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September 5, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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

Re: Medicare Program; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1807-P)

Dear Administrator Brooks-LaSure:

The American Urological Association (AUA) thanks you for the opportunity to provide comments on the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) proposed rule. The AUA is a globally engaged organization with more than 25,000 physician, physician assistant, and advanced practice nursing 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 11,000 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.

We thank the leadership of the Centers for Medicare & Medicaid's Division of Practitioner Services for meeting with our physician leaders to discuss these issues and respectfully submit comments on the following provisions of the proposed rule:

- CY 2025 Conversion Factor Update
- Valuation of Specific Services
- Development of Strategies for Updates to the Practice Expense Data Collection and Methodology
- Supply Pack Pricing Update
- Strategies for Improving Global Surgery Payment Accuracy
- Payment for Telehealth Services
- Non-Chemotherapeutic Complex Drug Administration
- Quality Payment Program Proposed Revisions

American Urological Association

CY 2025 Conversion Factor Update
CMS has proposed a 2.8% decrease to the conversion factor for CY 2025 as result of the statutory 0% update, a positive budget neutrality adjustment, and the expiration of the funding Congress provided in the Consolidated Appropriations Act, 2024. The AUA recognizes that the agency is constrained by existing statute and cannot implement policy to avert this cut or provide an increase.

However, CMS' lack of authority does not mitigate the concerns of urologists and other physicians who continue to absorb the increasing costs of running a practice, including salaries for clinical staff, supplies, and equipment, about the downward pressure on the conversion factor, which has only increased two dollars since 1992. There is no other Medicare payment system with similar stagnant reimbursement. The AUA continues to advocate for Congress to enact comprehensive reforms to Medicare physician payment, including annual statutory increases equal to the Medicare Economic Index and updates to the budget neutrality calculation. ***We urge CMS to work with Congress as appropriate to modernize the MPFS.***

Valuation of Specific Services
The AUA is an active participant in the American Medical Association's CPT Editorial Panel and Relative Value Scale Update Committee (RUC) and recognizes the work required to accurately define and value physician services. We believe that both these processes, which include input from practicing physicians, play an important role in supporting CMS' work to maintain the MPFS, and thank the agency for thoughtfully considering the RUC's recommendations for specific services, including accepting 90% of the RUC's recommendations in this proposed rule.

Intra-Abdominal Tumor Excision or Destruction (CPT codes 4X015, 4X016, 4X017, 4X018, and 4X019)
The five-code family that describes intra-abdominal tumor excision or destruction was developed by the CPT Editorial Panel to replace the existing three-code family, which did not consider the size of the tumors. The RUC surveyed this family at the September 2023 RUC meeting.

CMS proposed to accept the RUC recommended work values for all the codes in the family except those for CPT codes 4X018 and 4X019 based on the rationale that the RUC recommended the 25th percentile values for the rest of the family and chose to elevate the work values for these two services to inappropriately high levels. ***We thank CMS for accepting the RUC recommended work values for CPT codes 4X015-4X017 but respectfully disagree with the agency's assessment of the work involved in the services described by CPT codes 4X018 and 4X019.*** These two codes will be used for surgeries on the largest tumors or cysts. Since the initial code set was developed, the patient population receiving these services and the technology used to deliver them has changed. Specifically, the surgeon is typically operating on very large masses and encounters significant bleeding. ***Given the increased intensity of the work, the AUA supports the RUC's recommended work values of 45.00 RVUs and 55.00 RVUs for CPT codes 4X018 and 4X019, respectively, and urges CMS to adopt these values in the final rule rather than the proposed values.***

MRI-Monitored Transurethral Ultrasound Ablation of Prostate (CPT codes 5X006, 5X007, and 5X008)

The AUA appreciates that CMS accepted the RUC recommended values for the MRI-Monitored Transurethral Ultrasound Ablation of the Prostate services and urges that they be finalized. However, we do recognize that there were concerns about the survey respondents' lack of experience with these services, which were just converted from Category III to Category I CPT codes. Given this recent coding change, we are not surprised that survey respondents did not have more experience with these services.

Because these services will be placed on the RUC's New Technology List, they will be subject to review in three years. The AUA urges CMS to finalize the values as proposed knowing that there will be an opportunity to review in three years when urologists will have more experience with these procedures.

Bladder Neck and Prostate Procedures (CPT codes 5XX05 and 5XX06)
Thank you for accepting the RUC recommended work values for Bladder Neck and Prostate Procedure codes, which we urge be adopted in the final rule. For the PE for these services, CMS raised concerns about the potential duplication of supply items. After consulting with our expert panel, the PE supply items as listed are correct.

For CPT code 5XX05, the agency questioned the inclusion of supply item SB027 *gown, staff, impervious*, which is already included in supply pack SA042 *pack, cleaning and disinfecting, endoscope*, and supply item SB024 *gloves, sterile,* which is included in supply pack SA058 *pack, urology cystoscopy visit*. A total of three SB027 impervious staff gowns are required to deliver CPT code 5XX05 since one gown is used by the physician to place the transrectal block and two gowns are required for the physician and assistant for the actual procedure. The first gown cannot be reused because it was used for a transrectal procedure, and the actual procedure is performed on the bladder. Using two separate gowns ensures there is no cross contamination. For the same procedure, a total of three pairs of gloves – one non-sterile and two sterile—are required. One non-sterile pair of gloves is used for the block and is included in the SA058 pack, and two pairs of sterile gloves are used for the actual procedure, for the physician and assistant. SA058 *pack, urology cystoscopy visit* has one pair of sterile gloves and then one additional pair listed alone as SB024 *gloves, sterile*. The AUA urges CMS to adopt the direct practice expense inputs as transmitted by the RUC.

Telemedicine Evaluation and Management (E/M) Services (CPT codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)
The CPT Editorial Panel created and the RUC valued 17 new codes to describe telehealth services as part of its work to revise the E/M section of the CPT code book. In the discussion of this family of services, CMS recognizes that the new code family's RUC recommended values are nearly identical to those E/M services currently used to report new and established office E/M services.

After reviewing the agency's analysis, the AUA supports the proposal to assign a procedure status indicator of "I" to CPT codes 9X075-9X090, signifying that there is a more specific code that should be used in the Medicare program. Our members have valued the opportunity to provide virtual care since the pandemic and believe that it improves patient access and outcomes in certain situations. To date, there have been no issues with using the existing new and established patient office visit E/M services with the appropriate modifiers and place of

service codes. It will benefit our members and other practitioners to retain the simplicity of this coding system.

We do recognize that the new code family will appear in the CPT code book for 2025. To the extent possible, we urge CMS to release educational materials for practices on how to properly code for virtual visits for Medicare beneficiaries to limit confusion with the new code family's inclusion in the code book.

Development of Strategies for Updates to Practice Expense (PE) Data Collection and Methodology

The AUA appreciates CMS' efforts to ensure that PE inputs are based on the best available data as PE is a key and costly component of physician services. The most recent update to the PE clinical labor inputs were particularly destabilizing for many commonly billed urology services because they include many expensive supply and equipment inputs rather than clinical labor, so these efforts to ensure the stability and predictability of future updates to PE updates are of great interest to our members.

We continue to believe that the AMA's Physician Practice Information Survey (PPIS), which our members and their practices are actively participating in, will provide the most current information on the costs associated with running a medical practice. The survey results will represent the most precise and comprehensive understanding of the evolving costs of physician practices' expenses. ***We urge CMS to phase in the survey's results to avoid destabilizing cuts in payment to the extent possible.***

Additionally, we encourage CMS to review and update indirect and direct PE inputs at regular intervals to support accurate valuation of physician services. Recognizing that this requires significant effort by the agency and stakeholders, we underscore its importance particularly given the continued downward pressure on the MPFS. In a budget neutral system without positive updates to the conversion factor, allowing data to become outdated causes significant redistributive effects when updates are made. While academic practices may be able to better withstand the resulting reimbursement cuts, small and independent physician practices cannot. These practices provide critical access to Medicare beneficiaries in small and rural communities, and CMS' policy must support their continued viability.

Supply Pack Pricing Update

The AUA participated in the AMA RUC workgroup that was tasked in resolving the discrepancy in supply pack pricing where certain packs were valued higher than the sum of their parts. CMS chose to delay the implementation of the updated prices until the CY 2025 proposed rule. Correcting these pricing discrepancies will have large redistributive effects on the family of cystoscopy services, which are frequently billed by our members, as two cystoscopy supply packs will decrease in value—one by 67%. There is one supply pack commonly included in urology services, which does see an increase.

Supply	Current Price	Proposed Price 2025	Percent Change
Pack, drapes, cystoscopy	$17.33	$14.99	-14%
Pack, urology cystoscopy visit	$113.70	$37.63	-67%
Pack, cleaning and disinfecting, endoscope (SA042)	$19.43	31.29	+61%

CPT codes 52000 *(Cystoscopy)* and 52005 *(Cystoscopy & ureter catheter)* both see their values decrease by 21%, which includes the changes to the PE inputs and the conversion factor decrease. For context, CPT code 52000 was billed 770,017 times in 2022. ***To mitigate the impact of this change on independent practices, the AUA respectfully requests that CMS phase-in the supply pack changes over a four-year period like it has done for other PE changes with significant redistributive effects allowing independent urology practices to better prepare for the negative financial impact this change will have.***

Strategies for Improving Global Surgery Payment Accuracy
The AUA recognizes that the agency has longstanding concerns about the valuation of the surgical global packages and wants to reimburse the physicians who are providing the services within the global period appropriately. We appreciate the agency's thoughtful approach to addressing this issue. In this proposed rule, CMS outlines a policy to require that practitioners use the existing transfer of care modifiers for all 90-day global surgical procedures when a practitioner other than the one performing the procedure is expected to provide the pre- and post- operative portions of the service.

After carefully reviewing the policy and considering how this would apply in urology practices, the AUA respectfully requests that the agency delay the implementation of any reimbursement changes associated with this policy until CY 2026. In the interim, physicians should report the modifiers for informal transfers of care for tracking purposes. Additionally, the AUA recommends that CMS work with us and other stakeholders to refine the policy to ensure it can be uniformly applied across surgical specialties. We believe that it will be important to consult with ophthalmology about how they have integrated the transfer of care modifiers into their clinical practice to see if there is guidance that could be developed to apply across specialties based on their practice of using these modifiers more frequently than other physicians. At this point, we do not recommend that this policy be applied to the 10-day surgical global services. Any expansion of this policy should be delayed until data is collected, and the agency can refine the policy with input from the affected specialties.

Specifically, our members raised questions about informal transfers of care. They highlighted instances where a patient will see their primary care physician during the global period without notifying their surgeon in advance or the patient will elect to see their primary care physician for follow up and then return to the surgeon during the global period. In these instances, the surgeon either would not have notice to bill modifier -54 for surgical care only or would bill modifier -54 only to then deliver care during the global period. Additionally, it is also not clear

how appropriate billing by the surgeon and other practitioners delivering care within the global period will be enforced. We believe that extensive physician and practice education will be required to ensure that the modifiers are used appropriately, and surgeons will have to reform their practices to ensure that they are consulting with the patient about how their post-operative care will be delivered.

Based on the experience over the next year, the AUA urges CMS to work with the surgical specialties in the instance that any of the 90-day global surgical packages are determined to be misvalued to refer them to the CPT Editorial Panel and AMA RUC as appropriate.

Payment for Telehealth Services

Our members have reported that telehealth services have helped improve Medicare beneficiary access to timely care since the flexibilities were implemented at the start of the pandemic. The AUA continues to see telehealth services as an important tool for physicians to deliver high quality care to patients and appreciates CMS' efforts to expand access to telehealth services consistent with its statutory authority. Without Congressional action, the Medicare telehealth flexibilities, including the waiver of the originating site requirement and geographic restriction which allow individuals to receive virtual care in their homes, will expire at the end of this year. This is another area where the AUA is advocating for Congress to pass legislation immediately to make these flexibilities permanent, or to extend them should it not be feasible to make them permanent at this time.

Audio-only Communication Technology to Meet the Definition of "Telecommunications Systems"

CMS proposed to revise the definition of an interactive telecommunications system to include two-way, real-time audio-only communication technology for any telehealth service delivered to a beneficiary in their home if they are not capable of, or do not consent to, using audio-video technology if the physician can establish an audio-visual connection. ***We urge the agency to finalize this policy as proposed.***

Continued coverage of audio-only visits is a pressing health equity issue. Access to audio/visual telehealth technology varies widely by socioeconomic status and geographical location. AUA members' experience has demonstrated that patients living in poverty or in non-metropolitan areas are less likely to utilize audio/visual telehealth services. Additionally, many Medicare beneficiaries, particularly those who are older, may struggle to establish the simultaneous audio and visual connections required for telehealth services, either because they lack access to necessary connection or devices to facilitate simultaneous audio and visual connections, have difficulty navigating the appropriate devices, or refuse to appear on camera. The AUA believes this policy supports health equity and will help reduce health disparities by ensuring Medicare beneficiaries retain broad access to appropriate services.

Distant Site Practitioners

The AUA thanks CMS for proposing to allow distant site practitioners to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. This is an important step to protect physicians' privacy. ***We recommend that it be finalized as proposed.***

Direct Virtual Supervision

CMS proposes to continue to define direct supervision to permit the presence and immediate availability of the supervising practitioner through real-time audio and visual interactive telecommunications technology through December 31, 2025, and to permanently adopt the definition of direct supervision permitting a virtual presence for services that are lower risk.

The AUA appreciates CMS' continued review of its virtual supervision policies. ***We urge the agency to finalize its proposal for virtual supervision of "incident to" services considered to be lower risk but respectfully request that the agency consider making direct supervision via virtual presence for all other services to be permanent also rather than just providing a one-year extension.*** Our members have been providing direct virtual supervision for services including catheter placement without issue. This flexibility increases patient access, particularly in rural and underserved areas experiencing shortages of urologists. We are not aware of data that supports continuing limited extensions of this policy.

Non-Chemotherapeutic Complex Drug Administration
In the CY 2024 MPFS rulemaking process, CMS requested and received comment on payment for non-chemotherapeutic complex drug administration services to address stakeholder concerns that non-chemotherapeutic complex drug administration payment is inadequate due to the existing code structure and Medicare billing guidelines. Specifically, the agency asked if there were instances of "down coding or denials for the administration of non-chemotherapeutic infusion drugs." The AUA recommended that the codes for these services be referred to the CPT Editorial Panel to redefine them so they could be appropriately valued. We believed that this would ensure PE and work RVUs would reflect the skill and time associated with each procedure.

Based on comments received, CMS proposes to update the Medicare Claims Processing Manual, chapter 12, section 30.5, to modify the coding language to match the CPT code definitions for complex non-chemotherapy infusion code series stating that the administration for particular kinds of drugs and biologics may be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549.

The AUA supports this proposal. However, we suggest that an editorial change be made to these CPT codes in addition to the update to the Medicare Claims Processing Manual. While the header for these codes in the CPT book is "Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration," the codes themselves only use the term "chemotherapy" and do not use the words "or highly complex biologic agent administration." We believe an editorial change to the codes to include the phrase "or highly complex biologic agent administration" will further reduce the confusion around these codes and make them clearer for billing purposes.

Quality Payment Program Proposed Provisions

Urology Merit-Based Incentive Payment System (MIPS) Value Pathway (MVP)
CMS proposes inclusion of the *Optimal Care for Patients with Urologic Conditions* MVP for Performance Year (PY) 2025 implementation. This Urology MVP includes most of the quality measures and improvement activities identified through a multi-stakeholder consensus process that included AUA representatives. Overall, we believe the proposed MVP provides a meaningful MIPS participation option for urologists because it addresses a range of conditions treated by urology sub-specialists, includes various types of measures, and is robust enough to

support MIPS reporting for both AQUA Registry participants and non-participants alike. We particularly appreciate the inclusion of five of our Qualified Clinical Data Registry (QCDR) measures. However, ***we urge CMS to remove the Medicare Spending Per Beneficiary (MSPB) cost measure, the proposed Prostate Cancer cost measure, and the COVID-19 Vaccine Achievement for Practice Staff Improvement Activity (IA) from the MVP***.

Regarding the MSPB measure, we are concerned about the potential attribution of cases to consultant urologists, even though they likely have little control over the cost of the hospital episodes. For example, a patient admitted to the hospital with a urosepsis diagnosis may be managed by hospitalists but seen by a consulting urologist. While the urologist may be responsible for a substantial portion of their care, the overall costs of the inpatient stay and follow-up care post-discharge likely would be outside of the control of the urologist post-consult. Several finalized MVPs include specialty-specific cost measure options only, so there is precedent for not including an overall population-level cost measure such as the MSPB.

Regarding the Prostate Cancer cost measure, we request its removal from the Urology MVP, pending revision to account for variation in costs based on risk and severity of disease. We recognize the relevance and importance of including a measure that appropriately assesses costs for prostate cancer within this MVP. However, we believe this proposed measure does not accurately reflect appropriate and expected cost variation based on disease severity and patient needs and may, in fact, create unintended disincentives that would limit provision of appropriate, high-quality care. Prostate cancer is a highly heterogenous cancer type, and costs associated with treatment vary substantially depending on the risk and severity of the disease. While the Prostate Cancer cost measure stratifies based on metastatic and non-metastatic cancers, our experts believe this level of stratification is inadequate. We agree with feedback provided to CMS during field testing of the measure that the range of appropriate treatment, which varies from active surveillance to radiation, surgery or hormone treatment for non-metastatic cases, and from systemic therapy with radiation therapy to supportive or hospice care for metastatic cases, will vary substantially in cost. We remain convinced claims data are not sufficient to reflect risk stratification used in clinical settings to decide treatment based on cancer severity. Furthermore, during the 2024 Pre-Rulemaking Measure Review meetings, only 14% of the Recommendation Committee fully supported the measure for inclusion in the MIPS program, while the majority (71%) did not recommend this measure. Those who did not support the measure cited its inability to differentiate between high-risk localized or locally advanced patients and low-to-intermediate risk localized patients and their uncertainty that adherence to evidence-based treatment guidelines would improve performance on the measure.

Finally, ***we do not support inclusion of the COVID-19 Vaccine Achievement for Practice Staff IA*** in this MVP, as we believe a focus on this activity might shift focus from IAs that are more clinically relevant to urology and align more closely with the quality measures included in the MVP.

Transforming the Quality Payment Program

CMS continues to envision a full transition to MVP reporting and the sunsetting of traditional MIPS, and has requested feedback on making the transition by PY2029. While the AUA appreciates the need for adequate time to plan for such a transition, ***we believe completing the transition by PY2029 is premature***. We understand that if the six proposed MVPs are approved, up to 80% of specialties would have access to at least one applicable MVP.

However, this does not equate to 80% of clinicians having such access to MVPs or to measures within MVPs that are truly relevant and meaningful to their work, which is CMS's stated goal. This is a particular concern for those who provide subspecialty care. Moreover, the current inventory of relevant and adequate cost measures is still severely limited, even given CMS's cost measure development and maintenance efforts. Given the complexity of developing cost measures, it is not realistic to assume enough adequate measures will be available within the next four years. Finally, as illustrated by the request for information (RFI) in the current proposed rule, we agree with CMS that the nature, number, and magnitude of challenges related to MVP implementation are still unknown, and adequate time will be required to identify and address, sufficiently, the operational difficulties of MVP implementation, including those pertaining to subgroup reporting. The AUA recommends continuing to delay establishing a date for the transition until these issues are resolved.

Regarding subgroup reporting, given the lack of subspecialty measures within already-developed MVPs, the complexities associated with subgroup formation, and the overall confusion regarding options for MVP selection by multispecialty groups, the ***AUA encourages CMS to revise its policy for mandatory subgroup reporting for multispecialty groups beginning in PY2026***. Instead, CMS should continue its promotion of voluntary subgroup reporting, at least until MVP reporting itself becomes mandatory. However, we do support CMS's proposal to exempt multispecialty small practice TINs from mandatory subgroup reporting. In addition, ***the AUA encourages CMS to allow multispecialty practices maximum flexibility to form their own subgroups*** that most accurately reflect the team-based care provided. We strongly oppose CMS's suggestion to limit the number or size of a subgroup (both maximums and minimums), as such requirements would almost certainly conflict with practice workflows, which should be determined based on patient populations and clinician experience and expertise rather than arbitrary CMS regulation.

Regarding MVP development, the AUA supports expansion of already-developed MVPs to include measures and activities pertinent to subspecialties, as we believe CMS's earlier desire for an arbitrarily short list of measures and activities conflicts with the needs of subspecialists. However, we caution against including specialty-relevant measures across a large number of MVPs, as doing so would complicate the MVP selection process for clinician practices and increase need for support of many MVPs by QCDRs, both of which would add complexity and burden to the program. ***We do not support CMS's idea of developing an MVP applicable to multiple conditions or specialties or for cross-cutting measures as a "bridge" to full MVP participation***, since this would not meet the stated goals for MVPs and likely would further complicate the program (e.g., by eventually needing to prohibit certain clinicians from reporting specific MVPs).

Accordingly, ***we encourage CMS to continue efforts to simplify the MIPS program while continuing to provide flexibility in reporting options*** until stakeholders can identify and address the operational barriers of MVPs and all clinicians can optimally report via MVPs. ***Only then*** should CMS move forward with sunsetting traditional MIPS and, potentially, mandating subgroup reporting. Relatedly, we encourage CMS to provide funding to specialty societies to help defray the costs of developing relevant measures for use in both traditional MIPS and MVPs.

MVP Maintenance and Scoring

Beginning in PY2025, CMS proposes to calculate each population health measure for an MVP participant, use the participant's highest score for MVP scoring, and accordingly, remove the requirement for MVP participants to select a population health measure at the time of MVP selection. ***While the AUA supports this proposal, we also encourage CMS to retroactively calculate all population health measures and use the highest score for PY2024.***

Additionally, CMS proposes to require MVP participants to submit one improvement activity to achieve full credit (40 points) for the Improvement Activities (IA) performance category. ***While the AUA supports this proposal to simplify MVP participation requirements, we do not support CMS's recent trend of adding "cross-cutting" IAs across all MVPs***, as we believe this may stifle participation in more clinically relevant IAs that are more closely linked to MVP quality measures.

We support the proposed alignment in scoring of cost measures in MVPs with existing MIPS scoring policies and agree that participating subgroups in MVPs should continue to submit their affiliated group's data for the Promoting Interoperability (PI) performance category for PY2025 and beyond. We also support the proposed changes to the MVP maintenance process to allow flexibility for CMS in how they communicate submitted maintenance recommendations for MVPs prior to proposing them formally in rulemaking. However, ***we strongly urge CMS to convene key stakeholders for additional dialogue on potential policies and their feasibility after public commenting and other webinar communications prior to proposing changes via rulemaking***, in order to more fully understand the likely implications of such changes.

Regarding the proposed modifications to the Advancing Cancer Care MVP, ***we support the inclusion of measures Q102 and Q495*** (Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients and Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood, respectively). However, ***we do not support removal of Q144*** (Oncology: Medical and Radiation - Plan of Care for Pain) because we believe it is additive, rather than duplicative, of Q143, and the two measures should be used together. Also, ***we do not support the addition of the Prostate Cancer cost measure or the COVID-19 Vaccine Achievement for Practice Staff IA,*** for reasons noted above.

Data Submission for Performance Categories

Overall, the AUA supports CMS's proposal to narrow the minimum criteria to qualify as a data submission across the quality, IA, and PI performance categories in its efforts to prevent inadvertent override of approved reweighting decisions. While we appreciate the various system warnings already in place, we encourage CMS to continue to track instances of inadvertent override and further consider how to eliminate them.

Regarding treatment of multiple data submissions, we appreciate CMS's flexibility in allowing multiple data submissions, both across time and by multiple organizations, for the quality and IA performance categories. We agree with CMS's existing processes for such submissions and thus we favor CMS's proposal to codify them. Furthermore, we support CMS's proposal to modify its policy for scoring multiple data submissions for the PI performance category to assign the highest score in the event of multiple data submissions.

Quality Measures

The AUA appreciates CMS's recognition of the challenges associated with requiring an 80% data completeness threshold and therefore ***we strongly support CMS's proposal to maintain the data completeness criteria threshold of 75% through PY2028***.

Regarding proposed additions, deletions, and modifications to the list of quality measures, ***the AUA opposes the addition of the Prostate Cancer cost measure***, for reasons listed earlier. ***We also strongly oppose the removal of two measures relevant to urology (QPP104 and QPP144***). QPP104 (Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer) focuses on a "must-do" clinical process linked to overall survival over many years, as supported by multiple RCTs. While we acknowledge the low uptake of the measure, we disagree with CMS that it covers a limited patient population. In fact, the 2024 American Cancer Society reports a 5% per year increase in incidence of advanced-stage disease, ***making this measure even more relevant for urologists and others who provide care to those with prostate cancer***. We also oppose removal of QPP144 (Oncology: Medical and Radiation – Plan of Care for Pain) because we do not agree it is duplicative of QPP143. Instead, this measure, which focuses on a definitive quality action highly supported by patient advocates (i.e., documentation of a care plan), ***should be used in concert with QPP143***. Moreover, its inclusion in the program strengthens the Advancing Cancer Care MVP by encouraging both quantification and alleviation of pain. ***Finally, we support the modification of QPP432 to include both bladder and bowel injury***.

Regarding the proposed modifications to the Urology Measure Set, we oppose the removal of measure QPP104 for reasons listed above. We also oppose the addition of the Adult COVID-19 Vaccination Status measure, as it is not clear why this vaccination status measure has been proposed for inclusion when other vaccination-focused measures have not.

Improvement Activities

For PY2025, CMS proposes to eliminate the weighting of IAs and instead, require those participating in traditional MIPS to report only two IAs, or—if a non-patient facing MIPS eligible clinician or a small, rural, or HPSA practice—to report only one. ***The AUA supports these changes***. We also applaud CMS's efforts to streamline the inventory of IAs by keeping and/or modifying them to reflect vital aspects of clinical practice improvement. Together with the proposed reductions in the number of IAs required for reporting, we believe these changes will help to reduce the burden associated with the MIPS program. Further, we have no objections to codifying the seven IA removal factors, as proposed by CMS, nor do we object to the proposed IA additions, deletions, and modifications.

Performance Threshold

CMS proposes to leave the performance threshold at 75 points for PY2025 and to maintain its current policies for PY2025-PY2027, such that the performance threshold will be the mean of the final scores for all MIPS eligible clinicians from a prior period. ***The AUA strongly supports CMS's proposal to leave the PY2025 performance threshold at 75 points***. However, we continue to believe incremental increases in the threshold will not result in increased attention to quality and subsequent improvements in care and there ***urge CMS to retain a 75-point performance threshold beyond PY2025***.

Scoring of Topped Out Quality Measures

CMS is proposing to remove the 7-point cap for selected topped out measures beginning in PY2025, and to make this determination on an annual basis going forward. In general, we support CMS's efforts to address inequity in the MIPS program due to limited measure choice and we appreciate its consideration of scoring changes for topped out measures as one potential solution. However, we believe many measures ***only appear to be topped out*** due to the reporting incentives inherent in the MIPS program. Instead, it is likely there is still ample opportunity for improvement for these measures for many clinicians who do not report them. Thus, we do not agree lifting the 7-point cap should be limited to selected measures only, but should apply to ***all measures*** used in the program. This could encourage clinicians to report on specialty-specific measures rather than relying on cross-cutting measures they may otherwise select. Moreover, we encourage CMS to think more broadly about "limited measure choice", recognizing many specialists and subspecialists also have limited choice for measurement.

However, we are ***especially concerned*** that the proposed list of selected measures does not include QCDR measures. QCDR measures fill critical gaps in measurement by providing access to measures that are meaningful and relevant for specialists. Therefore, ***we urge CMS to remove the 7-point cap for QCDR measures, at minimum for those where measure choice is limited.*** In addition, while we understand CMS's desire to analyze relevant trends on an annual basis, we believe potentially "switching out" the 7-point cap on an annual basis would be confusing to clinicians. Thus, we recommend applying such decisions for at least 2-3 years. Moreover, it is not clear whether CMS is proposing removal of the 7-point cap at the measure level or the clinician level (i.e., would a 7-point cap apply for some clinicians but not others?). We urge CMS to make such decisions at the measure level, so scoring is consistent regardless of who is reporting a particular measure. Finally, we request CMS provide additional clarity on their methodology for this proposed scoring revision.

Scoring of Cost Measures

The AUA applauds CMS's recognition of the negative impact of the current cost category scoring methodology on the final MIPS score, particularly for those clinicians with costs near the measure's median value. CMS proposes to modify the cost category scoring methodology, such that it would be based on the standard deviation, median, and an achievement point value derived from the performance threshold. CMS further proposes to apply this modification beginning with PY2024. We understand, according to CMS's analysis, this modification would result in higher cost category scores overall and would address concerns that the current cost measure scoring methodology negatively impacts final MIPS scores more than other performance categories. Accordingly, ***we strongly support these proposed changes*** and the changes in terminology and language needed to codify these modifications. Further, we support CMS's proposal to exclude cost measures from the cost measure performance category scoring if data used to calculate the scores for those measures are impacted by significant changes or errors such that calculating the cost measure scores would lead to misleading or inaccurate results.

Reweighting Performance Categories

Beginning with PY2024, CMS proposes to permit reweighting for the quality, IA, and PI performance categories in the event it determines a clinician's data are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because submission was delegated to their third party intermediary that did not submit data as required. ***The AUA strongly supports this change, but also encourages CMS to consider additional***

modifications to the reweighting policy in the event of other circumstances outside of the clinician's control that negatively impacts ability to achieve complete data submission.

RFI on an Ambulatory Specialty Care Model

CMS is interested in developing a model for specialists in ambulatory settings that would leverage the MVP framework. Under this model, participants would not receive a MIPS payment adjustment. Instead, they would receive a payment adjustment based on a set of required MVP measures, where the final scores would be compared to those from a limited pool of other model participants of their same specialty type and clinical profile. ***The AUA believes such a model may be premature and would not support mandatory participation in such a model***. Many specialists still have little or no experience with MVPs to-date and adding such a model to the mix would generate confusion. Moreover, it is not clear how benchmarks for measures would be affected within the MIPS program (e.g., if specialty care model participants' scores are excluded from benchmark calculations, it could negatively impact ability to calculate benchmarks).

RFI on PROMs/PRO-PMs

Regarding guiding principles for the selection and implementation of PROMs and PRO-PMs, the AUA encourages CMS to revisit the 2019 and 2020 reports from the National Quality Forum (NQF) identifying best practices on the selection and data collection of PROs and PROMs, as well as the 2013 and 2021 NQF reports that delve more deeply into the development of PRO-PMs. These materials include other important concepts that are not included in the illustrative set of guiding principles proposed by CMS. Learnings from these reports suggest that selection and implementation of PROMs (and, by extension, PRO-PMs) is context dependent. Moreover, implementing PROMs and PRO-PMs are resource intensive for clinician practices, making it difficult to require use of both broad and condition-specific tools. Thus, for the MIPS program, CMS should focus on PRO-PMs that are more cross-cutting in nature (e.g., shared decision-making, goal attainment, etc.), while also allowing a generous menu of condition-specific PRO-PMs. In addition to funding development of PROMs and PRO-PMs, CMS could also fund efforts to explore how results from similar condition-specific PROMs might contribute to a single PRO-PM, thus allowing clinicians to use and report on PROMs that work best in their particular context. To promote more rapid uptake of PRO-PMs in the MIPS program, CMS also could consider modifying its scoring methodologies (e.g., by allowing "pay for reporting" for 3 years, with bonus points for those with the best performance) and develop and use process measures to promote PROM implementation.

We are grateful to CMS for the opportunity to provide these comments on the CY 2025 MPFS proposed rule and look forward to continued collaboration on these important policy issues. Please contact Maureen Cones, AUA Chief Legal and Policy Officer and General Counsel, at mcones@auanet.org with any questions.

Sincerely,

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