



BOARD OF DIRECTORS

September 24, 2019

Officers

John H. Lynch, MD
President

Scott K. Swanson, MD
President-elect

Robert C. Flanigan, MD
Immediate Past President

John D. Denstedt, MD
Secretary

David F. Green, MD
Treasurer

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

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

Section Representatives

Roger E. Schultz, MD
Mid-Atlantic

E. Ann Gormley, MD
New England

Frederick A. Gulmi, MD
New York

Chandru P. Sundaram, MD
North Central

Barry A. Kogan, MD
Northeastern

Anthony Y. Smith, MD
South Central

Martin K. Dineen, MD
Southeastern

Eric J. Zeidman MD
Western

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-P)

Dear Administrator Verma,

The American Urological Association (AUA) appreciates the opportunity to provide comments on the CY2020 Physician Fee Schedule proposed rule. The AUA is a globally-engaged organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy.

Headquarters

Michael T. Sheppard, CPA, CAE
Chief Executive Officer

1000 Corporate Boulevard
Linthicum, MD 21090

U.S. Toll Free: 1-866-RING-AUA
(1-866-746-4282)

Phone: 410-689-3700

Fax: 410-689-3800

Email: AUA@AUAnet.org

Websites: AUAnet.org
UrologyHealth.org
UrologicHistory.museum

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

- Payment for Evaluation and Management (E/M) Visits
- Care Management Services

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

- Reimbursement for Online Digital Evaluation Services (e-Visits)
- Review and Verification of Medical Record Documentation
- Therapy Services
- Valuations of Specific Services
- Request for Information (RFI) on Bundled Payments
- Scope Systems
- Stark/Physician Self-Referral Law Advisory Opinion Process
- Open Payments Program
- Improper Prescribing and Patient Harm
- Physician Supervision for Physician Assistant (PA) Services
- Quality Payment Program (QPP)/Merit-Based Incentive Payment System (MIPS) Provisions

Payment for Evaluation and Management (E/M) Visits

The AUA supports the agency's continued effort to reduce administrative burden and improve the valuation of E/M services that our members bill. We appreciate CMS' willingness to revise the E/M documentation and payment policies finalized in last year's Physician Fee Schedule (PFS) and to adopt the revised E/M code definitions developed by the American Medical Association (AMA) CPT Editorial Panel and RUC-recommend values for these services in place of the single payment rate policy for level 2-4 services previously finalized. The AUA is confident that the revised outpatient code family will both reduce providers' documentation burden and accurately value these services.

We also appreciate the agency's proposal to adopt the RUC recommended work RVU for the prolonged service code, 99XXX, which can be billed with level 5 E/M codes when a provider chooses to bill by time.

We support the adoption of a single complexity add-on code, GPCX1, which will be available to all for visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition. This code will capture additional resource costs required to deliver certain types of urological care to complex patients. The AUA would welcome the opportunity to work with CMS and other specialty societies to properly define this service and make sure this code is used appropriately for the most complex patients.

Global Surgical Packages

CMS rejected the RUC's recommendation to apply the outpatient E/M visit increases to the 10- and 90-day global services. The agency stated that outpatient E/M visits are not directly included in the valuation of these global services and that the work RVUs are generally valued using magnitude estimation, a technique that ranks work in relation to a reference using a ratio scale, which differs from the process used for E/M in general.

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

Following the release of this proposed rule, 53 specialty organizations, including the AUA, signed an AMA-sponsored letter sent to CMS in opposition to this proposal. The letter urged CMS not to finalize the agency's original proposal and instead to apply the RUC recommended E/M changes to the global codes. The AUA believes the agency must apply these updated E/M values to the global codes. It is imperative that CMS take this crucial step because to do otherwise will result in the following unintended consequences:

- *Disruption to the relativity in the fee schedule:* Applying the RUC-recommended E/M values to stand-alone E/M services, but not to those included in the global surgical packages, will disrupt the relativity between codes across the Medicare PFS. Congress mandated that the services on the PFS be valued relative to one another since its inception in 1990.¹ Any refinements made to the values of PFS services over the past 27 years have maintained that concept of relativity. Since the implementation of the PFS, E/M codes have been revalued three times — in 1997 after the first five-year review, in 2007 after the third five-year review, and in 2011 (after CMS eliminated consultation codes and moved those work RVUs into the office visit codes). When the payments for new and established office visits were increased in these instances, CMS also increased the bundled payments for these post-operative visits in the global period. **The AUA recommends that CMS do the same now.**

- *Creation of specialty differentials:* Per the Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the “Secretary may not vary the . . . number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.”² **The AUA recommends that CMS adjust the global codes, as failing to do so is tantamount to paying some physicians less for providing the same E/M services, in violation of the statute.**

- *Violation of the Medicare Access and CHIP Reauthorization Act (MACRA) §523(a):* CMS refers to the ongoing global code data collection effort as a reason for not applying the RUC-recommended changes to office visit E/M codes to the 10 and 90-day global services. The agency also states that it is required to update the global surgical package values based on objective data on all of the resources used to furnish the services included in the package. These arguments conflate two separate issues. The issue that CMS raises regarding the MACRA legislation is unrelated to maintaining relativity across the PFS based on current data in the CMS work/time file. In fact, §523(a) specifically authorizes CMS to make adjustments to surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project.³ **The AUA recommends that CMS make adjustments to the global services.**

¹ Omnibus Budget Reconciliation Act of 1989, HR 3299. (1989).

² Omnibus Budget Reconciliation Act of 1989, HR 3299. (1989).

³ Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, HR 2, §523(a). (2015).

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

- *Ignore recommendations endorsed by nearly all medical specialties:* The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits must be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. **The AUA recommends that CMS accept the RUC recommendations.**

Care Management Services

The AUA supports CMS' efforts to increase the utilization of existing care management services and adopt new care management services. Urologists have not widely adopted these services because of the numerous billing requirements imposed on their use.

In particular, the AUA recommends that CMS implement its proposal to create two G-codes for Principal Care Management (PCM) services. A number of urological conditions will meet the services requirements to typically be expected to last between three months and a year, or until the death of a the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. However, urologists and other providers will bill these services only if CMS does not impose restrictive and burdensome documentation requirements.

Reimbursement for Online Digital Evaluation Services (e-Visits)

CMS proposes to pay separately for six new non-face-to-face codes to describe the care provided for patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. These new codes are for established patients only and cover the cumulative time over a seven-day period required to deliver this care.

The AUA would like to express our strong support for this proposal to reimburse for this non-face-to-face care being provided by our members. Our members already deliver care in this manner that is not being reimbursed and we believe more urologists will deliver these services once it is reimbursed. Most importantly, reimbursement for these services will allow patients to receive more efficient care and will limit the burden associated with return office visits. CMS does not address the documentation requirements for these services, but AUA urges the agency not to impose burdensome documentation requirements on these services that would outweigh the value of these services in order for them to achieve their stated purpose.

Review and Verification of Medical Record Documentation

The AUA supported the final policy included in last year's PFS that allowed a physician, resident, or nurse to document in the medical record that the teaching physician was present

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

at the time the service was delivered and eliminated the requirement for the teaching physician to document the extent of his own participation in the review and direction of the services furnished to each beneficiary and instead allowed the resident or nurse to document the extent of the teaching physician's participation.

Accordingly, the AUA supports CMS' proposal to provide the same relief for nonphysician practitioners authorized to deliver Part B services, including NPs, CNSs, CNMs and PAs. **The AUA recommends that CMS finalize this policy as proposed.**

Therapy Services

The AUA appreciates the agency for proposing changes consistent with §50202 of the Bipartisan Budget Act (BBA) of 2018, which repeals caps on Medicare payment for certain therapy services.⁴ We agree with CMS' proposal to create modifiers to identify services that are performed by physical therapy and occupational therapy assistants (PTA/OTA) and setting a *de minimis* of a 10 percent standard for when the modifiers apply to specific therapeutic services.

Practice Expense for CPT Code 64561 – SA022 Kit, percutaneous neuro test stimulation

CPT code 64561 (Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed) is routinely performed and billed by providers in a physician office setting. The primary purpose is to conduct a sacral nerve evaluation on patients suffering from chronic urinary retention, urge incontinence and frequency, and chronic fecal incontinence who have failed conservative therapy. CMS has covered Sacral Nerve Stimulation since 2002. The National Coverage Determination (NCD 230.18) requires office-based test stimulation before patients can receive a permanent sacral nerve stimulator to treat urinary incontinence symptoms.

In order to perform the office-based test stimulation, a percutaneous neurostimulation kit is purchased by the provider for each case. The kit is identified as CMS code SA022 ("kit, percutaneous neuro test stimulation") as part of the direct practice expense inputs for CPT code 64561 under "Supplies." In the 2018 StrategyGen Market Research Report, SA022 was revalued with a recommended price of \$114.52. This revaluation would result in a 22% decrease in payment for 64561 as proposed for CY 2020, and a 41% decrease by CY 2022, relative to CY 2018.

The AUA believes that the recommended price of \$114.52 is insufficient to reflect the cost associated with SA022, and that there may be some misunderstanding around what items comprise the sacral nerve test kit. In particular, it appears that the line item reflecting the device that generates the neurostimulation, which is the most expensive component of the test kit, was not included in the revised practice expense calculation, which instead reflects

⁴ Bipartisan Budget Act of 2018, HR 1892, §50202. (2018).

the costs of the test kit leads only. We have attached a copy of a current invoice (Attachment A for the neurostimulation kit.

The AUA requests that CMS revisit the recommended price for SA022 and use current invoice price to establish the proper reimbursement for percutaneous neurostimulation kit.

Proposed Valuation of Specific Services

Drug Delivery Implant Procedures (CPT Codes 11980, 11981, 11982, 11983)

CPT code 11981 was identified as being performed by a different specialty than the one that originally surveyed this service. The code family was referred to the CPT Editorial Panel to better define these services and differentiate between the use in musculoskeletal procedures and use in urological or gynecological procedures. The CPT Editorial Panel approved the addition of six add-on codes to describe orthopedic drug delivery to differentiate the service from the service described in code 11981. The revised code family was then sent to the RUC for valuation.

- 11980 (Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin))

The AUA agrees with CMS' support of the RUC's conclusion that the value and total time for this service are unchanged.

For the following codes (11981, 11982 and 11983, If CMS uses a crosswalk, rather than the RUC recommended values, the CPT code should be one that is defined by similar work, not similar time.

- 11981 (Insertion, non-biodegradable drug delivery implant)

For CPT code 11981, CMS disagrees with the RUC recommended work RVU of 1.30 because the service incurs a 23 percent reduction in the new total physician time. Instead, the agency proposes a work RVU of 1.14 and accepted the RUC survey recommendations for time using CPT code 67500 *Retrolbulbar injection; medication* (Injection of medication into cavity behind eye) with 1.18 work RVUs and 33 minutes of total time as a comparator code. No PE time refinements are proposed.

The AUA disagrees with CMS' crosswalk to CPT code 67500. The typical patient undergoing a retrolbulbar injection of medication is a 50-year-old male with posterior scleritis while the typical patient having a drug delivery device inserted in CPT code 11981 (Insertion, non-biodegradable drug delivery implant) is an elderly male with metastatic prostate cancer. Prostate cancer patients will have poor nutritional status and poor wound healing characteristics adding to the intensity of placing a non-biodegradable device in a specific location in the upper arm. Thus, during insertion of the implant in the typical patient

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

with poor muscular tone, careful attention must be given to avoid damage to the muscles and vasculature of the upper arm.

The original valuation of CPT code 11981 was not based on a valid survey like that of the RUC; the source of its current valuation is listed as “CMS/Other”. The AUA does not know what crosswalk or methodology was used in the original valuation of this service and does not believe it was resource-based; therefore, CMS should not compare the current time and work to the surveyed time and work to value the service. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. The application of this flawed methodology will compromise the integrity of this resource-based relative value scale system.

As proposed by CMS, CPT code 11981 will have a work RVU 0.04 higher than CPT code 11980. The RUC noted that CPT code 11981 is a different procedure than CPT code 11980. The latter is the subcutaneous implantation of a biodegradable compounded pellet that can be placed anywhere in the body with a needle and trocar. Whereas, CPT code 11981 is the insertion of a non-biodegradable implant that must be placed in a specific location in the arm. Therefore, the physician time and work is different. A 0.04 work RVU difference does not accurately reflect the relativity of these two services.

The typical patient undergoing CPT code 11980 is a middle-aged male with testosterone deficiency. These patients are relatively healthy with excellent wound healing characteristics. There are multiple locations in the body that the biodegradable pellets described in 11980 can be placed including the subcutaneous tissues of the buttocks. This typical patient differs significantly from the typical patient in CPT code 11981 described above. The patient who receives the service described by CPT code 11981 has metastatic cancer, has been on androgen deprivation therapy, and has poor muscular tone making safe and successful placement of the drug delivery device significantly more intense than the placement of a biodegradable pellet in a relatively healthy, middle-aged male. As stated previously, a work RVU difference of 0.04 does not accurately account for this substantial difference in work intensity.

The AUA does not believe CMS is using a valid method to propose a work RVU for CPT code 11981.

The AUA recommends that CMS independently review the surveyed time and work and not compare it to the invalidated CMS/Other source of the current time and work and urges CMS to accept the RUC recommended work RVU of 1.30 for CPT code 11981.

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

- 11982 (Removal, non-biodegradable drug delivery implant)

CMS is proposing a work RVU of 1.34 rather than accepting the RUC-recommended value of 1.70 RVUs. For CPT code 11982, the agency contends the RUC-recommended work value is too high because there is a 25 percent reduction in the new total physician time (33 minutes). Instead, CMS proposes a work value of 1.34 using CPT code 64486 Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed) (work RVU of 1.27 and 35 minutes total time) as a comparator service.

As with CPT code 11981, the typical patient and physician work required for CPT code 11982 differ significantly from the typical patient and physician work required for the CMS selected crosswalk to CPT code 64486. If time were the only criteria to choose an appropriate crosswalk, 11982 could just as easily be crosswalked to the 2015 RUC reviewed CPT code 31579 (Laryngoscopy, flexible or rigid telescopic, with stroboscopy) with a work RVU of 1.88 and a total time of 34 minutes. CPT code 11982 is another service with an original valuation of CMS/Other. As with other services with this valuation, it does not accurately capture physician time or direct practice expense inputs from the current dominant specialties performing this service.

The AUA recommends that CMS adopt a work RVU of 1.70 based on the 25th percentile of the valid RUC survey for CPT code 11982 and that CMS independently review the surveyed time and work and not compare it to the invalidated CMS/Other source of the current time and work.. The RUC value is supported by CPT codes 54150 (Circumcision, using clamp or other device with regional dorsal penile or ring block) with a work RVU of 1.90 and 12004 (Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) with a work RVU of 1.44.

- 11983 (Removal with reinsertion, non-biodegradable drug delivery implant)

CMS is proposing a work RVU of 1.91 rather than the RUC-recommended work RVU of 2.10 for CPT code 11983. The agency states that CPT code 62324 (Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance) with a work RVU of 1.89 and 43 minutes total time is a more appropriate comparator since CPT code 11983 incurs a 42 percent reduction in the total physician time.

Like the other codes in the family, the current source of time for CPT code 11983 is CMS/Other. CMS should not compare the results of a valid survey to the current valuation whose source is unknown and not resource-based. Instead, CMS should refer to the valid

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

RUC survey and propose the 25th percentile work RVU of 2.10 that is a 36% decrease in value. This value is supported by comparisons to CPT codes 55700 (Biopsy, prostate; needle or punch, single or multiple, any approach) with a work RVU of 2.50; 54150 (Circumcision, using clamp or other device with regional dorsal penile or ring block) with a work RVU of 1.90; and 52281 (Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female) with a work RVU of 2.75. These comparator codes are more appropriate than using an anesthesia procedure as CMS proposes because the intensity of the work required of the two services is not comparable and negates the validity of the RUC survey. If a crosswalk is used, rather than the RUC-recommended values, the CPT code should be one that is defined by similar work, not similar time.

CMS is again using a flawed methodology to value CPT code 11983 as it has proposed for the other codes in the family. CMS' proposals for CPT codes 11981, 11982 and 11983 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. **The AUA recommends that CMS independently review the surveyed time and work and not compare it to the invalidated CMS/Other source of the current time and work. We urge CMS to accept the RUC recommended work RVU of 2.10 for CPT code 11983.**

Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442)

- 52441 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant)

For CPT code 52441, CMS disagreed with the RUC recommended work RVU of 4.50 and instead proposed a work RVU of 4.00. The agency's proposed valuation is based on crosswalk to CPT code 58562 (Hysteroscopy, surgical; with removal of impacted foreign body) that is 4.00 work RVUs and has identical intraservice time. Additionally, removal of a foreign body is not the same procedure as placement of an implant. Because these are unrelated procedures, the AUA believes this is an inappropriate crosswalk.

In 2014, the transprostatic implant was only FDA approved for the treatment of benign prostatic hyperplasia in patients with lateral enlargement of the prostate. The implant was not approved for use in patients with a median lobe in which the enlarged prostate protrudes significantly into the bladder. In December 2017, the FDA expanded the indication for the transprostatic implant to include patients with a median lobe. Deploying a transprostatic implant in a patient with a median lobe is significantly more intense than the use of the device in patients with only lateral growth of the prostate, due to the significant potential for injury to the trigone of the bladder and the ureteral orifices. Thus, while the intra-service time to complete the procedure has decreased since the initial survey secondary to expected diffusion of knowledge, the procedure has become more technically challenging, requiring

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

more delicate placement of the transprostatic elements and significantly increasing the intensity of the procedure justifying maintain the work RVU of 4.50.

The AUA recommends that CMS accept the RUC recommended work RVU for CPT code 52441.

- 52442 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure))

For CPT code 52442, CMS proposed a work RVU of 1.01 rather than the RUC-recommended value of 1.20. The agency's proposed valuation is based on a crosswalk from 36218 (Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)) which has an identical intraservice time. The CMS proposal disregards all factors that go into the work value apart from time. Based on CMS' crosswalk and subsequent valuation a rank order anomaly would be created relative to other urologic procedures. There was an intense discussion about the increase in intensity and complexity of these services supported by the Food and Drug Administration (FDA) approval to perform this service on the median lobe of the prostate. Rather than solely base the value for 52442 on time-based crosswalk methodology, CMS should consider the clinical information that was available to the RUC when the RUC recommended maintaining the work RVU value of 1.20. While the intra-service time based on survey data did decrease, this decrease in time occurred in concert with the expanded indication for use of the transprostatic implant in patients with complex prostatic anatomy including median lobes. Use of the device in patients with median lobes, as discussed regarding CPT code 52441, substantially increases the intensity of the procedure due to the risk of injury to the trigone of the bladder and ureteral orifices. Therefore, while diffusion of knowledge has led to a decrease in intra-service time, the increased intensity of the procedure in patients with complex prostatic anatomy justifies maintaining the work RVU value of 1.20 for CPT code 52442.

The AUA recommends that CMS accept the RUC recommended work RVU for CPT code 52442. We urge CMS to accept the RUC recommended work RVU of 1.20.

Orchiopexy (CPT Code 54640)

- 54640 (Suspension of testis)

The CPT Editorial Panel revised this service to describe an additional approach for orchiopexy and indicate that hernia repair is reportable with this service. CMS is proposing to accept the RUC-recommended value of 7.73 work RVUs and the direct PE inputs.

The AUA is pleased that CMS supports the RUC's recommendation. We also agree with CMS' conclusion that hernia repair should be reportable with this service.

Urography (CPT Code 74425)

- 74425 (Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation)

CMS is proposing the RUC-recommended work RVU of 0.51, a total time of 24 minutes, and the direct PE inputs. **The AUA thanks CMS for supporting the RUC-recommended work RVU, total time, and direct PE inputs.**

Biofeedback Training (CPT Codes 908XX and 909XX)

- 908XX (Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; initial 15 minutes of one-on-one patient contact)

CPT code 90911 was identified as potentially misvalued on a RAW screen of codes with a negative IWP/UT and Medicare utilization over 10,000 or 1,000 for Harvard valued and CMS or other source codes. The CPT Editorial Panel replaced this service with two new codes to describe biofeedback training; the first for the initial 15 minutes of one-on-one patient contact and then the second code describes each additional 15 minutes of biofeedback training.

The AUA is pleased that CMS supports the RUC's recommendation work RVU of 0.90.

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

- 909XX ((Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; each additional 15 minutes of one-on-one patient contact)

The AUA is pleased that CMS supports the RUC’s recommendation work RVU of 0.50.

For both 908XX and 909XX, CMS is proposing to designate them as “sometimes therapy” procedures which means that an appropriate therapy modifier is always required when billed by therapists. The AUA agrees with this proposal as these procedures are performed in a physician’s office and will not require the use of the modifier for physical therapy (GP), occupational therapy (GO), or speech-language (GN) pathology plan of care.

Scope Systems

During reviews of direct PE input recommendations, CMS has regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. The agency is proposing to establish 23 new scope equipment codes based on the recommendations of the RUC workgroup convened to address this issue and will establish new equipment codes for the scopes and replace the existing scope equipment codes with eight new equipment codes for which it has pricing. For the non-priced codes, CMS requests additional feedback from stakeholders on their pricing.

In response to these changes, the AUA has provided invoices to CMS through the RUC and will continue to provide invoices as they are received from members.

Advisory Opinions on the Application of the Physician Self-Referral Law

In response to potential updates to the advisory opinion process, the AUA hopes that more stakeholders will participate in the process by submitting advisory opinion requests and CMS will be able to offer more guidance to the industry through its published advisory opinion responses.

Hypothetical Fact Patterns

Currently CMS only accepts requests for advisory opinions that involve existing arrangements, as well as requests that involve arrangements into which the requestor plans to enter. Based on comments received in response to the June 2018 CMS RFI, CMS has asked for comments on whether this should be expanded to advisory opinion requests that involve hypothetical fact patterns and general questions of interpretation. The AUA encourages CMS to expand the process. Although CMS expressed concern that this may lead to a sharp increase in the number of advisory opinion requests that could overwhelm the agency, we believe that sufficient safeguards can be put in place to ensure that only thoughtful and complete requests are accepted for responses.

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

The acceptance of hypothetical fact patterns will fill a void that has existed related to analysis and interpretation of financial arrangements under the Stark law. It can be difficult, at times, to know whether an arrangement complies with the Stark law. Due to the strict liability nature of the law, there has been concern in the industry that submitting an advisory opinion request for existing arrangements can evolve into a self-disclosure if, based upon certified facts submitted, CMS determines the arrangement is in violation of the Stark law. Allowing the submission of hypothetical arrangements would provide an opportunity to ensure compliance with the Stark law before the arrangement is in place.

The AUA appreciates CMS's proposed change clarifying that the request for an advisory opinion must "relate to" (rather than "involve") an existing arrangement or one into which the requestor, in good faith and supports possible future expansion to include detailed requests related to hypothetical arrangements. However, the proposed revision to the language at § 411.370(b) regarding matters that qualify for advisory opinions and the parties that may request may be somewhat helpful but will not have the positive impact that expansion to hypothetical issues would have.

Due to the complex nature and steep consequences for a mistaken interpretation of the Stark law, we believe that requestors will appreciate the opportunity to submit an expanded universe of fact patterns to the agency. The AUA believes that CMS' authority to decline an advisory opinion request where the requestor does not describe the arrangement with a level of detail necessary for CMS to issue an opinion and where the requestor does not timely respond to CMS's request for additional information offers sufficient protection against large numbers of advisory opinion requests that could bog down the agency.

Simultaneous Investigations

CMS also proposed to amend § 411.370(e)(2), which restricts CMS from issuing advisory opinions if another government agency is already issuing an opinion on a similar request. The AUA agrees that while it is appropriate for CMS to consult with other HHS components and governmental agencies, including OIG and DOJ, on pending advisory opinion requests, we believe the current regulation is too restrictive. Compelling CMS to not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities unnecessarily limits CMS' ability to issue timely guidance to requestors engaged in or considering legitimate business arrangements.

The proposed change would give CMS more discretion to determine, after consulting with the OIG and the DOJ, whether acceptance of the advisory opinion request is appropriate. This clarification would be a welcome change to the regulations. The AUA notes that the analysis under a strict liability statute, such as the Stark law, differs from the analysis that other agencies conduct for compliance with other laws and regulations. We note that whether an arrangement is or is not a "financial relationship," as defined under the Stark law, or that an arrangement satisfies the elements of an exception to the physician self-referral

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

law, is a separate and distinct inquiry from any determination by law enforcement that the arrangement does or does not violate the anti-kickback statute and should be treated as such.

Timeline for Issuing Advisory Opinions

Currently a 90-day timeline is in place for the issuance of most advisory opinions. In this rule, CMS proposed to shorten the timeline to 60-days which would begin on the date that CMS formally accepts a request for an advisory opinion and would be tolled while any outstanding request for information lies with the requestor. While this appears to be a favorable change for timelier issuance of advisory opinions, it is unclear if CMS would be able to meet such a deadline. Perhaps additional resources are needed in order to ensure that CMS can respond in a timely manner to make the guidance issued more meaningful to the requesting parties. Assurance that a request would receive a response within 60-days may be a factor in the implementation of many of the innovative payment arrangements being considered in the healthcare industry.

In conjunction with the standard timeline being shortened, CMS also put forth an expedited option. This would offer the opportunity to pay \$440 an hour for the work on an advisory opinion to have it issued within 30 days of the request. While this option would be favorable for those parties looking for an interpretation on an important issue, possibly related to a transaction with an impending deadline, this would be a helpful option only if it can be met. Certain parties would likely make use of the expedited option for as long as CMS is able to perform the required analysis in the established time period.

Certification Requirements

For the certification requirement in requests for advisory opinions, CMS proposes to revise the language to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requestor in order to ease the requirements related to a request submission. CMS is also considering eliminating the certification requirement given that section 1001 of Title 18 of the United States Code prohibits material false statements in matters within the jurisdiction of a federal agency. The AUA does not find the existing certification requirements to be unduly burdensome related to the advisory opinion process. Any change to this portion of the regulations would make the process slightly easier but we do not believe it would ultimately impact whether a requestor chooses to submit a request or not.

Fees for Advisory Opinions

CMS currently has the ability to charge requestors for an initial fee as well additional costs that exceed the initial fee. In this rule, CMS proposed adoption of an hourly fee of \$220 for preparation of an advisory opinion, which reflects the costs incurred by the agency for the work related to issuing such an opinion. The AUA is not opposed to the application of an hourly fee for the work related to issuing an advisory opinion. With the imposition of an hourly charge the AUA does not believe that the initial fee would be necessary going forward. The hourly charge may also contribute to requests being submitted only by parties

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

who are requesting meaningful advice under the process thereby limiting the potential increase in advisory opinion requests that may follow expansion of the process.

Reliance on Issued Advisory Opinions

The AUA supports CMS' efforts to consider regulatory changes that not only clarify current CMS policies but also to make advisory opinions a more useful compliance tool for stakeholders. We believe it is a helpful clarification to include the proposed change to § 411.387(a) that an advisory opinion would be binding on the Secretary of HHS and that a favorable advisory opinion would preclude the imposition of sanctions against the parties requesting the opinion, as well as any individuals or entities that are "parties to the specific arrangement with respect to which the advisory opinion is issued." We also suggest that CMS consider expanding the application of an issued advisory opinion so that it is binding not only on the Secretary of HHS but also on the Department of Justice as well as any potential qui tam relators. This would offer requestors of advisory opinions the assurance that the analysis of the agency charged with interpreting the application of the Stark law would prevent others from initiating investigations or cases contrary to a conclusion in a CMS advisory opinion.

Similarly, the proposed change at § 411.387(b) that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion would likely be helpful. Perhaps even a streamlined advisory opinion approach can be developed for such a request. For these requests, CMS will have already conducted the applicable legal analysis needed and would focus on the facts of the new request compared to the issued opinion upon which it was based. The AUA believes that this would help the industry gain the guidance it is seeking and provides CMS with a straightforward approach to provide that guidance.

Open Payments Program

Expanding the definition of a covered recipient

The AUA supports CMS' proposal to expand the definition of a covered recipient to also include "mid-level practitioners," including PAs, NPs, CNSs, CRNAs, and CNMs beginning January 1, 2022 consistent with the requirements of the SUPPORT Act. We believe this proposal will provide great transparency in manufacture reporting of payments or transfers of value made to physicians and teaching hospitals.

Data Reporting

The Open Payments program excludes certain payments or other transfers of value from having to be reported, such as educational materials intended for patient use. CMS' Open Payments Frequently Asked Questions (FAQs) published on June 28, 2019 states the following, "The educational material exclusion is limited to materials and items directly benefiting patients or intended for patient use as required by the Affordable Care Act Section 6002. Educational materials, such as medical textbooks or journal reprints, which are

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

educational to covered recipients but are not intended for patient use or directly beneficial to patients are not included in the exclusion.”⁵

The AUA disagrees with CMS’ long-standing decision to require reporting of medical textbooks and journal reprints. This requirement makes it more difficult for busy physicians to stay abreast of the latest advances in medical care.

The Sunshine Act excludes several types of “payments” from the reporting requirements, including “educational materials that directly benefit patients or are intended for patient use.”⁶ In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles, and abstracts of these articles are not directly beneficial to patients, nor are they intended for patient use. We believe this conclusion is not consistent with the reality of clinical practice where patients benefit directly from physicians keeping abreast of the most current clinical information and the agency’s conclusion is not supported by the statutory language or congressional intent.

Independent, peer reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. The exclusion for items that directly benefit patients was designed with medical textbooks and scientific medical journal supplements and reprints in mind since these clinical tools are often used side-by-side with a patient as a first resource to help diagnose and treat unfamiliar medical issues. The inclusion of these resources as reportable transfers of value presents a clear disincentive for clinicians to accept high quality, independent educational materials; an outcome that was unintended when the provision was passed into law.

The FDA noted the “important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications.”⁷ FDA guidelines provide that medical reprints should be distributed separately from information that is promotional in nature, specifically because the reprints are designed to promote the science of medicine, are educational, and intended to benefit patients. CMS’ decision not to exclude medical textbooks or journal reprints has not only made doctors less likely to accept these materials but also, according to medical societies that develop many of these educational materials, has made industry less likely to distribute these materials due to the reporting burden. We believe the Sunshine Act was

⁵ Centers for Medicare and Medicaid Services (CMS), (2019). Open Payments Frequently Asked Questions (FAQS). Retrieved from <https://www.cms.gov/OpenPayments/Downloads/open-payments-general-faq.pdf>

⁶ Patient Protection and Affordable Care Act, HR 3590, §6002. (2010).

⁷Food and Drug Administration (FDA), (2009). Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. Retrieved 9/5/19 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-reprint-practices-distribution-medical-journal-articles-and-medical-or-scientific-reference>

designed to support the dissemination of this type of educational material without unnecessary reporting.

We recommend that CMS update its interpretation to include educational materials, such as peer-reviewed journals, journal reprints and abstracts, and medical textbooks as “educational materials that directly benefit patients” and, therefore, these items should not be reported under the Open Payments program.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

While the AUA recognizes the importance of protecting the Medicare program and beneficiaries from potential harm, we believe that CMS’ enrollment policies concerning improper prescribing and patient harm do not strike the right balance with the goal of ensuring access to specialized care; are duplicative of current safety mechanisms; and create excessive uncertainty and burden for clinicians as they engage in the practice of medicine.

With respect to CMS’ proposal to specify that CMS may revoke Medicare enrollment for providers who have a pattern of improper prescribing of Part B drugs (in addition to Part D drugs), we are concerned that some specialties will be unfairly targeted and prevented from legitimate prescribing. As we have previously commented, what may be considered excessive prescribing for the general population could be clinically appropriate given a patient’s individual circumstances, particularly in pain management and palliative care. We note that many “off-label” uses are clinically appropriate and represent the standard of care.

Given the consequence of enrollment revocation or denial on a practitioner’s livelihood – including mandatory termination of participation in Medicaid and certain other federal health programs – as well as the potential impact on the availability of specialty physicians across the country including underserved areas, we believe that that CMS’ proposed standard is unacceptable and must not be finalized.

The AUA opposes CMS’ improper prescribing policies and CMS’ new enrollment revocation and denial proposals.

Physician Supervision for Physician Assistant (PA) Services

The AUA Census Statement on Advanced Practice Providers states that “in clinical practice, the role of the PA is as part of a team practicing medicine with physician supervision.⁸” The AUA opposes CMS’ proposal to revise the physician supervision requirement for PA services under Medicare. CMS proposes to grant PAs the flexibility to practice in accordance with state law requirements rather than the current general supervision requirement. In the absence of a state law, the agency proposes that the physician supervision requirement be met by “documentation in the medical record of the PA’s approach to working with physicians in furnishing their services.” With respect to those states without supervision laws, CMS’ proposal to consider the “PA’s approach to working with physicians” in

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

furnishing services fails to meet the statutory requirement that PAs must furnish services under the supervision of a physician. Additionally, CMS' proposal would create unnecessary variation in standards for care furnished by PAs, based on differences in states laws that we believe would not be appropriate for a federal program. As such, we recommend that CMS not finalize this policy, and instead retain the general supervision requirement that is currently in place.

Quality Payment Program (QPP)/Merit-Based Incentive Payment System (MIPS)

Provisions

Request for Information on a new MIPS Value Pathways Initiative

CMS is proposing a new MIPS Value Pathways (MVP) framework that would connect measures and activities across the 4 MIPS performance categories (Quality, Cost, Improvement Activities and Promoting Interoperability). The new pathways would incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. By 2021, CMS proposes to move from reporting on activities under the four MIPS performance categories and transition to the new MVP framework with a unified set of measures centered on a specific condition or specialty. Under the MVP framework, clinicians would report on a smaller set of measures that are outcomes-based, specialty-specific and more closely aligned with the Advanced APMs.⁸

The AUA agrees that many MIPS participants feel overwhelmed by the many participation options and streamlining the program such that a single set of quality data can be reported to fulfill the requirements for all four performance categories is a good idea. However, the AUA does not support making the MIPS Value Pathways (MVPs) mandatory.

When MIPS was introduced in 2017, providers, including many AUA members, made a good-faith effort to participate in the program by investing significant time, energy and capital to obtain new technology, alter workflow, hire additional personnel, and educate staff. Providers made these changes with the understanding that MIPS would be a required program for the foreseeable future. Now after only three years, CMS is proposing to significantly alter the program's reporting requirements. The agency must recognize that providers cannot afford to make additional financial investments in such a short time period. Not only will the changes required for MVP participation place a large burden to providers and practices, but it may also halt any quality improvement these clinicians might have undertaken through MIPS participation.

Providers and patients should not be penalized because MIPS is not functioning as CMS envisioned. Providers have participated in MIPS at high rates and embraced the opportunity

⁸ American Urological Association, AUA Consensus Statement on Advanced Practice Providers, 2013 Linthicum, Maryland, U.S.A., Retrieved on September 11, 2019 from <https://www.auanet.org/advocacy/comment-letters-and-resources/advanced-practice-providers>.

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

to improve quality of care. Furthermore, this is only year four; CMS should allow the program to continue for several more years without significant changes.

The AUA urges CMS to clearly indicate that the MVP is a voluntary program that may not be applicable to all specialties and conditions even after it is fully implemented. Practices that see value in the changes required by MVPs will be free to do so, and those that want to continue their established MIPS practices can do that as well. If there is as much value to MVP participation as CMS believes, then migration from “traditional MIPS” to MVPs will happen organically and at a pace that is appropriate for individual practices and providers.

Additionally, the AUA urges CMS to consider piloting the MVP program and provide an incentive, such as automatically being named an exceptional performer, for participation. Providers would be motivated by their peers who participate successfully and the pilot would allow for CMS and providers to develop a set of best practices for participation. Additionally, CMS should develop added incentives to encourage and assist small and rural practices to participate. The agency should reconsider assigning bonus points to these practices to level the playing field for them as well as make MVP participation attractive.

CMS also states that it “does not want to have too many MVPs.” While that is understandable, it is highly unlikely that one or two MVPs will be applicable to all providers in one specialty. It is nearly impossible for CMS to predict which measures or improvement activities are “meaningful” to a provider. In urology alone, a minimum of four or five MVPs would be needed to address the primary subspecialties in our field. Therefore, the AUA urges CMS not to be too restrictive when developing MVPs. The AUA is also concerned that it will be difficult for many specialists to meet the case minimums for many measures since many specialists subspecialize. We do not want to return to the days of the Physician Quality Reporting System when specialists had few relevant measures upon which to report.

CMS states that value indicators will be assigned to participants and used in Physician Compare as part of the MVPs. The value indicator will show how well a participant has scored in all four performance categories. The AUA urges CMS not to establish this indicator. The scoring methodology for each MIPS category is very complex and we are concerned that creating one composite score will oversimplify the performance data for patients. Providers that score well in all four categories will have four good scores as opposed to those with deficiencies in one performance area having that masked by high scores in the remaining areas. We do not believe that presenting a score for each category will be confusing for patients.

The AUA recommends that Qualified Clinical Data Registry (QCDR) measures be utilized within MVPs and CMS must continue to encourage their use both as part of MVPs and in traditional MIPS.

Qualified Clinical Data Registries (QCDR)

CMS proposes a number of changes related to QCDRs. The section that follows focuses on the provisions that will have the most impact on QCDRs.

QCDRs Should Not be Required to Provide Educational Services in Quality

Improvement

Since their implementation, QCDRs have become an important method for clinicians to meaningfully participate in MIPS. Most QCDRs are run by specialty societies, many of which are small nonprofit organizations. Beginning with the 2021 MIPS performance year, CMS is proposing that QCDRs must foster services to clinicians to improve quality of care to patients by “providing educational services in quality improvement and leading quality improvement initiatives.” Organizations like the AUA, with three dedicated registry staff, do not have the bandwidth to support educational services on top of the quality improvement (QI) initiatives we have already taken on.

Additionally, the purpose of QCDRs is to provide clinicians with a way to satisfy MIPS reporting obligations. While we commend QCDRs that voluntarily take on providing educational services, we do not believe this should be a CMS requirement. Requiring QCDRs to engage in additional QI, unrelated to MIPS, has no regulatory basis. We’re also concerned that proposals such as these will only increase the burden on QCDRs. The AUA is concerned these new requirements may encourage organizations to drop their QCDRs and incentive them to become QRs. This would allow the organization to continue facilitating its MIPS submissions, but face less rigorous mandates from CMS. Ultimately, this would only hurt clinicians participating in the MIPS. For these reasons the AUA urges CMS not to finalize this new requirement.

QCDR Measures Failing to Meet Benchmarking Requirements, After Two Consecutive Years, Should NOT Be Removed

Beginning with the 2020 performance period, CMS is proposing to place greater preference on QCDR measures that meet case minimums and reporting volume requirements for benchmarking. QCDR measures that do not meet this requirement, after being in the program for two consecutive performance years, would not be approved for MIPS purposes. The AUA strongly opposes this proposal. We’ve found it can take several performance years for clinicians to become familiar enough with a QCDR measure to where they are comfortable reporting on it. Therefore, two consecutive performance years is not enough time to meet the requirements needed for a CMS benchmark to be established.

Additionally, if this proposal was approved, all of the AUA’s specialty specific measures would be rejected for the 2020 performance year because we would fail to meet this requirement. This would be a huge loss to our organization, as we’ve dedicated numerous resources to the development of our specialty specific measures. Not only that, but it would also undermine AUA members’ ability to report on measures that are meaningful to their day-to-day practices. Therefore, we respectfully reject this new proposal.

Multi-Year Approval Cycle for QCDR Measures

The AUA supports the two-year approval cycle for QCDR measures. Currently, CMS approves QCDR measures on an annual basis. Beginning with the 2021 performance year, they are proposing to allow measures to receive a two-year approval assuming the measures is not topped out; duplicative of a more robust measure; reflective of an outdated clinical guideline; or in need of QCDR measure harmonization. The AUA has previously supported this policy and we thank CMS for considering it for the 2021 performance year.

We feel that this new proposal will reward registries in good standing. It will also help to reduce some of the burden associated with the annual self-nomination process. Lastly, this new policy would allow QCDRs more time to focus on developing and testing new measures, as well as validating the data we have for our existing measures. For these reasons, we urge CMS to accept this proposal.

QCDRs Measures Should Not be Required to be Fully Developed and Tested Prior to Self-Nomination

The AUA urges CMS not to finalize its proposal to require QCDR measures to be fully developed and tested prior to the self-nomination process. Currently, CMS does not require QCDR measures to be tested until after they have been implemented in the MIPS program. The AUA feels it would be extremely burdensome to invest time and money into measure testing, with no certainty that the measure will ultimately be approved by CMS. Another concern we have is that the two-month self-nomination process is not nearly enough time to fully develop and test a new measure. In order to comply with this new requirement, registries would be forced to start the measure development process much earlier in the calendar year. We urge CMS to reconsider this proposal, as we do not believe that QCDRs should be required to fully test their measures until they have been approved.

Proposed Changes to the Consumer Assessment of Healthcare Providers and Systems Survey

CMS has requested comment on expanding the use of Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for MIPS for those participating individually. The AUA supports expanding the use of this survey in this manner. We believe the information provided in this survey will be beneficial for individual reporter as well as for group reporters. Individual reporters may experience greater benefit than group reporters do since the feedback received would be tied their individual performance making the information more actionable to improve quality.

However, the AUA urges CMS to carefully consider how this survey may be expanded. We agree that there may be value in adding new measures, but the agency must consider that all providers, not just primary care providers, will use this survey. The questions must be applicable across all specialties, and the AUA recommends piloting new questions before

they are officially implemented. Another benefit of a pilot would be to determine if new open-ended, narrative questions are meaningful and actionable.

The AUA recommends CMS allow certain CAHPS questions be scored pass/fail rather than establishing a new scoring system or benchmarks. Pass/fail scoring will recognize that the true value of certain questions is the collection of patient feedback itself.

Proposed Changes to the MIPS Cost Category

CMS proposes to revise the measure attribution requirements for Cost category measures creating separate requirements for individuals and groups. The Total Per Capita Cost (TPCC) measure attribution would also be modified to exclude certain clinicians who primarily deliver certain non-primary care services. The AUA urges CMS to implement these proposed attribution changes. We believe they will prevent specialists from being responsible for care he or she never provided as well as providing a more appropriate timeframe for the care which he or she will be attributed.

Request for Information on Integration of Patient-Generated Health Data into EHRs Using CEHRT

CMS is interested in ways the Promoting Interoperability performance category could adopt new elements related to patient-generated health data (PGHD) that represent clearly defined uses of health IT; are linked to positive outcomes for patients; and advance the capture, use, and sharing of PGHD. For example, CMS asked about ways to reward providers for engaging in activities that pilot promising approaches for capturing PGHD and incorporating it into CEHRT or ways to reward those implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD. The AUA suggests that credit for such activities be given in the Improvement Activities performance category instead of Promoting Interoperability. We believe the innovation associated with expanding the use of PGHD is more consistent with the goals of Improvement Activities category rather than the Promoting Interoperability category.

Proposed Changes to the MIPS Quality Category

The AUA has observed that many MIPS participants refrain from using new measures because they will only receive three points despite their performance if the measure cannot be benchmarked. We believe this policy is unfair to those who choose to report on new measures. Instead, the AUA recommends those who report on new measures receive a higher score; however, if CMS is unwilling to do that, the measure could be scored pass/fail until a benchmark can be established. If the case minimum and data completeness thresholds were attained, the participant would “pass” and be scored on five measures. If he/she failed, then they would receive a zero for the measure and be scored on six measures.

The AUA believes CMS’ proposal to increase the performance threshold for the 2022 performance year to 45 points and 60 points in the 2023 performance year will further discourage providers to report on new Quality measures. Participants may not want to report

American Urological Association
Comments for 2020 Medicare Physician Fee Schedule Proposed Rule

on measures without benchmarks that are only eligible for three points given the total score that needs to be achieved even if these measures are more appropriate than measures that have been in the program longer.

Quality Measures

The AUA has concerns about the proposed MIPS Quality Measure A.1 International Prostate Symptom Score (IPSS) or American Urological Association – Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia. This measure was conditionally recommended by the MAP for inclusion in a federal program pending a full evaluation by NQF as there were concerns expressed regarding the feasibility of the measure collection. Specifically there were concerns about the measure’s ability to feasibly obtain response rates electronically or in a clinic setting. While the developer indicated that the measure was tested using multiple EHR formats, MAP members indicated that additional testing with multiple EHRs is encouraged and should be completed. While the AUA supports patient reported outcome measures, we recommend against including the measure in the MIPS program until a full evaluation is completed and a recommendation is rendered by the NQF.

Proposed Changes to the Improvement Activities Category

CMS requests comment on whether only Improvement Activities with clinical outcomes should be part of the program in the future. The AUA strongly opposes this. If used appropriately all Improvement Activities have value for providers and patients. While the immediate outcome may not be clinical, there may be clinical improvement in the future.

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

Sincerely,



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



David F. Penson, MD, MPH
Chair, Science & Quality Council