolling out the components of the AUC program due to operational complexities.

The AUC Program is expected to be implemented while clinicians will still be adjusting to the Quality Payment Program, which alone requires tremendous physician practice resources, placing additional administrative and financial burdens on clinicians with little evidence of clinical benefit. CMS claims that multiple CDSMs will be available that can integrate directly into, or be seamlessly interoperable with, existing EHR systems. Most clinicians are still struggling with cost associated with updating their EHR systems to the 2015 edition of health information technology. Considering that only two of the 16 CDSMs currently posted on CMS' website are free, we are concerned that the added cost may prohibit some clinicians from integrating CDSMs into their EHR systems in an efficient and cost effective manner. We also are concerned that certain components of the AUC program will be too onerous for ordering clinicians to comply with if simultaneously implemented with the Quality Payment Program, which could result in ordering clinicians inaccurately labeled as outliers and unfairly subjected to further policy restrictions such as prior authorization. **Until such time as the overlap of the two programs is thoroughly assessed, operational complexities are resolved, and more CDSMs are available at no cost, we urge CMS to delay the effective date of the Medicare AUC Program indefinitely.**

Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

The AUA commends CMS for its willingness to retroactively reduce the CY 2016 Physician Quality Reporting System (PQRS) reporting requirements in order to minimize the CY 2018 payment adjustment for clinicians that failed to successfully report quality measure data. Since the inception of PQRS, clinicians have raised concerns about the challenges associated with reporting, and nine quality measures across three National Quality Strategy (NSQ) domains has proven to be onerous for many. Reducing the number of quality measures will certainly create greater continuity between the final year of the PQRS program and the beginning of MIPS; however, many clinicians who attempted, but were unable to successfully report the required number of measures due to lack of applicable measures, will still be unfairly subjected to financial penalties in CY 2018. Although CMS claims the PQRS Measure Applicability Validation (MAV) process for claims-based reporting of individual measures does not penalize physicians with insufficiently reporting quality measures, almost half of all physicians were subjected to PQRS payment adjustment in CY 2016. **Therefore, we urge CMS to apply PQRS penalties in CY 2018 only to clinicians who failed to report any quality measure data and provide full relief from**



penalties for clinicians that did report data but did not meet the required threshold for satisfactory participation.

Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016

The AUA appreciates the steps CMS has proposed to align reporting requirements for the Medicare EHR Incentive Program clinical quality measures (CQMs) with the proposed modifications for PQRS for the CY 2018 payment adjustment. As CMS has acknowledged, the complexity of the CY 2016 reporting criteria and requirements prohibited many clinicians from satisfactorily reporting CQMs through the PQRS portal, subjecting them to a negative payment adjustment in CY 2018. As such, CMS now proposes to reduce the previously finalized required number of CQMs from 9 covering at least 3 NQS domains to 6 CQMs with no domain requirement to align with the modified requirement proposed for the CY 2016 PQRS reporting period and the transition year of the Quality Payment Program. **The AUA supports the proposed modifications for CQMs and urges CMS to finalize the policy.**

Value-Based Payment Modifier and Physician Feedback Program

Current policy mandates the Secretary apply the Value Modifier (VM) to items and services furnished under the Medicare PFS no later than January 1, 2017 for all clinicians. For CY 2018, CMS proposes to reduce the automatic VM payment adjustment from -4.0 percent to -2.0 percent for group practices with 10 or more clinicians and from -2.0 percent to -1.0 percent for individual and small group practices of two to nine clinicians that fall within Category 2 of the VM. The AUA is very appreciative and encouraged by the proposal to minimize the impact of the automatic downward VM adjustment; however, when coupled with the payment adjustment required under sequestration, the impact will be substantial nonetheless, particularly for individual and small group practices. President Trump's first Executive Order, issued on January 20, 2017, provides for the Secretary of Health and Human Services (HHS) to exercise discretion and authority to waive provisions that would impose a fiscal or regulatory burden on healthcare providers. **Therefore, we urge CMS to use its full authority to completely refrain from applying the VM for CY 2018.** We believe this approach will better support CMS' goals for program alignment and ensure smooth transition from the final year of the VM to the first year of MIPS. The AUA also fully supports CMS proposal to hold harmless all groups and individual clinicians in Category 1 of the VM from a downward payment adjustment is triggered under the quality tiering methodology for the last year of the VM program.

Physician Compare

The AUA applauds CMS for the decision not to report on the Physician Compare website the CY 2018 quality tiers for cost and quality based on the CY 2016 data, or payment adjustments based on cost and quality tiers, or indicate if the clinician or group was eligible to but did not report PQRS quality measures to CMS for CY 2016. Similar information in the past has not been completely comprehensible to clinicians, and the proposed changes to



the 2016 PQRS reporting criteria and subsequently to the value modifier would make clinicians that reported data in CY 2016 appear as outliers in CY 2018. Rather than adding confusion to those who may be hoping to compare one year's information to the next, we agree it is best to leave the data out.

Request for Information on CMS Flexibilities and Efficiencies

We appreciate that the 2018 Physician Fee Schedule proposed rule includes proposals that help address some of the burdens associated with the legacy quality reporting programs. Reducing the maximum VM penalty, the 2016 PQRS requirements and the Meaningful Use reporting requirements under the Medicare EHR Incentive Program, certainly are steps in the right direction. As CMS continues to transition to the Quality Payment Program, we would like to use this opportunity to urge CMS to better align other administrative and financial burdens imposed by the Physician Fee Schedule and other Medicare program federal regulations that have the potential to jeopardize patient access to medically necessary health care services under the Quality Payment Program.

Electronic Health Records

Increased use of EHRs has recently been reported as the leading cause of burnout and professional dissatisfaction among urologists. While we realize that a legislative change is required to eliminate the all-or-nothing meaningful use measurement standard from the base score of the Advancing Care Information (ACI) performance category of MIPS, CMS can modify current policy to allow clinicians to earn partial credit. The pass or fail construct has been the single greatest barrier under the current EHR Incentive program and well-intended clinicians deserve partial credit for their efforts to demonstrate meaningful use. Despite the fact that the Quality Payment Program adopts a more flexible scoring methodology for EHR use by allowing clinicians to choose measures that better align with their clinical practice, the base score still requires clinicians to report data on mandatory measures, or fail the ACI performance category all together. In this respect, the ACI category is still an all-or-nothing standard. Also, CMS should establish an alternative pathway to achieve credit for the ACI performance category by granting full credit to clinicians that use certified EHR technology to participate in a qualified clinical data registry (QCDR).

Prior Authorization

Over the past several years, Medicare Advantage plans have imposed increasingly onerous prior authorization requirements for medical procedures and services that are not applicable under the Physician Fee Schedule. The growing burden of prior authorization requirements substantially increases clinicians' costs and imposes significant hardship on Medicare patients seeking access to medically necessary services. We urge CMS to improve transparency and standardize processes for prior authorization under the Medicare Advantage program prior to implementation of the Other Payer advanced alternative payment model under the Quality Payment Program.



Regulatory Review

Finally, we ask that CMS refrain from simultaneously publishing multiple regulations with competing deadlines. Regulations governing the Physician Fee Schedule, the Quality Payment Program, and the Outpatient Prospective Payment System and Ambulatory Surgical Centers are extensive in volume and riddled with intricate proposals, thereby making them complex and difficult for stakeholders most affected by these programs to understand. Often times, 60 days for public comment is not adequate time to carefully review, analyze and draft well thought-out comments that can have long-term implications. Also, on several occasions, proposals unrelated to these programs have been included in the regulations, creating additional challenges for stakeholders to determine the applicability, if any, of the proposals. Again, we urge CMS to give consideration to the time constraints associated with review of these regulations and allow adequate time to the extent possible by law.

Collecting Data on Resources Used in Furnishing Global Services

While not addressed in the proposed rule, we would like to reiterate some of our concerns about collecting data on resources used in furnishing global services; particularly, with the claims-based data reporting implementation process and the definition of a practice. We also would like to request more information regarding the global codes list for 2018, along with more information on the survey conducted by the RAND Corporation.

In the CY 2017 PFS, CMS set forth a global codes data collection policy consisting of three components: (1) claims-based data reporting; (2) a survey of practitioners; and (3) data collection from accountable care organizations (ACOs). For claims-based reporting, CMS finalized a policy whereby practitioners who are in groups of 10 or more practitioners and who are located in any of nine specified states would be required to report CPT code 99024 for every post-operative visit that they provide related to any CPT code on a list of 293 10- and 90-day global codes specified by CMS. This mandatory data collection began July 1, 2017. Additionally, few details are known about the other two components, specifically, the survey of practitioners and data collection from ACOs. Due to insufficient time and lack of effort on behalf of CMS to educate clinicians about the policy or provide a detailed plan for data validation, we believe the data that will be collected will be inherently flawed and of low statistical quality. **Therefore, we strongly urge that CMS not use data collected via the claims-based data collection methodology to revalue global codes starting in 2019.**

Practices of 10 or more practitioners are required to report the postoperative CPT code 99024 to CMS via claims. For the purposes of postoperative data reporting, "practice" is defined, not as practitioners sharing the same tax ID number (TIN) as CMS defines groups in all other cases of CMS reporting, but rather, those who share "business or financial operations, clinical facilities, records, or personnel." This definition has led to confusion for AUA members. **To avoid further confusion, we strongly urge CMS to revise the**



definition of a “practice” to conform to the definition of a group used in other cases of CMS reporting to be those practitioners sharing a TIN.

In addition, in early 2017 CMS posted the list of 293 10- and 90-day global codes to be reported starting July 1, 2017 based on the articulated frequency criteria. However, CMS made no attempt to discuss or update the list of codes in the proposed rule for 2018 to ensure that the list of codes continues to meet CMS’ finalized criteria. We are now uncertain whether these are the same codes that practitioners should use for reporting in 2018. **However, if CMS continues to require the reporting of 99024 in certain scenarios, we ask that CMS clarify whether practitioners should use the 2017 list of high volume/high value 10- and 90-day global codes or whether CMS plans to release a new list for 2018 reporting.**

We also have very little information regarding the survey of practitioners (the second component of global codes data collection). The CY 2017 PFS final rule stated that the survey will be in the field by mid-2017, yet we do not know enough about the survey to begin educating our members on what to expect. In addition, it is critical that we have the opportunity to review and provide feedback on the survey design, methodology, content, and analysis. At this point, our understanding is that just one member of a selection of specialties will be interviewed and only those without payment expertise have been considered. **We have many questions and concerns regarding the survey development and we urge CMS not to move forward with the practitioner survey until it has been thoroughly vetted and the specialties to be surveyed have had an opportunity to review it and provide feedback.**

Conclusion

The AUA appreciates the opportunity to provide comments on the Physician Fee Schedule proposed rule for CY 2018. If you have any questions or wish to discuss our comments, please contact Lisa Miller-Jones at (202) 403-8501 or lmiller@auanet.org.

Sincerely,

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

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

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

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