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September 10, 2018

Electronically Submitted

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (RIN 0938-AT31)

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 provide comment to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule that provides updates to the Medicare Physician Fee Schedule for calendar year (CY) 2019, as well as to the Quality Payment Program and other Medicare Part B payment policies. The AUA appreciates CMS' strong interest in reducing burden for the medical community and in driving innovative use of technology to improve access to and quality of care. Specifically, the AUA applauds CMS' proposals to establish separate payment for communication-technology based services. The AUA also supports many of CMS' proposals to reduce documentation burden associated with office and outpatient evaluation and management (E/M) services, as further detailed below, which we believe reduce redundancy, streamline documentation requirements, and increase access to home visits. However, we have several concerns with CMS' proposals to reform payment for office and outpatient E/M services – including the proposal to collapse level 2 through 5 visits and to require a multiple procedure payment adjustment for E/M services provided on the same day as other applicable services – and we urge CMS to work with the

medical community to develop alternative proposals for E/M payment and coding, rather than finalizing the E/M payment policies included in the proposed rule.

We provide additional feedback on these and other policies below, and we look forward to working with CMS on these important issues.

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

Low Volume Codes

CMS is proposing to add CPT code 74445 (X-ray exam of penis) to the list of low-volume codes assigned to an "expected specialty" and proposes that this code would be assigned to Urology as the expected specialty. CMS notes that for each of the codes add to this list, only the professional component (reported with the -26 modifier) is nationally priced, and that the global and technical components are priced by the Medicare Administrative Contractors (MACs). ***The AUA requests that CMS price both the professional and technical component of this code nationally, rather than delegating pricing of the technical component to the MACs, in order to ensure consistent payment and transparency.***

Direct PE Inputs for Specific Services

The AUA appreciates the opportunity to comment on the following proposed changes to direct PE inputs for CY 2019:

- **Price Increase for Scope Video Systems (ES031).** CMS proposes to update the price of the scope video system (ES031) from its current price of $33,391 to a price of $36,306 for CY 2019. ***The AUA supports this change and appreciates CMS' decision to make this update in 2019, rather than waiting to implement the price increase in CY 2020 along with other potential scope equipment changes.***
- **Addition of Endoscope Disinfector (ES005) to CPT code 52000 (Cystourethroscopy (separate procedure).** ***The AUA supports the addition of an endoscope disinfector to 52000 and to add 22 minutes of equipment time to match the equipment time of the other non-scope items included in the code. The AUA requests that this addition apply to all endoscopic urologic procedures that do not include the endoscope disinfector.***

Proposed Communication Technology- Based Services

CMS proposes to pay for services that are "routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology." This set of services would not be subject to the statutory restrictions that apply specifically to Medicare telehealth services.

The AUA commends CMS for developing this paradigm, which allows for the coverage and payment of services that will serve to increase access to timely and appropriate care for patients. This is particularly important for patients who live in rural and underserved areas, where workforce shortages may otherwise necessitate long travel times to see specialists. The AUA believes that urologic patients will see significant benefit from these changes.

For all the communication technology-based services that CMS contemplates, we ***recommend that clinicians fully disclose information about these billable services and obtain informed consent from patients that should be documented in medical records. The AUA recommends that CMS allow such informed consent to be obtained verbally or in writing, including upon the initial establishment of the patient-physician relationship. However, we request that CMS more clearly specify the elements of documentation that must be included in the medical record.***

More broadly, we request that CMS provide a definition framework, to help policymakers, practitioners, payers, and the public understand how to accurately provide these services and what key components are required for billing purposes. We acknowledge that there are several program integrity considerations that need to be addressed and therefore ***we recommend that CMS proceed with caution given potential redistributional effects that may occur if these proposals are finalized.***

Brief Communication Technology-based Service (e.g. Virtual Check In) (GVCI1)

Effective January 1, 2019, CMS proposes to pay separately for GVCI1 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can 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 an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). CMS seeks input on this proposal, including what types of communication technology are utilized by physicians or other qualified health care professionals in furnishing these services (defined as physicians' service furnished using communication technology), whether verbal consent should be noted in the medical record for each service, whether the agency should consider broadening the window of time and/or circumstances in which this service should be bundled, and how clinicians could best document medical necessity of the services.

In general, the AUA supports this proposal, which would increase patients' ability to receive timely assessment, reduce patient burden associated with unnecessary office visits, and allow for more high-value use of in-office clinical resources. For example, a urology patient could be assessed through this new virtual check-in to assess an acute kidney stone episode. Such an episode could be

evaluated by non-face-to-face means, and as long as certain clinical elements are not present, patients would be able to forego an in-office visit.

In finalizing this proposal, the AUA recommends:

- ***That CMS allow all secure communications modalities that are compliant with HIPAA privacy and security standards to be used in the completion of the virtual check-in. This may include video, texting, email, apps, and patient portals to facilitate the patient's ability to transmit information to their health care provider.***
- ***That documentation requirements for the virtual check-in itself be specific to the chief complaint of the non-face-to-face communication. The AUA disagrees that the documentation should have to establish that any previous or ensuing E/M visits is not related.***
- ***That CMS finalize the 24-hour timeframe after a virtual check-in, after which a separate E/M visit would be permissible, as we would expect services that take place after this timeframe to address changes in patient clinical status that reasonably warrant separate evaluation and management by the clinician.***

Additionally, CMS proposes to price this distinct service at a rate that is lower than existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology. However, we believe that there are additional complexities in determining practice expense that may not be currently captured in CMS' valuation. As such, ***the AUA recommends that CMS refer this code to the CPT and RUC for evaluation and repricing for CY 2020, while still making the code available at the proposed rate for CY 2019.***

Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

CMS proposes to pay separately for GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). CMS seeks comment on the assumption that these are separately identifiable services, and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. CMS further asks if these services should be limited to established patients.

The AUA generally supports CMS' proposal to make separate payment for GRAS1. This is a valuable service that, like the virtual check-in, facilitates timely assessment and avoidance of unnecessary office-visits. For example, this service – through the use of HIPAA-compliant secure patient portals and apps – could be used to assess urologic patients with hematuria, or blood in the urine. This is a common

occurrence in urologic patients, and difficulty in ascertaining the exact severity of hematuria often leads to unnecessary in-person visits. With the option of 'store and forward' visualization by the clinician, more precise and effective care could be provided while potentially allowing a patient to forego an in-office visit.

The AUA believes that this service could be effectively used with both new and established patients, as visual assessment of many clinical conditions is possible without further information about a patient's clinical history or status. ***As such, the AUA recommends that CMS expand the availability of this code to new patients.***

Interprofessional Internet Consultations

CMS proposes to begin paying separately for the following six codes that describe interprofessional internet consultation services:

- CPT 99446 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review)
- CPT 99447 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review)
- CPT 99448 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review)
- CPT 99449 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review)
- CPT 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes)
- CPT 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time)

The AUA applauds CMS for supporting coverage and payment of these codes for the delivery of interprofessional consultations. For multiple urologic conditions, such as renal stones, renal cysts, and renal masses, interprofessional consultation is

critical for accurate diagnosis and/or for development of an optimal treatment plan – particularly when patients experience complications or multiple comorbidities. Additionally, to the extent that specialist input is currently sought through scheduling separate visits for patients, availability of these codes will reduce the need for in-person visits when appropriate consultative input could be accomplished by electronic means.

Finally, in addition to the approval of interprofessional internet consultations, we continue to support the ability of physicians to provide telehealth services directly with patients under Medicare telehealth rules.

Update on the Global Surgery Data Collection

CMS provides an update on its global surgery data collection efforts, noting that the data collected suggests that post-operative visits are not being furnished as part of 10-day global surgical codes. CMS therefore seeks comment on how to approach 10-day global codes for which the preliminary data suggest that post-operative visits are rarely performed. CMS also requests comment on whether it should consider changing the global period or reviewing the code valuation.

The AUA is concerned that – despite CMS and stakeholder efforts to educate our affected surgeons on the need to accurately report post-operative visits using CPT code 99024 – many clinicians did not understand the importance of such reporting, resulting in limited reporting and incomplete data collection. Without complete and accurate reporting, we do not believe there is sufficient data to determine whether or not physicians are performing post-operative visits or to support changes in global periods or code valuations. ***As such, we urge CMS to retain existing global periods and code valuations without modification.***

Proposed Valuation of Specific Codes

Dilation of Urinary Tract (CPT codes 50X39, 50X40, 52334, and 74485)

CMS proposes refinements to RUC recommendations for the following codes:

- 50X39 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed);
- 50X40 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed; including new access into the renal collecting system); and
- 52334 (Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde).

For a fourth code 74485 (Dilation of ureter(s) or urethra, radiological supervision and interpretation), the AUA appreciates that CMS is proposing to adopt the RUC-recommended work RVU of 0.83 for CPT code 74485.

50X39

For CPT code 50X39, CMS disagrees with the RUC recommended work RVU of 3.37 and proposes a work RVU of 2.78 based on a direct crosswalk to CPT code 31646 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay) (work RVU= 2.78, intra-service time of 30 minutes, total time of 70 minutes), which was spurred by examining various "intraservice time ratios". The components of total time (pre-service time, intra-service time, post-service time, post-operative visits) consist of differing levels of physician intensity with code specific durations—and it is therefore inaccurate to apply time ratios from one code to the another, as has been done, when more than one type of physician time is involved. For the procedure code that is being bundled into 50X39 (50432), CMS rejected the RUC recommendation in CY 2016 based on flawed assumptions, where the agency inadvertently failed to consider the bundling of 50390 (Aspiration and/or injection of renal cyst or pelvis by needle, percutaneous) into CPT code 50432 as part of their CY 2016 review. The further reduction of 50X39 based on comparisons to the already arbitrarily reduced value for code 50432 will further compound the underlying service's misevaluation. For CPT codes 50694 and 50695, when these services were last valued, CMS implemented a much lower value than the RUC recommended work RVUs, though implemented the RUC recommended time.

The RUC recommendation is strongly supported by reference codes 52287 (Cystourethroscopy, with injection(s) for chemodenervation of the bladder) and 52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands). CMS failed to consider these reference codes as the Agency instead mistook the codes included in the SOR as the codes that the RUC cited as support for its recommendation. ***The AUA urges CMS to accept a work RVU of 3.37 for CPT code 50X39.***

CMS states that it "considered a number of parameters to arrive at the proposed work RVU of 2.78." We are concerned that these "parameters" mostly (or more likely only) take into account time, RVU, and ratios of time and RVU failing to account for clinical differences in work and intensity of work. The RUC recommended values were based on discussions involving patient population, work intensity, specific procedural details as well as time. Based on this multimodal input as detailed in the RUC rationale crosswalks to other genitourinary procedures were felt to be supportive of the recommended valuation for 50X39. As opposed to the rationale surrounding the crosswalks in the RUC rationale, the CMS proposed crosswalk to 31646 seems at best random. The patient populations, risks, and procedural specifics have nothing in common. Basically, CMS chose a procedure which is less work and therefore, a lower RVW. CPT 50X39 is more work.

50X40

For CPT code 50X40, CMS disagrees with the RUC recommended work RVU of 5.44 and proposes a work RVU of 4.83 based on adding the increment between the RUC recommendations between codes 50X39 and 50X40 (2.07 RVUs) to the CMS proposed RVU for CPT code 33X05. CMS made a tabulation error when summing the increment to their proposed value for 50X39. Adding the CMS proposed work RVU of 2.78 to the 2.07 increment would actually equal 4.85.

CMS also disagrees with the RUC recommended intra-service time of 60 minutes and instead proposes an intra-service time of 45 minutes. CMS did not provide any clinical rationale for why they rejected the intra-service time, instead only noting that they typically accept the survey median intra-service time. The specialties recommended and the RUC agreed that the survey 75th percentile intra-service time better represents the additional time needed to introduce the guidewire into the renal pelvis and/or ureter, above and beyond the work involved in perform 50X39. Only 15 minutes of additional intra-service time is insufficient to account for the additional amount of physician work inherent to performing this service. CMS' proposal to reduce the intra-service time appears to be the principle driver for also proposing an alternate work RVU. Also, neither reference code that CMS noted as being the basis of the RUC recommendation was actually included in the RUC rationale, but instead only in the SOR form submitted by the specialty.

CMS supported their valuation with a crosswalk to CPT code 36902 Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty. However, the RUC recommended value for 36902 in 2016 was rejected by CMS, and CMS created a lower value. For 36902 the RUC recommended 6.00 and then CMS reduced it to 4.83. So, CMS is using as a comparator a code that they changed in 2016. This is a methodology that the RUC in their own deliberations has rejected in the past - using a code as a comparator which was reduced by CMS. In addition, CMS mistook the codes included in the SOR as the codes that the RUC cited as support for its recommendation. A careful reading of the RUC minutes supports this. The fact that the RUC agreed with the 75th percentile, which is unusual, means that the RUC agreed with the specialties' arguments. The specialties recommended and the RUC agreed that the survey 75th percentile intra-service time better represents the additional time needed to introduce the guidewire into the renal pelvis and/or ureter, above and beyond the work involved in perform 50X39.

For one of the procedure codes bundled into 50X40 (CPT code 50432), CMS rejected the RUC recommendation in CY2016 based on flawed assumptions, where the Agency inadvertently failed to consider the bundling of 50390 Aspiration and/or injection of renal cyst or pelvis by needle, percutaneous into CPT code 50432 as part of their CY2016 review. The further reduction of 50X39 based on comparisons to the already arbitrarily reduced value for code 50432 will further compound the underlying service's misevaluation.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference codes 52235 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm) and 50694 Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, without separate nephrostomy catheter. CMS failed to consider these reference codes as the Agency instead mistook the codes included in the SOR as the codes that the RUC cited as support for its recommendation. ***The AUA urges CMS to accept a work RVU of 5.44 for CPT code 50X40.***

52334

The AUA appreciates that CMS is proposing the RUC-recommended work RVU of 3.37 for CPT code 52334.

CMS is proposing refinements to the RUC-recommended direct PE inputs for the codes in this family. For CPT code 52334, the equivalent of Confirm availability of prior images/studies (CA006) did not exist when this service was last reviewed by the Practice Expense subcommittee in 2002. Many surgical procedures and other types of services that do not have imaging bundled involve the physician reviewing images and studies before performing the service. This review is not duplicative with image-guidance codes as it instead involves reviewing distinct previous studies. That was the intent of the Practice Expense Spreadsheet Update Workgroup when they created CA006, was for CA0006 to be used for multiple types of services instead of only imaging. Midway through the discussion of code 52334, CMS erroneously referenced the wrong code number ("52234") several times. If the Agency was inadvertently reviewing the wrong code when considering the RUC's practice expense recommendations for 52334, CMS should again review this service while reviewing the historical information for the correct code.

The AUA notes that Section 220(e) of the Protecting Access to Medicare Act of 2014 (PAMA) specifies that for services that are not new and revised, if the total RVU for a service would be decrease by 20 percent or more as compared to the total RVUs for the previous year the applicable adjustments shall be phased in over a 2-year period. According to these guidelines, CPT code 52334 should be subject to phase-in for CY2019 because it will decrease more than 20 percent and is not a new or

revised code. ***As such, the AUA urges CMS to add CPT code 52334 to the list of codes subject to phase-in for significant RVU reductions for CY 2019.***

X-Ray Urinary Tract (CPT code 74420)

CMS is proposing to adopt the RUC-recommended work RVU of 0.52 for CPT code 74420 (Urography, retrograde, with or without KUB). ***The AUA supports adoption of the RUC-recommend work RVU of 0.52.***

However, CMS proposes refinements to the practice expense (PE) inputs for this code. CMS is removing 1 minute of clinical activity, *Confirm order, protocol exam* (CA014). CMS' reason for this refinement is inaccurate, and th***e AUA strongly encourages CMS to reverse this proposal.*** This service is distinct from the other X-ray services reviewed during this cycle and requires CA014.

The RUC formed a Workgroup to revise the practice expense spreadsheet and implemented the changes for the January 2017 RUC meeting to address differences in standards and conventions between specialties. We believe this spreadsheet addressed all the changes necessary to incorporate current medical practices. To that end, the Workgroup determined that the clinical activity *Patient clinical information and questionnaire reviewed, order confirmed and exam protocoled* should be divided into two line items, the first in the pre-service period and the second in the service period as follows:

- Pre-service period: Review patient clinical extant information and questionnaire (CA007)
- Service period: Confirm order, protocol exam (CA014)

The AUA notes that the RUC recommendations for CA014 do not have time listed – not because the work is not performed, but because the work is listed under clinical activity *Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled/prepared by radiologist*, with a standard of 2 minutes, in the old imaging PE spreadsheet. This clinical activity does not exist in the new PE spreadsheet and as stated above is divided into CA007 and CA014, with a standard of 1 minute for each activity.

The RUC recognizes that the refinement CMS is proposing has no effect on the total clinical labor direct costs since the total minutes remain the same. However, the refinement is inaccurate and will have long term effects on the direct practice expense inputs across the payment schedule if not corrected. As such, the RUC requests that CMS accept 1 minute of clinical staff time as originally recommended by the RUC for CA014 to maintain a standard of 1 minute for that clinical activity, for CPT code 74420, and wherever the refinement has been proposed throughout the RUC reviewed codes for CY 2019. ***The AUA supports these RUC recommendations. The RUC also provides further recommendations on individual refinements of direct PE that the AUA also supports.***

Transurethral Destruction of Prostate Tissue (CPT codes 53850, 53852, and 538X3)

CMS proposes to accept the RUC's work RVUs for the following two CPT codes:

- 53850 (Transurethral destruction of prostate tissue; by microwave) (work RVU of 5.42)
- 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) (work RVU of 5.93)

The AUA supports CMS' proposed adoption of the RUC's recommended work RVUs for these two codes for transurethral destruction of prostate tissue.

However, CMS proposes a refinement to the RUC-recommended work RVU for 538X3 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy), from 5.93 to 5.70.

The AUA disagrees with CMS' proposal to change the work RVU from the RUC recommendation of 5.93 to a work RVU of 5.70 for CPT code 538X3. As with all endoscopic surgical procedures on the prostate, there is a significant risk of bleeding, urinary retention and damage to the external urinary sphincter with resultant incontinence of urine if not performed properly.

CMS cites 24071 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; 3 cm or greater) as a better crosswalk. To perform this procedure requires basic open surgical skills with a scalpel, scissors and suture and knot tying that all surgeons are already expert at performing. It involves making a superficial skin incision in the arm and dissecting a subcutaneous tumor, typically a lipoma (a benign fatty tumor). Stress is minimal, no arteries, veins or nerves are in danger with very minimal risk for long-term or permanent disability. In contrast, the skill and intensity due to the potential for bleeding and damage to the external urinary sphincter are the reasons that CPT code 538X3 should be considered a higher value than CMS is proposing and the same value as CPT code 53852.

CPT codes 53852 and 538X3 both involve somewhat similar hand held endoscopic devices. The AUA expert panel cannot explain why the time is 5 minutes less; however, the intensity and skill required are similar. There is more experience with 53852 as it has been performed for a number of years so the estimates of time are probably more reliable. As 538X3 is a new code where the clinical practitioners are still in the learning phase, and few urologists are performing it, the estimates of time may be based on limited experience. The RUC offered work RVU crosswalk values to more adequately match the survey reductions in time. For CPT code 538X3, the RUC supported a direct work RVU crosswalk to CPT code 67917 Repair of ectropion; extensive (eg, tarsal strip operations) (work RVU = 5.93 and 33 minutes intra-service time) and believes it is a better reflection of the work involved in furnishing CPT code 538X3 than the CMS-proposed crosswalk.

Thus, in conclusion the skill and intensity (because of the potential for bleeding and damage to the external urinary sphincter with the risk of permanent incontinence) are the reasons that 538X3 should be considered at a higher value than CMS proposes and should be given the same value as 53852 (5.93) as the RUC recommended.

Phase in of RVU Reductions for 53850 and 53852

In reviewing phase-in of significant RVU reductions for CPT codes 52380 and 52382, there will be a significant reduction in the current work value and in the Non Facility Practice expense. PAMA specifies that for current or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more compared to the total RVUs for the previous year, the adjustments in work, PE and MP RVUs should be phased in over a 2-year period. CMS considers a 19 percent reduction as the maximum 1-year reduction for the service to the maximum allowed amount (that is, 19 percent) and then phases in the remainder of the reduction. According to these guidelines, both CPT codes 53850 and 53852 should be subject to phase in for CY2019 because they will decrease more than 20 percent and are not new or revised codes. ***The AUA urges CMS to add CPT codes 53850 and 53852 to the list of codes subject to phase-in for significant RVU reductions for CY 2019.***

Ultrasound Exam – Scrotum (CPT code 76870)

CPT code 76870 Ultrasound, scrotum and contents was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CMS is proposing a work RVU of 0.64 for CPT code 76870 Ultrasound, scrotum and contents), as recommended by the RUC. ***The AUA supports this valuation as proposed.***

However, CMS is proposing refinements to direct PE inputs from this service. CMS is removing 1 minute from clinical activity, *Confirm order, protocol exam* (CA014) and adding 1 minute to clinical activity, *Prepare room, equipment and supplies* (CA013). ***We disagree with this refinement.*** The RUC requests that CMS remove the minute of clinical staff time that was added to CA013 to maintain a standard of 2 minutes for that clinical activity and accept 1 minute of clinical staff time as originally recommended by the RUC for CA014 to maintain a standard of 1 minute for that clinical activity. Please see an explanation of this request in our comments on CPT code 74420 (Urography, retrograde, with or without KUB) provided above. ***The AUA supports the RUC recommendations. The RUC also provides further recommendations on individual refinements of direct PE that the AUA also supports.***

Valuation of Prostate Biopsy Pathology Services HCPCS Code G0416)

In the MPFS Proposed Rule for CY 2017, CMS proposed to modify the valuation of G0416 without acknowledging the breadth of services covered. Notably, the College of American Pathologists and American Society of Cytopathology presented

information to the RUC sufficient to meet its "compelling evidence" standard, such that the RUC recommended an wRVU of 4.0 for this code. Nevertheless, CMS rejected that recommendation and proposed to adjust the wRVUs for G0416 based on the wRVUs of CPT Code 88305. Accordingly, CMS used the intraservice time ratio between G0416 and 88305 to arrive at a proposed wRVU amount of 3.60. Notwithstanding opposition from the RUC and the physician community, CMS finalized a work RVU of 3.60 for HCPCS G0416 for CY 2017.

CMS continues to value the professional component of CPT G0416 at a level that would equate to fewer than five instances of CPT Code 88305. CMS reduces the technical component of CPT code G0416 from approximately 10.2 to merely 8.3 instances of CPT 88305 – a reduction of 19%! There is no dispute that the standard of care is to analyze at least 12 tissue cores to properly assess for the presence of prostate cancer. As proposed, CPT code G0416 would have a global RVU value of only 51.6% that of 12 instances of CPT code 88305 (which has already been devalued). CMS recognizes that there has been no change in laboratory processing technique that justifies such a reduction by maintaining the technical component (TC) of CPT 88305 at 0.83 RVUs. If CMS is going collapse prostate needle biopsy (PNB) and prostate saturation biopsy (PSB) services into a single code, the Agency should establish a valuation for G0416 based on an objective analysis of the work actually done in reviewing prostate tissue collected through PNB. ***The AUA requests CMS provide a comprehensive explanation for this additional reduction.***

Evaluation & Management (E/M) Visits

The AUA commends CMS on addressing significant administrative burdens contributing to physician burnout through the CMS' "Patients over Paperwork" initiative, through which CMS established an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience. The AUA and our physician community are grateful for your efforts to simplify the documentation requirements associated with Evaluation and Management (E/M) services. However, we are concerned that the proposed changes in the 2019 Medicare Physician Fee Schedule – particularly the changes related to coding and payment for E/M services – may lead to many unintended consequences if they are implemented as proposed.

As CMS recognizes, excessive E/M documentation requirements do not just take time away from patient care; they also make it more difficult to locate medical information in patients' records that is necessary to provide high quality care. Physicians and other health care professionals are extremely frustrated by "note bloat," with pages and pages of redundant information that makes it difficult to quickly find important information about the patient's present illness or most recent test results. Several of the documentation policy changes included in the proposed rule would go a long way toward alleviating this problem, and as such, ***the AUA urges immediate adoption of the following proposals:***

1. ***Allow physicians the option to document visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current guidelines.***
2. ***If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients).***
3. ***Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient.***
4. ***Remove the need to justify providing a home visit instead of an office visit.***
5. ***Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty.***

Implementation of these policies will streamline documentation requirements, reduce note bloat, improve workflow, and contribute to a better environment for health care professionals and their Medicare patients.

As noted in item 5 above, AUA supports eliminating the prohibition on billing same-day visits by practitioners of the same group and specialty. This will allow patients to be seen by more than one physician who has multiple specialty affiliations in a practice and recognize the changing practice of medicine while reducing administrative burden. It will also eliminate the need for patients to return on another day to be treated for multiple conditions.

Regarding the proposal to collapse payment rates for eight office visit services for new and established patients down to two each, the AUA believes there are a number of unanswered questions and potential unintended consequences that would result from the coding policies in the proposed rule. ***We oppose the implementation of this proposal because it could hurt physicians and other health care professionals in specialties that treat the sickest patients, as well as those who provide comprehensive primary care, ultimately jeopardizing patients' access to care.*** We also believe that more guidance is necessary to determine whether it is appropriate to report the E/M visits based on time, medical decision-making or current E/M guidelines. Additionally, ***we urge that the new multiple service payment reduction policy in the proposed rule not be adopted as the issue of multiple services on the same day of service was factored into prior valuations of the affected codes.***

Finally, we note that CMS' E/M payment proposals also have significant impact on certain services, such as chemotherapy administration, that may be an unintended consequence of altering the current practice expense methodology to accommodate the proposal. The CY2019 Proposed Rule did not disclose the impact of the E/M payment collapse on indirect practice expense for other services. CMS' impact analyses in the Proposed Rule also do not appear to account for these large changes. Therefore, most stakeholders are not even aware of the impact of the policy change

on specialty-specific indirect practice cost indices (IPCIs). In the past, changes in specialty-level IPCI year-to-year have had relatively minimal impact on Medicare payment. It is unclear whether CMS even accounted for the specialty level-IPCI change when designing their E/M payment collapse and multiple procedure reduction proposal. Also, given this additional impact on the indirect practice expense for all services, it is unclear whether the proposed E/M payment collapse and E/M MPPR are budget neutral. ***The AUA concludes that the development of an E/M IPCI distorts the relativity of the RBRVS and should not be implemented.***

The medical community wants to help CMS work through the complicated issues surrounding the appropriate coding, payment, and documentation requirements for different levels of E/M services. Toward that end, the AUA strongly supports the American Medical Association's creation of a workgroup of physicians and other health professionals with deep expertise in defining and valuing codes, and who also use the office visit codes to describe and bill for services provided to Medicare patients. The charge to this workgroup is to analyze the E/M coding and payment issues in order to arrive at concrete solutions that can be provided to CMS in time for implementation in the 2020 Medicare Physician Fee Schedule. We understand that a number of CMS personnel monitored the initial conversations of the workgroup, and we look forward to their active participation in this process going forward.

The AUA encourages the administration to adopt in the final rule the documentation changes outlined above. Such policy modifications will significantly reduce the documentation burden so health care professionals can spend more time with patients. ***We also urge the administration not to finalize its proposals to adjust payment for E/M services, including its multiple procedure payment adjustment, and instead fully embrace the assistance of the workgroup and work together with the medical community on a mutually agreeable policy that will achieve our shared goal of simplifying E/M documentation burdens while mitigating any unintended consequences.***

Teaching Physician Documentation Requirements for Evaluation and Management Services

CMS proposes to revise its regulations to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team. ***The AUA supports this proposal, which will alleviate documentation burden that teaching physicians currently experience, allowing them to focus on their patient care and teaching responsibilities.***

Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)

CMS seeks public comment on reducing by 50 percent the low expenditure threshold, which determines which laboratories are subject to reporting requirements for applicable data on payments made by private payers for laboratory services. ***The AUA opposes this policy, which would reduce the low expenditure threshold $6,250 in CLFS revenues during a data collection period.*** If CMS were to finalize such a reduction, a large number of physician office laboratories and small independent laboratories would be required to report the applicable data, which would create a significant burden on the currently excluded practices that have not developed the capabilities and do not have the resources to report on commercial laboratory reimbursement. Further, given CMS' belief that increasing participation from physician office laboratories would have minimal overall impact on payment rates, we believe that implementing a reduction in the low expenditure threshold would result in costs that would far outweigh the benefits of such a change.

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments

CMS proposes that effective January 1, 2019, wholesale acquisition cost (WAC)-based payments for Part B drugs utilize a 3 percent add-on in place of the 6 percent add-on currently in place. The AUA has several concerns about this policy, which has the potential to affect new cancer drugs that are often administered by urology specialists as a last-line defense to treat cancers that are unresponsive to existing treatments. CMS has noted that the 6 percent add-on raises "concerns because more revenue can be generated from percentage-based add-on payments for expensive drugs, and an opportunity to generate more revenue may create an incentive for the use of more expensive drugs." We take issue with this underlying assumption and note that the vast majority of physicians do not know the difference in pricing between various prescribing options for a particular patient. If they do, in most cases, the difference in add-on percentage is not so great that it influences clinical judgment. However, a reduction in reimbursement for WAC-based services would have the potential to significantly harm practices' financial viability – particularly those in small practices who may not be able to negotiate favorable pricing on new drugs. Given all of the above, ***the AUA urges CMS not to finalize the proposed reduction in the add-on percentage for WAC-based payments.***

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The AUA generally supports clinician use of AUC for advanced diagnostic imaging services, as we believe clinical decision support mechanisms (CDSMs) can play a valuable role in supporting decision making to prescribe clinically appropriate services. However, we disagree that current requirements that link consultation of AUCs and associated reporting requirements to payment for advanced diagnostic imaging services support delivery of higher-value care. The AUA believes that the current AUC program places excessive burden on physicians with little evidence of clinical benefit. Additionally, we believe that the AUC program is duplicative of – and even inferior to – the Quality Payment Program (QPP), which CMS established to implement the physician payment reforms enacted under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The QPP already holds clinicians accountable for quality and patient outcomes, as well as resource use. For instance, there are a number of existing measures for appropriate use of imaging in the Quality performance category of MIPS. Additionally, CMS finalized the availability of Improvement Activity IA_PSPA_29, Consulting AUC Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging, for the CY 2018 QPP performance year – essentially folding key aspects of the AUC program into MIPS.

Given the establishment of the Merit-Based Incentive Payment System following the enactment of the AUC requirements in PAMA, the AUA believes that a separate AUC program for advanced diagnostic imaging is neither necessary or appropriate as a standalone program. However, we recognize that AUC reporting is congressionally mandated, and that any changes to the Program require legislative action. As such, ***we urge CMS to work with Congress to terminate the duplicative requirements that the AUC program imposes***. And until such time as Congress terminates the AUC program, ***we urge CMS to pursue policies that minimize the burden of the program on the medical community***.

Physician Self-Referral Law

Writing/signature Requirement

In this proposed rulemaking CMS addressed both the writing and signature requirements related to the Bipartisan Budget Act of 2018 and the physician self-referral (Stark) law regulations, and in doing so has provided helpful guidance. The CY 2016 PFS final rule included CMS's discussion of its longstanding policy that the writing requirement in the compensation arrangement exceptions of § 411.357 can be satisfied by a "collection of documents." The preamble discussion on this topic was beneficial in offering support for an analysis of a writing requirement that viewed contemporaneous documents evidencing the course of conduct between the parties as satisfactory for this element of the exception. The Bipartisan Budget Act of 2018 added subparagraph D, "Written Requirement Clarified" to section 1877(h)(1) of the Act. The proposed addition to § 411.354(e) adding a special rule

on compensation that includes the collection of documents for a writing requirement eliminates any potential ambiguity that could have existed between the statute and the regulations. ***The AUA appreciates this clarification from CMS in the regulatory text.***

Signature requirement

While the previous regulations to the Stark law provided for parties to obtain signatures, where applicable, within 90 consecutive calendar days following the date on which the compensation arrangement became noncompliant, the use of this provision was limited to once every 3 years with respect to the same physician. The Bipartisan Budget Act added subparagraph E "Signature Requirement" to section 1877(h)(1) and provided that the applicable signature requirement is not limited to specific exceptions and entities are not limited in their use of the rule to only once every 3 years with respect to the same physician. The AUA appreciates that CMS is updating the regulatory text to comport with the statute. Additionally, it is helpful that CMS made it clear that this change has been in effect since the effective date of the Bipartisan Budget Act on February 9, 2018.

CMS proposed two options for the placement of the provision within the Stark regulations. While both proposals provide clarification, ***the AUA supports the option of deleting § 411.353(g) in its entirety and codifying in § 411.354(e) the special rule for signature requirements in section 1877(h)(1)(E).*** We believe this provides a clear reflection of the statute in the regulations.

Holdover

The AUA agrees that the provision in the Bipartisan Budget Act of 2018 addressing the indefinite holdover of a lease or personal service arrangement under certain circumstances at 1877(e) of the Act is substantively identical to the existing regulatory provisions and no revisions are necessary. Permitting holdovers for those arrangements that remain on the same terms as the previous arrangement and within fair market value for the duration of the holdover period is a useful change to the Stark Law resulting from the CY 2016 PFS final rule revisions from CMS.

Merit-Based Incentive Payment System (MIPS)

Low-Volume Threshold

CMS proposes to establish a third criterion under which an eligible clinician could be exempt from MIPS (based on furnishing 200 or fewer covered professional services to Medicare Part B-enrolled individuals) based on low-volume. CMS also proposes that if an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold criteria, then such eligible individual or group could choose to opt-in to MIPS.

The AUA supports the proposal to allow clinicians the flexibility to opt-in to MIPS for performance year 2019 if they meet or exceeds one, but not all, of the low-volume threshold criteria. However, we are concerned that CMS' low-volume threshold policies may be reducing MIPS eligible clinicians' ability to receive upward payment adjustments for high performance that are commensurate with the expense and burden that they have experienced. Many of our clinicians achieved high performance scores under MIPS as a result of their efforts and investments, only to find that that they qualified for minimal upward payment adjustments for the first MIPS payment year. While we recognize that there are several factors that contribute to the size and distribution of upward payment adjustments, including the level of the performance threshold, ***we request that CMS monitor the impact of the low-volume threshold policies – including the proposed opt-in policy – on the upward payment adjustments available under MIPS, to ensure that payment incentives align with high performance demonstrated under the program.***

MIPS Performance Period

Consistent with prior comments, the AUA supports CMS' proposal to maintain a continuous 90-day performance period for the MIPS Improvement Activities and Promoting Interoperability performance categories. However, we believe that the reporting periods should be consistent across-the-board, particularly during the early years of the program, and ***we therefore urge CMS to establish a minimum performance period of a continuous 90-day period for the Quality performance category*** as well. We are concerned that the lack of standardization across the Quality, Improvement Activities, and Promoting Interoperability performance categories will lead to further misalignment in the MIPS program. Additionally, we are concerned that a full year reporting period for the Quality performance category is overly burdensome and believe that a continuous 90-day period is sufficient to collect representative data on the quality performance of a MIPS eligible clinician or group. ***Thus we suggest that a full year reporting period for the Quality performance category should be optional for those clinicians who are unable to meet data submission requirements within a 90-day period.***

Quality Performance Category

CMS contemplates several changes for the Quality performance category that raise several concerns for the AUA, as detailed below.

Proposals Related to Measure Prioritization, Selection, and Removal

CMS discuss several changes and considerations related to the selection of measures that would remain available for reporting under the MIPS program, including:

- Incremental removal of process measures;
- Accelerated removal of extremely topped out measures; and
- Exclusion of qualified clinical data registry (QCDR) measures from the topped-out measure lifecycle finalized in the CY 2018 QPP final rule.

Many of these changes are driven by CMS' Meaningful Measures initiative, which seeks to identify the highest priority areas for quality measurement and improvement. However, the AUA is concerned that this initiative may be misguided, for example in the determination of high priority areas, and may in fact lead to added burden for clinicians due it its resulting limitation on the availability of meaningful measures for specialists, particularly surgeons.

To this point, CMS proposes to implement an approach to incrementally remove process measures after taking several considerations into account. The AUA believes that process measures – even those that are topped out – have value and can often be directly linked to improved patient outcomes. Many of these evidence-based measures reflect critical aspects of the delivery of care, and high performance on such measures should rightfully be considered a success for quality improvement. However, CMS fails to recognize the value in incentivizing performance that is consistent with these evidence-based measures. Further, we believe that the ongoing availability of such measures is necessary given the limited number of measures that are available to many specialties and subspecialties. For example, some urologists with highly specialized practices may only have sufficient patients to report in a limited subset of the measures available through the AUA's AQUA QCDR. It is critical that specialists and subspecialists have meaningful measures on which to report, and further reducing the number of measures runs counter to this. ***As such, the AUA strongly disagrees with CMS' proposal to incrementally remove process measures.***

Similarly, CMS proposes to accelerate the removal of measures deemed extremely topped out, potentially allowing for removal of such measures in the next rulemaking cycle after they achieve the extremely topped out designation. ***The AUA strongly opposes this proposal for extremely topped out measures.*** As noted in previous years, the AUA disagrees that topped out measures should be removed from MIPS; instead, we have suggested that CMS maintain those measures and assign them a lower point value. We continue to believe this would be a more appropriate approach for addressing topped out measures, even those that are deemed to be extremely topped out, given the limited availability of measures that apply to certain specialties and subspecialties. Additionally, while we have concerns with measure removal, the existing policy that CMS finalized in last year's rule, which provided for a 4-year lifecycle to remove topped out measures, provided certainty, consistency, and sufficient time for stakeholders to prepare for the removal of topped out measures. CMS' proposal to accelerate the removal of extremely topped out measures would leave insufficient time for clinicians to prepare for the removal of such measures and would disadvantage those clinicians who have long relied on them to demonstrate high quality performance in their specialty or subspecialty.

Furthermore, CMS is proposing to exclude QCDR measures from the 4-year topped out timeline that was previously finalized, noting that QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle. As such,

when a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, CMS states that it may not be approved as a QCDR measure for the applicable performance period, without any advance notice or transition opportunity. ***The AUA opposes this policy, which creates inconsistency between the standards for reviewing QCDR measures and MIPS measures. Instead, CMS should apply the same 4-year timeline for removing topped out measures.*** Adhering to this same timeline will help to align policies for QCDR and other MIPS quality measures, provide sufficient time to validate measure benchmarks, and provide predictability to the clinicians who report applicable measures and would benefit from a transition period to adjust their reporting strategy.

Should CMS decide to move forward with measure removal under finalized versions of any of the above proposals, we stress the importance of monitoring the removal of such measures on patient outcomes and provider burden. ***In the event gaps in care reemerge, we recommend that CMS establish a process to quickly reinstate the topped out measures without having to go through various stages of approval.***

Finally, the AUA strongly opposes CMS' specific proposal to remove measure #48, Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 years and Older. This measure is a meaningful measure for urologists, urogynecologists, and primary care providers. Urinary incontinence is a prevalent concern among female Medicare beneficiaries, and proper assessment and treatment as supported by this measure can prevent more serious long-term complications. Furthermore, urinary incontinence can have a significant impact on quality of life yet many women are hesitant to speak about it. By retaining this measure to encourage providers to assess urinary incontinence, patient engagement would continue to be fostered.

Limitation of Part B Claims Collection Type to Small Practices

CMS proposes to limit the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and to allow clinicians in small practices to report claims as a group. While the AUA appreciates that the claims collection type remains available to small practices, AUA disagrees that it should be limited to only clinicians and groups in small practices. A great number of clinicians have relied on the Part B claims option, which provides flexibility – particularly for clinicians who are part of multi-specialty practices that may use other data collection types to report on measures that are not applicable to individual clinicians – to report on measures that are more meaningful to their specialty or subspecialty. Elimination of this reporting option will significantly increase burden on providers who have long relied on this option, and who may have limited ability to adopt other avenues for collecting data. As such, ***AUA strongly recommends that CMS not finalize its proposal to limit participation via the Part B claims collection type to small practices.***

Cost Performance Category

CMS proposes to increase the weight of the cost performance category to 15 percent for the CY 2021 MIPS payment year. ***The AUA opposes any increase in the weight of the cost category for the third MIPS program year.*** The AUA is pleased to be involved with Wave 2 of the CMS MACRA Episode-Based Cost Measure development efforts through participation on the Clinical Subcommittee on Urology and appreciates the opportunity to work with CMS to provide urologic clinical expertise. However, new measures have not yet been tested or finalized that apply to urologic specialists, meaning that to the extent that they are assessed under this category, their performance will be based on the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures, which we do not support as appropriate measures for assessing their cost performance. ***As such, we recommend that the weight of the cost category remain at 10 percent for the 2019 MIPS performance period and that CMS only increase the weight when better cost measures are available to assess most MIPS eligible clinicians under this category.***

Improvement Activities (IA) Performance Category

CMS proposes to make several modifications to its ongoing study on factors associated with reporting quality measures (for which clinicians can receive credit under the IA performance category). ***The AUA supports CMS' continuation of the study to gather data on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures, including CMS' proposal to increase the sample size of the study, which would allow more clinicians to participate and increase CMS' ability to conduct rigorous statistical analysis with sufficient power.***

Promoting Interoperability Performance Category

Electronic Health Record (EHR) Certification Requirements Beginning in 2019

Under the Advancing Care Information performance category (now called Promoting Interoperability) requirements finalized for the 2017 and 2018 MIPS performance periods, MIPS eligible clinicians had flexibility to use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two Editions. However, beginning with the 2019 MIPS performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria.

While we understand CMS' interest in phasing out out-of-date health information technology, we urge CMS to consider that transitioning EHR systems is a timely and expensive process. Many clinicians will need additional time to transition to 2015 Edition certified EHR technology (CEHRT), given that not all vendor products may be available on the market by the end of 2019 and that physician offices experience additional financial and technical challenges to upgrading technology in their practices.

As such, we suggest that CMS delay the requirement to use 2015 Edition CEHRT until the 2020 MIPS performance year. We believe this additional transition year would give clinicians enough time to select their new EHR system and complete the transition.

Proposed Scoring Methodology

CMS proposes to establish a new scoring system for the Promoting Interoperability performance category that would move away from the current base, performance, and bonus score methodology. Under its proposal, CMS would also reduce the number of required objectives and performance under this category would primarily be based on performance on each required measure. Additionally, CMS would no longer provide bonus points for this category based on completion of specific improvement activities; instead, bonus points would be limited to reporting on two new optional opioid measures.

While the AUA appreciates CMS' proposals that would streamline reporting, focus on interoperability, and reduce burden, we are concerned that the scoring methodology as proposed continues to retain an all-or-nothing standard by requiring clinicians to report on each measure in order to receive any score for the entire performance category. As such, ***we urge CMS to offer clinicians the greatest flexibility in selecting measures to report, and not require the use of every measure to receive credit; rather, CMS should provide partial credit for each measure a clinician reports.*** Eliminating the all-or-nothing requirement and instead providing partial credit for any measure will allow clinicians to focus on those measures that are most meaningful to their practice.

Additionally, the AUA disagrees with CMS' proposal to remove bonus points for completing certain improvement activities using CEHRT. We believe this proposal moves away from the concept of allowing measures or activities to receive credit across multiple categories. Additionally, we believe the bonus encourages the use of CEHRT and should therefore be retained.

Finally, the AUA continues to request that CMS establish an alternative pathway to achieve credit for the Promoting Interoperability performance category that relies on the use of CEHRT to participate in a QCDR. We believe that the current requirements for the performance category do not fully leverage the use of CEHRT to improve the value and quality of clinical care, the way that could be accomplished by linking the use of CEHRT to participation in QCDRs to receive credit, given QCDRs' role in driving improvements in the value of health care. For clinicians who utilize CEHRT to participate in QCDRs, an alternative pathway for achieving full credit as we recommend would align incentives to adopt CEHRT and improve quality, and also allow one activity to receive credit across multiple categories in order to simplify participation and reduce provider burden.

Small Practice Bonus

The AUA disagrees with CMS's proposal to apply the small practice bonus points only to the quality performance category. The AUA believes that, by applying the small practice bonus to the quality performance category level rather than to the final score, CMS is proposing a change that further complicates a scoring system that is already difficult to navigate and understand. Additionally, we are concerned that this proposal generally reduces the available bonus points for small practices relative to last year's proposal, despite the lack of evidence suggesting that small practices need less assistance. We also believe that this proposal unfairly disadvantages those small practices that could be assessed under the Cost performance category, or that choose to report under the Promoting Interoperability performance category rather than seeking an exception, as it overly relies on reweighting of those categories to reach almost-comparable levels of bonus points as are available for performance in 2018. Indeed, small practices that choose to report under the Promoting Interoperability performance category may require more assistance than those who seek a hardship exception, given the additional investments in EHR systems that they will have made, yet they would receive fewer bonus points than those who received an exception. Additionally, it appears that – in certain cases – this policy could unfairly advantage clinicians and practices who may not have 6 applicable measures by allowing for a bonus of greater than 5 points. For example, if a clinician only has three measures that are available and applicable, then the denominator for the quality score would be only 30 points. In this case, a 3-point bonus added to the numerator could translate to over 8 bonus points added to the final score if the Cost and Promoting Interoperability performance category scores were reweighted to 0. Rather than allowing the small practice bonus to vary based on which performance categories are weighted and how many measures are reported, ***the AUA urges CMS to reconsider its proposal and instead continue to apply a 5-point small practice bonus points to the MIPS final score for the purposes of the 2021 MIPS payment year.***

MIPS Performance Threshold

CMS is proposing a performance threshold of 30 points for the 2021 MIPS payment year. While we understand CMS' aim is to achieve more complete reporting and better performance, we believe that this would be an excessively steep increase from the 2020 MIPS payment year, for which the performance threshold is set at 15 points. Many AUA members have expressed challenges with MIPS reporting and were worried about meeting the 15-point performance threshold for the 2020 MIPS payment year. ***Therefore, the AUA urges CMS to refrain from doubling the performance threshold to 30 points for the 2021 MIPS payment year; rather, we believe a more gradual increase would be more appropriate in order to give clinicians more time to adjust to the demands of the MIPS program. Specifically, we recommend that CMS instead increase the performance threshold to 20 points for the 2021 MIPS payment year, which would reflect a 5-point increase from the 2020 MIPS payment year.***

Additionally, as CMS contemplates setting the performance threshold for the 2022 MIPS performance period, ***the AUA advocates that CMS consider multiple options for establishing the performance threshold, such that CMS can find a performance threshold that is less aggressive than the current estimate – which is based on the estimated mean final score for 2017 – but that still challenges providers to achieve a reasonable performance level that promotes value in the delivery of care.*** We are concerned that a performance threshold of between 63.50 points and 68.98 points for the 2022 MIPS performance period will be unattainable for those clinicians currently struggling with the 15-point performance threshold.

Third Party Intermediaries

Proposed Update to the Definition of a QCDR

Beginning with the 2022 MIPS payment year, CMS proposes to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. As a part of the self-nomination process, CMS would look for entities that have quality improvement expertise and a clinical background. CMS would also follow up with the entity via, for example, email or teleconference, should it have a question as to whether or not these standards are met. Additionally, entities can also meet this definition by signing a written agreement with an external organization that has expertise in medicine and quality measure development.

We support CMS' proposed update to the definition of a QCDR. In past years, we have seen entities with predominately technical backgrounds applying to become QCDRs because of the financial rewards that could be attained. However, these organizations lack a complete understanding of measure constructs and are not in the business to improve the overall quality of patient care. CMS' proposal rightfully identifies this risk and would prevent such entities from participating as QCDRs.

Self-Nomination Period

CMS proposes to update the self-nomination period from its current timeframe (September 1 of the year prior to the applicable performance period until November 1) to July 1 of the calendar year prior to the applicable performance period until September 1.

The AUA disagrees that an earlier self-nomination period is appropriate and requests that CMS continue to open the self-nomination period on September 1. We believe that advancing the initiation of the self-nomination period would negatively impact the life cycle of QCDRs and the maintenance process for QCDR measures. ***However, we request that CMS consider extending the self-nomination period to a minimum of 90 days.*** In our experience operating the AQUA QCDR, we have found it excessively challenging and burdensome to complete the self-nomination period in the 60 days that are currently allocated, including to supply all of the required information and respond to additional requests. For

example, during previous self-nomination periods, QCDRs have been asked to provide additional measure information with less than a 24-hour turnaround time. We believe a longer self-nomination period would alleviate the time pressure that has likely driven expedited requests we have historically experienced.

QCDRs Seeking Permission from Another QCDR to Use an Existing, Approved QCDR Measure

CMS proposes that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place. Thus, under CMS' proposal, QCDRs would have no choice but to agree to the license agreement if they would like their measures to be available for reporting under MIPS.

As a measure steward and operator of a QCDR, the AUA strongly rejects this proposal and urges CMS to instead allow QCDRs to enforce their ownership rights on the measures they develop. QCDRs – an in particular the medical societies that operate many of QCDRs with quality improvement expertise and clinical backgrounds – have assumed significant cost and burden to develop applicable quality measures, yet CMS' proposal would lead QCDRs to lose full rights to those measures as soon as they are approved for MIPS use. Such an outcome would reduce their incentives – as well as the financial resources available – to invest in developing, testing, implementing, and maintaining measures. If third parties can routinely use these measures without paying royalties or licensing fees, medical societies may no longer be able to dedicate resources to developing or updating QCDR measures that best capture quality performance data on the measures most appropriate for each specialty.

Advanced APMs

Although the QPP was developed as a two-part program – comprised of both MIPS and Advanced APMs – specialist physicians, such as urologists, have limited options to qualify for participation under the Advanced APM track. The lack of opportunities for specialists to participate in Advanced APMs is disappointing for specialists who provide high quality care and would like to contribute to a coordinated care model in a meaningful way and receive the potential benefits for such activities. The potential benefits of Advanced APM participation are not insignificant when comparing the results of the first performance year where the positive bonus for those practitioners who successfully performed under MIPS was significantly less than the 5% lump sum available to those clinicians who participated successfully in an Advanced APM.

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was created under MACRA to review physician-focused payment models submitted by individuals and stakeholder entities. The PTAC must then make recommendations to the Secretary of Health and Human Services on whether such models should be implemented. Although the PTAC has reviewed and provided favorable recommendations on many models reviewed to date, these models have not been implemented, and we have not seen any indication that CMS intends to move forward with these models. ***We encourage CMS to pursue testing of these models to facilitate greater engagement by specialists in the goal of achieving higher quality and more intentional resource usage. We also encourage CMS to provide more guidance on Advanced APM development to stakeholders considering submitting payment models to the PTAC.***

More broadly, the AUA also encourages CMS to consider Advanced APM options that would include specialists such as urologists in the models. Not only will new and expanded Advanced APM opportunities provide specialists with the opportunity to be successful under the QPP, beneficiaries will be included in models where they receive high-quality care and the Medicare program will benefit from the cost savings achieved. Excluding specialists from consideration in developing alternative payment models reduces the impact of the QPP as a whole by reducing the number of physicians who are truly interested in full participation in efforts towards the successful transition to value-based payments.

Use of CEHRT in APMs

In 2019 for Medicare APMs and 2020 for Other Payer APMs, CMS proposes to increase from 50 to 75 the percentage of an APM's participating physicians that will be required to use CEHRT in order for the APM to qualify as an Advanced APM. ***The AUA recommends that new CEHRT requirements for Medicare APMs be deferred to 2020 like Other Payer APMs.*** There is already a requirement to upgrade to 2015 edition CEHRT in 2019; physicians participating in APMs should not face too many new health information technology (health IT) requirements in a single year.

We also recommend that CMS take a different approach to assessing APMs' use of health IT to coordinate and improve patient care. CEHRT has come to be widely viewed as a tool for documenting, reporting and billing instead of as a tool for improving clinical care, coordination, and patient engagement.

To be successful in APMs, the AUA believes physicians need health IT that responds to and supports physician, patient, and care team interactions, not merely CEHRT. Instead of requiring that 75 percent of APM participants use CEHRT, ***CMS should retain the current 50 percent requirement and allow APM entities to attest that an additional percentage of APM participants are either using CEHRT or using health IT that "builds on" or is an extension of CEHRT, such as plug-and-play modules, to achieve the specific goals of the APM.*** Health IT that builds on or is an extension of CEHRT is a concept taken directly from CMS' priorities in its call for new PI measures. For instance, in addition to using certified EHRs, APMs would be

able to attest to using customized messaging or care coordination technology developed for the unique needs of the patients in that APM. This approach balances the importance of using CEHRT while rewarding APMs for using innovative technology that meets physician and patient needs. This approach will also encourage significant improvements in technology to be developed that would lessen the burden on physicians. CMS needs to encourage health IT developers to listen to APM participants and learn what they need to enter, retrieve, exchange, and analyze data, instead of developing technology that is only as advanced as the federal government requires.

There is also concern that physicians, including physicians participating in APMs, have little to no control over their EHR's ability to help achieve the APM's goals. Health IT companies frequently charge fees for each and every requirement imposed by federal reporting programs. Vendors need to be held accountable for producing tools to advance care outcomes without burdening physician practices or APMs with exorbitant fees and lack of usability.

Conclusion

The AUA appreciates the opportunity to provide comments on these important policies that affect physician payment and performance for CY 2019. If you have any questions or wish to discuss our comments, please contact Stephanie Stinchcomb, Director of Reimbursement and Regulation, at (410) 689-3786 or sstinchcomb@auanet.org.

Sincerely,

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