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1000 Corporate Boulevard
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U.S. Toll Free: 1-866-RING-AUA (1-866-746-4282)
Phone: 410-689-3700
Fax: 410-689-3800
Email: AUA@AUAnet.org
Websites: AUAnet.org
UrologyHealth.org
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October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program; CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or MA-PA plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule (CMS-1734-P)

Dear Administrator Verma,

The American Urological Association (AUA) appreciates the opportunity to provide comments on the CY 2021 Medicare Physician Fee Schedule (MPFS) proposed rule. The 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.

Our members appreciate the policy flexibilities that the Centers for Medicare & Medicaid Services (CMS) has implemented in response to the COVID-19 public health emergency and welcome the opportunity to work with you to ensure that Medicare beneficiaries continue to receive the highest quality care during the pandemic. The AUA is pleased to provide comments on the additional proposals and requests for comments on the agency's pandemic-related policy changes and how

these changes may be preserved to improve patient access once the public health emergency concludes.

As such, we will provide comments on the following provisions of the proposed rule:

- Valuation of Specific Codes
- Refinements to the Outpatient Evaluation and Management Services Policy
- Telehealth and Other Services Involving Communications Technology
- CY 2021 Updates to the Quality Payment Program, including the MIPS Value Pathways and Qualified Clinical Data Registries

Proposed Valuation of Specific Services

Transrectal High Intensity Focused US Prostate Ablation (CPT Code 558XX)

CPT code 558XX (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance) is a new Category I code that will be effective January 1 and replaces a temporary HCPCS C-code which was established July 1, 2017 for the ablation of prostate tissue. CMS disagreed with the RUC recommended work value of 20.00 which was based on a valid survey.

Instead, CMS proposed a work RVU of 17.73 for this service based on a crosswalk to CPT code 69930 (Cochlear device implantation, with or without mastoidectomy), which has a similar total time and identical intraservice time to CPT code 558XX. The agency believes a work RVU of 17.73 more appropriately values this service based on total time ratios to the two key reference service codes 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*) (work RVU = 21.36, intra-service time of 180 minutes and 448 minutes total time) and 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*) (work RVU = 13.60 and 274 minutes total time). CMS believes that the total time ratios to the two reference service codes indicate that the RUC recommended value is somewhat overstated and does not accurately reflect the physician time involved.

The AUA strongly disagrees with CMS' proposed work RVUs for CPT code 558XX, as the RUC recommended work value of 20.00 RVUs is based on valid survey data in which 80% of survey respondents chose MPC code 55840 as the top key reference code, in comparison to only 16% who chose the second key reference service code 55873. AUA cannot support a total time ratio methodology between these two services since the survey respondents were not equally split. Although code 558XX has less total time less than the top key reference service code 55840, 71% of all survey respondents who selected code 55840 rated code 558XX much more intense and complex, further supporting a higher work RVU of 20.00.

The AUA recommends CMS consider a more appropriate crosswalk to CPT code 42420 (*Excision of the parotid tumor or parotid gland*), as they have similar intensities, CPT code 558XX and CPT code 42420 have IWPUTS of 0.0780 and 0.0779

respectively. **The AUA strongly urges CMS to accept a work RVU of 19.53 for CPT code 558XX based on this alternate crosswalk.**

Item	AUA Survey	AUA Proposed	CMS Proposed
	558XX	42420	69930
Name	HIFU	Excise Parotid	Cochlear Implant
RVU	20.00	19.53	17.73
Intra Time	180	180	180
IWPUT	**0.0780**	**0.0779**	**0.0673**
Total Time	373	383	387

Colpopexy (CPT Codes 57282, 57283)

For these services, CMS disagreed with the RUC recommended work RVUs of 13.48 and 13.51 for CPT codes 57282 and 57283 respectively and instead has proposed to decrease the work RVUs to 11.63 and 11.66 for these services. The RUC recommendations for both these services were based on a robust survey completed by AUA members, and we strongly recommend that CMS adopt these RUC recommended work values.

Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus) (CPT Code 57282)

CMS has proposed that their recommended work RVU of 11.63 for CPT code 57282 based on the RUC recommended interval of 0.03 less than the work RVUs of 11.66 for CPT code 57283 being proposed by CMS. The AUA strongly discourages this methodology in valuing services by increment as this inaccurately treats all components of the physician time as having identical intensity. Furthermore, CMS' proposed value for CPT code 57282 accepts the RUC work RVU increment between the two services, but not the RUC recommended value. The AUA recommends that CMS accept the RUC recommended value based on the survey rather than values derived by increments.

CPT code 57282's current value and time was derived from the Harvard studies, and therefore, is not resource based. AUA cannot support comparing the original Harvard value of this service, which is over 25 years old and whose source is unknown, to time and work derived from a recent survey. Prior to this point, CPT code 57282 had never been surveyed by the RUC. The IWPUT for the current times and work RVU (0.014) is inappropriately low for this intense major surgical procedure, not that much higher than the intensity for pre-service scrub/dress/wait time, which strongly implies the current total times are inflated relative to the current work RVU and not valid for comparison to the new times. During the initial Harvard study, only overall post-operative time data was surveyed; data on the number and level of hospital and office post-operative visits were not collected. The hospital total time was estimated at 88 minutes and the office visit total time was estimated at 57.5 minutes. These times were "converted" to E/M visit codes by a

CMS contractor for practice expense RVU review using an algorithm some years after the original Harvard study. Thus, this is the first time the RUC has had the opportunity to review the hospital and office visits for code 57282 and also the first time survey data was collected on the number and level of post-operative visits, making comparison between historic Harvard times and modern RUC times precarious at best. In addition, the difference in the intra-service time can be attributed to the multiple points of attachment, which was not done in the past. The largest difference in the total time comes from the hospital visit time assigned by Harvard in 1992. Therefore, **CMS' rationale to recommend a lower work RVU for code 57282 based on the "significant decrease in total time" is completely flawed and unjustified**.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to the top key reference service, CPT code 57260 *Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed;* (work RVU = 13.25, 90 minutes intra-service time and 241 minutes total time), and MPC 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)* (work RVU = 13.16, 75 minutes intra-service and 236 minutes total time), and reference code 55873 *Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)* (work RVU = 13.60, 100 minutes intra-service and 274 minutes total time). The RUC agreed that the higher intra-service and total time as well as the additional post-operative (99213) visit for code 57282 justifies the higher work value. **The AUA strongly urges CMS to accept a work RVU of 13.48 for CPT code 57282.**

Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy) (CPT Code 57283)

For CPT code 57283, the RUC recommended a work RVU of 13.51. CMS disagrees with the RUC recommended work RVU of 13.51 and is proposing the current work RVU of 11.66 for code 57283 based on the total time ratio between the current total time of 349 minutes and the new recommended total survey time of 231 minutes. CMS bases their recommended work RVU on the proposed survey decrease in total time, however, the agency states that, since total time has decreased and the intensity has increased due to the change in technique and knowledge necessary to perform the service, the agency will propose to maintain the current work RVU of 11.66 instead of the RUC recommended work RVU of 13.51 to account for these decreases in time while still accounting for the increase in intensity.

The AUA strongly disagrees with the CMS statement that the decreased total time for code 57283 should result in a lower work value than the RUC recommendation. When developing its recommendation, the RUC agreed that although the current times of code 57283 have changed according to robust survey data, the overall intensity and complexity has increased significantly. For code 57283, the extent of

dissection required to engage the target ligaments and tissues as well as the importance of suturing the ligaments with more precision and at multiple sites is now standardized. Additionally, the extensive dissection that is required to isolate the uterosacral ligament increases risk of trauma and debilitating complications due to the proximity of the uterosacral ligament to the ureter. Thus, the ureter must be checked to confirm that it has not been trapped or kinked in the repair. The RUC agreed that there is compelling evidence that there has been a change in the physician work necessary to perform this service due to a change in technique and knowledge of the problem. The compelling evidence is also strongly supported by documentation in the peer-reviewed medical literature.

Furthermore, CMS compares code 57283 to reference codes 19350 (*Nipple/areola reconstruction*) (work RVU = 9.11 and total time of 229 minutes) and 47563 (*Laparoscopy, surgical; cholecystectomy with cholangiography*) (work RVU = 11.47 and 238 minutes of total time). CMS is incorrect in proposing a work RVU of 11.66 based on referencing CPT codes 19350 and 47563. For example, a nipple reconstruction procedure, CPT code 19350, involves an incision made externally on the breast to dissect a small amount of tissue at the site where the nipple will be made. The surgical site is external to the body without proximate anatomical structures that would be affected by a subcutaneous incision. In fact, per the RUC database, CPT code 19350 can be performed under local anesthesia and is performed in the office setting 19 percent of the time. With nipple reconstruction, the surgeon takes the area freed by the incision and then forms it into a nipple shape and small sutures are then used to secure the form. With CPT code 57283, the surgical site is internal and in a confined anatomic space close to the elements of the urinary tract that need to be avoided when dissecting tissue. As stated above, CPT code 57283 requires extensive dissection to engage different levels of the ligament for multiple site attachment of the vaginal apex and would never be performed under local anesthesia or in the office.

Similarly, CPT code 47563 does not include the amount of dissection and tissue reattachment that CPT code 57283 does. CPT code 47563 involves excision of tissue through a laparoscope, not rebuilding a pelvic floor. In addition, the radiographic work included in CPT code 47563 is not comparable to the intensity or risk of performing a surgical procedure.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to the top key reference service (KRS) code 57260 *Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed;* (work RVU = 13.25, 90 minutes intra-service time and 241 minutes total time) and reference code 55873 *Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)* (work RVU = 13.60, 100 minutes intra-service and 274 minutes total time). The RUC also noted that the significantly higher intra-service time and additional post-operative (99213) visit upholds its recommendation

for the survey 25th percentile work RVU as supported by the survey. **The AUA strongly urges CMS to accept a work RVU of 13.51 for CPT code 57283.**

Laparoscopy Colpopexy (CPT code 57425)
The RUC had recommended a work RVU of 18.02 for CPT code 57425 (Laproscopy, surgical, colpopexy (suspension of vaginal apex)) based on robust survey data, but CMS instead proposed to decrease the work RVU to 17.03 for this service. The agency points to the total time ratio between the current total time of 404 minutes and the recommended survey total time of 351 minutes in support of its alternate value. The AUA does not agree with the decrease in total time for this service should result in a lower work value than what the RUC recommended since the intraservice time required to perform the service increased significantly.

When finalizing its recommended value, the RUC found there was compelling evidence to support the increase – surgical techniques and technology have changed drastically – which has changed the physician work. **The AUA, therefore, urges CMS to accept the RUC recommended work value of 18.02 based on a robust survey and an increase for which compelling evidence was found rather than setting a value based on the change in time and inappropriate reference codes.**

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic
The AUA thanks CMS for its efforts to reduce the administrative burden associated with the outpatient E/M codes as well as to more appropriately value these services. Our members participated in the RUC survey of this code family used to develop the values for this family as finalized in last year's MPFS, and the AUA continues to support the documentation and valuation policies as finalized in the CY 2020 rule.

CMS estimates that urology would see an eight percent increase in reimbursement as a result of the policies in the proposed rule. The AUA believes this estimate oversimplifies what this policy means in reality for individual urologists and practices. The benefit will ultimately depend on their case mix; while many of our members devote the bulk of their practices to helping patients manage their chronic urological conditions, many perform a significant number of procedures. Based on information we have collected from our members, the AUA estimates our members will see increases that range from two to six percent.

Despite this, we continue to support the policy CMS has finalized, but urge the agency to work with the Secretary to mitigate the negative effects of this policy change. The AUA recognizes that CMS is statutorily mandated to implement MPFS changes in a budget neutral manner, but practices already struggling during the COVID-19 pandemic will be devastated by the 10.6 percent cut to the conversion

factor that has resulted from the redistributive impact of the E/M policy. **Medicare beneficiaries continue to require access to urological procedures as well as chronic urological care, and therefore, the AUA strongly recommends CMS and the Department of Health and Human Services use all of the tools at their disposal, as well as work with Congress, to address this issue.**

Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)

The driving force behind the outpatient E/M changes was to reduce the burden associated with the 1995/1997 documentation guidelines. As a result, physicians will have the option to document these services either based on medical decision making or total time spent on the date of service beginning January 1, 2021. **The AUA continues to support the implementation of CPT add-on code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes*) to capture additional time spent on the date of service above that for a level 5 visit as well as CMS proposal that CPT code 99XXX is only available once a physician has exceeded the maximum, rather than the minimum, time associated with a new or established patient level 5 visit.**

However, the AUA urges CMS to reconsider its policy that requires a provider to spend a full 15 minutes beyond the maximum level 5 time before CPT code 99XXX can be billed as this contradicts CPT's guidance for time-based codes which considers a unit of time to be attained when the midpoint is passed (e.g., a code requiring 15 minutes can be reported when 8 minutes have passed). **To be consistent with existing CPT coding conventions and reduce confusion, we recommend that CMS align its reporting rules for 99XXX with CPT's coding conventions for other time-based services.**

As the AUA has worked with its members to develop these comments, we have identified these scenarios in which CPT code 99XXX would be available to our members who choose to bill by time and hope the following examples are useful to the agency:

- A 72 year old established patient with a history of superficial bladder cancer now found to have high-grade muscle invasive bladder cancer. Discussion with patient and spouse about radical cystectomy and urinary diversion.
- A 65 year old woman with severe overactive bladder symptoms, refractory to conservative treatment, considering implantation of an InterStim device for neuromodulation.

Comment Solicitation on the Definition of HCPCS Code GPC1X

In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X to describe the "visit complexity inherent to evaluation and management associated with the medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition." The AUA supported this add-on code in last year's comments and continues to do so since much of the care delivered by our members will fall into the second part of the code's definition.

Despite our support of the service, the AUA appreciates the agency's desire to work with stakeholders to better define it as this will help the association educate its members on its proper use. **Our members believe this code will help capture the additional work required to treat patients with disease processes that last a year or longer or will lead to their death. This type of urological condition requires active monitoring outside of patient visits which is not recognized in the current coding structure.** Examples of these situations include:

- A 78 year old woman with overactive bladder that has been present for decades who has failed multiple first-line therapies and continues to have distress presents for a discussion of second and third-line therapies.
- A 78 year old man with metastatic prostate cancer on LHRH therapy presents as his PSA continues to rise despite hormone blockade.
- A 65 year old woman with hypocitraturia who is a recurrent stone former and is on potassium citrate returns to discuss a new kidney stone and lab values.

The AUA welcomes the opportunity to continue to work with CMS to better define this service to capture the currently uncompensated care of certain types of E/M work.

<u>Telehealth Proposals</u>

The telehealth flexibilities implemented by CMS during the COVID-19 public health emergency have been invaluable to urologists and their patients. Since the start of the pandemic, our members have found that telehealth has allowed them to meet the needs of their patients including those with non-routine issues, such as kidney stones and prostate disorders. Outside of the pandemic, telehealth's expansion will play a critical role in reducing the barriers created by the shortage of urologists in certain geographical areas. Additionally, telehealth facilitates coordination of care for patients who require family members or caregivers to assist in the encounter due to an intellectual or language barrier. In many cases, these facilitators are unable to physically be present at an in-person visit, which may result in an insufficient encounter leading to the deferral of care until it is urgent, complex, and expensive. Telehealth also provides greater access to patients with limited mobility for whom navigating an in-person visit can be overwhelming, such as patients with

spinal cord injuries or other significant impediments to mobilization. The AUA applauds CMS for considering to extend certain telehealth policies on a temporary basis, or be made permanent once the public health emergency concludes. We would like to provide the following specific comments on a number of telehealth policies.

Permanent and Temporary Addition of Services to the Telehealth List
The AUA supports and appreciates the agency's proposal to add the following eight services to the Medicare telehealth services list permanently: GPC1X, 99XXX, 99334-5, and 99347-8. These services are similar to those already on the Medicare telehealth list and the addition of these services will allow AUA members to continue seeing their patients while protecting their health and safety during the public health emergency and once it concludes. We also support the agency's proposal to create a new category of services to the telehealth list on a temporary basis through the end of the year when the public health emergency ends. We agree this will allow the agency to collect data on certain services when delivered via telehealth and appropriately determine whether these services should eventually be added to the permanent telehealth list.

Virtual Check-in
The AUA supports the agency's proposal to develop and value a code to describe a longer virtual check-in of 11-20 minutes than the current G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). Despite this proposal, the AUA believes there will be a significant need to provide telephonic E/M care to patients once the public health emergency concludes.

Audio-only Visits
The AUA greatly appreciates the agency for expanding the use of telehealth through both audio/video and audio-only visits during the public health emergency. These flexibilities have improved the delivery of care for AUA members and their patients. **We recognize that CMS regulations do not allow these audio-only visits to be covered post-pandemic, however these services play such an important role in delivering care that we recommend that CMS amend its telehealth regulations to allow for audio-only services to continue to be provided once the public health emergency concludes.**

In the Medicare population, there are significant barriers to delivering care with a simultaneous audio/visual connection, which include patients' lack of access to the appropriate communications devices and broadband connection, and some may lack the ability to use the technology required for their visits. Additionally, telehealth services delivered with a simultaneous audio/visual connection do not

allow for necessary translation services for patients or for a patient's family member or caregiver to participate in the visit. When this audio/visual connection is disrupted, AUA members are forced to rely on audio-only connection or else they have to defer care until the patient can attend an in-person visit. During this time, the patient's condition may worsen or become more complex and expensive to treat.

AUA members have reported that there is not a significant difference in quality of care for the vast majority of encounters for audio-only and audio/visual visits. Data from Kaiser Permanente show that from February 2019 to February 2020, thirteen urology departments in southern California saw a total of 8209 patients through telephone E/M services, and maintained patient satisfaction scores (access to care, provider satisfaction, overall experience) in the 85-90 median percentile. Additional data from 2015 to 2020 in northern California shows patient satisfaction scores for telephone visits in the 89-90 median percentile. Audio-only visits have played an important role in patient care when face-to-face visits are not feasible, as we have seen during the COVID-19 public health emergency. **We welcome the opportunity to work with CMS to explore how to expand patient access to audio-only care while limiting potential fraud and abuse.**

Direct Supervision

In light of the experience of urologists during the public health emergency, AUA supports the permanent extension of permitting teaching physician presence through audio/video real-time communication during the patient visit and allowing Medicare payment for teaching physician services when a resident furnishes telehealth services while a teaching physician is present using audio/video real-time communications technology.

Today's technology allows residents to communicate with attending urologists virtually to evaluate patients. During the public health emergency, AUA members have successfully supervised residents with urological examinations, endoscopies, and accomplishing difficult urinary catheterizations (DUC). Patients often present to the emergency room in excruciating pain with kidney stones. Telemedical supervision allows the resident to initiate treatment without the delay of waiting for the arrival of the attending urologist, allowing better quality care and faster turn over in a crowded emergency room. Technology prevents residents from having to wait for a urologist to travel to the ER and therefore, has the potential to reduce the turnaround time for patients in the ER. **Given this experience, AUA is supportive of the proposal to permit teaching physician presence via audio-visual real time communication, as it permits effective supervision of resident physicians while increasing access to needed urological care. The AUA also proposes permitting teaching presence via telephone only at the discretion of the supervising physician. There are instances where telephone only is satisfactory to the clinical scenario and the AUA supports the clinical judgment of the physician to determine which modality should be used.**

AUA members are also using these flexibilities to provide supervision of their office staff remotely. This grants significant flexibility not only during public health emergencies, but also to expand access to care in rural and underserved areas where patients access to certain services is limited. One example of this phenomenon is the remote supervision of intramuscular injections by staff. **AUA encourages CMS to support policies that permit remote supervision of staff, given its potential to increase access to urological care after the end of the COVID-19 public health emergency.** Indeed, more than 95% of the respondent urologists surveyed as part of AUA's Payment Policy Priorities Survey indicated that, if Medicare retains all the telehealth flexibilities put in place during the COVID-19 public health emergency, they would continue to provide telehealth services. This data suggests that telehealth services will continue to be a key tool to ensuring access to urologic care after the public health emergency. For that reason, CMS should maintain the telehealth and remote supervision flexibilities implemented during the public health emergency so that patients have greater access to urologic care.

Finally, the AUA supports any incident-to service that is billable in person, to be billable with telemedical supervision, both audio-visual and telephone only, at the discretion of the physician. The AUA appreciates CMS' concern for patient safety and the agency's request for guardrails that should be implemented. The AUA fully supports the clinical judgement of the physician as a sufficient guardrail for telemedicine, including audio/visual and audio-only communications. We believe these tools are used at the discretion of the physician and should not be over-regulated.

MIPS Value Pathways (MVP)

The AUA supports CMS' proposal to delay the transition to MIPS Value Pathways (MVP) in response to the public health emergency as providers work to address COVID-19 in their communities. In the proposed rule, the agency stated that it will revisit potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period. We recognize that this would mean that in the CY 2022 rulemaking cycle, the agency may simultaneously propose an initial set of MVPs while also establishing implementation policies. The AUA urges the agency to ensure that finalized implementation policies will offer flexibility so specialty societies feel comfortable investing in the development of MVPs, and for specialists to view MVPs as a viable participation option. We hope the agency will use this time to work with stakeholders to develop MVPs that are relevant to all clinicians in various specialties. The AUA welcomes the opportunity to work with the agency to ensure the MVPs allow for reduced burden and meaningful participation for all physicians.

We recognize that the agency is proposing additions to the framework's guiding principles and establishing new criteria to develop and select MVPs. As such, we wish to provide comments on the following proposed criteria:

- Utilization of measures and activities across performance categories: MVPs should include the entire set of Promoting Interoperability (PI) measures
    - It is our understanding that 11 measures exist for this category and practices are able to apply for exceptions for the measures that do not apply. The AUA seeks confirmation on our assumption of this criteria.
- Intent of Measurement: Does the MVP act as a vehicle to incrementally phase clinicians into APMs? How so?
    - For your consideration, the AUA would like to point out that, depending on the "phase-in" timeline, this may be a problem for some small and rural practices, as these practices typically do not have the infrastructure to make changes like larger practices. We ask that you will consider a timeline with greater flexibility for providers in these practices.
- Appropriateness: (1) Is the MVP reportable by multiple specialties? If so, has the MVP been developed collaboratively across specialties? (2) Prior to incorporating a measure in an MVP, is the measure specifications evaluated, to ensure that the measures is inclusive of the specialty or sub-specialty?
    - The AUA is concerned that this criterion may be burdensome on specialties during the measure development process. While AUA would include other specialties and sub-specialties in the development process, it may be difficult to include every sub-specialty that the measure may affect. This process would be expensive and extraordinarily time consuming and possibly slow the development of needed quality measures. The AUA seeks clarity from CMS regarding what the agency considers "inclusive."
- Measures and Improvement Activities Considerations - MIPS Quality Measures: To the extent feasible, does the MVP avoid including quality measures that are topped out?
    - The AUA requests clarity from the agency regarding their definition of "topped out." The AUA believes that CMS has not been clear about what they consider "topped out" in the past and this will have an impact on which measures are included and which are not. Additionally, the AUA urges CMS to include topped out measures when there are no other measures relevant to the specialty available. As the agency is aware, the measures development process is long and expensive and should the agency exclude topped out measures there may not be replacement measures readily available.
- Measures and Improvement Activities Considerations - MIPS Quality Measures: To the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP. Broadly applicable (cross-cutting)

quality measures may be incorporated if relevant to the clinicians being measured.
    - The AUA would like to acknowledge that it may be difficult for specialty organizations to contribute specialty specific measures into broad MVPs that are not specialty specific. For example, it may be difficult for AUA to contribute urology measures to MVPs that are not urology specific MVPs.
- Measures and Improvement Activities Considerations - Promoting Interoperability (PI) Measures: Must include the full set of PI measures
    - While the AUA recognizes that CMS is working to promote interoperability and increase physician use of electronic health records, the AUA believes this criterion may contribute to additional administrative burden on clinicians, as it will take significant time for practices to implement all of these measures. We hope the agency will continue to work towards reducing administrative burden on clinicians.

Finally, to ensure meaningful engagement by urologists and other specialists, the AUA recommends CMS consider the following priorities regarding the proposed MVP framework as future policies related to this program are developed:

- Preserve clinician choice – The AUA believes MVP participation should remain voluntary and clinicians should be able to choose whether they want to stay in traditional MIPS.
- Adopt new participation mechanisms and scoring rules that support more meaningful engagement by specialists – CMS must address certain foundational aspects of MIPS before the framework can improve each specialist's experience. Therefore, the agency should consider (1) permitting sub-group reporting and (2) removing scoring caps on measures that lack a benchmark.
- Avoid the use of administrative-based population health measures – CMS must consider more effective ways to minimize reporting burden, while ensuring meaningful reporting and impactful performance assessments. We recommend the agency consider working with specialty societies to explore better ways to tie claims data to more robust clinical data collected by registries.
- Provide more flexibility in regards to (PI) requirements – The AUA recommends CMS work with specialty societies to develop alternative pathways to comply with the PI category that look beyond EHR functionality and instead recognize diverse and innovative ways of using of electronic health data to improve clinical outcomes.
- Allow for more innovative thinking with regards to cost measures – Many specialties still lack relevant cost measures. Therefore, we recommend CMS

evaluate alternative options for developing and considering cost measures outside of the Acumen process.

- Enhanced transparency and iterative feedback – The AUA requests that the agency establish a transparent and iterative process for providing stakeholder feedback when an MVP has been approved, disapproved, or is being considered. We ask that this process provide for a two-way dialogue in which stakeholders have a follow-up opportunity to respond with additional rationale.

Qualified Clinical Data Registries (QCDR)

Since their implementation, QCDRs have become an important method for clinicians to meaningfully participate in MIPS. Most QCDRs are run by specialty societies, many of which are small nonprofit organizations. Since 2014, AUA has operated the AUA Quality (AQUA) Registry, which provides participants with national benchmarking on the performance of urologic care measures and practices regarding the diagnosis and treatment of urologic diseases, quality measures meaningful to urologists, and automated tools for quality improvement and easy reporting. AUA supports CMS' proposal to allow QCDRs to support MVPs beginning with the 2022 performance period. AUA is concerned, however, by the proposal to require that QCDRs conduct annual data validation audits. While AUA appreciates the need for QCDRs to utilize accurate information, the proposed audit structure will impose significant costs on the small nonprofit entities, such as the AUA, that operate these registries. AUA appreciates and supports the proposal to finalize the policies published in the May 8, 2020 Interim Final Rule with Comment period delaying certain QCDR requirements. This delay will relieve medical societies and physicians of the burden associated with the QCDR measure approval criteria during the COVID-19 pandemic and provide adequate time to complete the requirements after the conclusion of the public health emergency.

The AUA appreciates the opportunity to provide comments on this proposed rule. If you have any questions or wish to discuss our comments further, please contact Keith Hawman, Policy Manager, at (410) 689-4045 or khawman@auanet.org.

Sincerely,

Eugene Rhee, MD, MBA
Chair, Public Policy Council

Matthew E. Nielsen, MD, MS, FACS
Chair, Quality Improvement & Patient Safety Committee