September 8, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

The American Urological Association (AUA) is a leading advocate for the specialty of urology, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy. On behalf of our nearly 15,000 members in the United States, the AUA welcomes the opportunity to submit comments in response to the Physician Fee Schedule (PFS) for calendar year (CY) 2016.

CY 2016 Identification of Potentially Misvalued Services for Review

Public Nomination of Potentially Misvalued Codes

In the proposed rule, the Centers for Medicare & Medicaid Services (CMS) notes that new CPT codes 52441 Cystourethroscopy with insertion of permanent adjustable transprostatic implant; single implant and 52442 Cystourethroscopy with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant were nominated for review as potentially misvalued.

It is our understanding that a statement from the manufacturer regarding the PE and cost of the implants was misinterpreted to imply that the direct practice expense (PE) inputs are inaccurate, including the cost of the implant. CPT codes 52441 and 52442 were reviewed by the RUC in April 2014 for CY 2015.
CMS agreed with the RUC recommendations for the practice expense (PE) direct inputs and their values are still accurate. The AUA believes that the PE inputs are incorrect; these codes should not be reviewed again. CPT codes for new technologies and procedures are routinely reviewed three years after their initial valuation. Therefore, we urge CMS to allow the RUC to follow its usual process and review the new codes at their routinely scheduled time. Until then, we request that CMS withdraw CPT codes 52441 and 52442 from the list of potentially misvalued services.

**Potentially Misvalued Services of $10,000,000 or More**

In the CY 2015 PFS rule, CMS proposed and finalized the high expenditure screen as a tool to identify potentially misvalued codes in the statutory category of “codes that account for the majority of spending under the PFS.” The screen looked at high expenditure services by specialty that exceed $10,000,000 in allowed charges. Included in the CY 2015 screen were CPT codes 52000 Cystourethroscopy separate procedure, 51720 Bladder instillation of anticarcinogenic agent (including retention time), 51728 Complex cystometrogram (i.e., calibrated electronic equipment; with voiding pressure studies (i.e., bladder voiding pressure), any technique, 51798 Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging, and 55700 Biopsy, prostate; needle or punch, single or multiple, any approach. CMS postponed review of these services in anticipation of the resources needed to revalue services with 10- and 90-day global periods.

For CY 2016, CMS has re-run the high expenditure screen using the same criteria finalized in last year’s rule; however, in addition to the above-mentioned CPT codes, CMS has identified CPT codes 51700 Bladder irrigation, simple, lavage and/or instillation, 51702 Insertion of temporary indwelling bladder catheter; simple (e.g., Foley) 51729 Complex cystometrogram (i.e., calibrated electronic equipment); with urethral pressure profile studies (i.e., urethral closure pressure profile), any technique, 51784 Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique are components of the urodynamics diagnostic testing, and 51797 Voiding pressure studies (VP); intra-abdominal voiding pressure (AP) (rectal, gastric, intraperitoneal).

As stated in our comments on the CY 2015 PFS proposed rule, although CPT code 52000 is identified as a high expenditure, the procedure has not changed in time, work or practice expense PE since it was reviewed during the third Five-Year Review in 2005. The RUC confirmed that a physician work RVU of 2.23 was appropriate for this code. It is vitally important that CMS recognize that the cystourethroscopy is a tool that every urologist uses to diagnose multiple urologic conditions, such as bladder cancer, urinary tract stones, hyperplasia of the prostate, and other urethra and urinary tract disorders. Without it, a major spectrum of urologic conditions cannot be properly diagnosed.

CPT code 51720 also is used by urologists in the management of bladder cancer and to reduce the risk of cancer recurrence. To effectively prevent the return of noninvasive bladder cancer, patients often receive several treatments. These treatments can reduce the
risk not only of recurrence but progression to potentially lethal and costly muscle-invasive disease. This procedure has not changed over the years in both time and PE.

CPT code 51798 was reviewed in 2002 when it was transition from a temporary G-code to a Category I CPT code, and then again during the third Five-Year Review. This is a high volume urologic tool used to determine urinary retention in patients with benign prostatic hyperplasia, strictures and other urinary conditions. The post-voiding residual urine determines the size and amount of urine retained in the bladder. Although this code has high volume, there is no physician work associated with this procedure. Historically, services without physician work have been excluded from any review screen criteria, and therefore CPT code 51798 should be removed from the screen.

CPT code 55700 also was reviewed by the RUC during the third Five-Year Review. At that time, the RUC made some changes based on survey data and determined that 2.58 was the appropriate physician work RVU for this code. This procedure is used frequently to diagnose prostate cancer when there is an abnormal digital rectal examination and a rising prostatic specific antigen. It is also essential to active surveillance, a critical strategy for low-risk prostate cancer that avoids both the morbidity and costs of surgery, radiation, and other treatment. The technology for this procedure has not changed since the last review and neither has the time and physician work.

CPT code 51700 is used with sodium chloride (saline solution) to irrigate and/or instill medications into the bladder. This procedure is commonly used to irrigate blood clots or other debris from the bladder or to administer non-chemotherapy medications into the bladder for other urologic conditions. Although CPT code 51700 has not been surveyed since 1995, over the years, the physician work, time to perform the procedures, clinical staff times, supplies and equipment (practice expense) for this procedure has not changed.

CPT code 51702 is used to insert an indwelling (Foley) urinary catheter into the bladder. In many instances, patients present to the urologist in urinary retention (the inability to urinate without assistance). This could be a result of medication complications, medical conditions, urinary tract injury or surgical complications. Urinary retention can be either chronic or acute. Acute urinary retention can cause great discomfort or pain. The inability to urinate is a potentially life-threatening medical condition requiring immediate emergency treatment. Conditions such as benign prostatic hyperplasia (BPH), urethral stricture, urinary tract stones, cystocele, rectocele, constipation, and certain tumors and cancers can cause an obstruction causing urinary retention. This procedure is used frequently in the urologic treatment for urinary retention until the cause of the retention can be addressed. Over the years, the physician work, time to perform the procedures, clinical staff times, supplies and equipment (practice expense) for this procedure has not changed.
In February 2008, the RUC reviewed CPT codes 51726, 51772, 51795, and 51797 identified through the Codes Reported Together screen, as they are reported together more than 95 percent of the time. The RUC referred all four codes to the AMA CPT Editorial Panel for creation of new CPT codes to bundle services and to reorganize the coding structure to reflect the typical procedures performed. As a result, CPT codes 51772 and 51795 were deleted. CPT code 51726 was designated as the base code, and CPT codes 51727, 51728, 51729 were bundled for CY 2010. CPT code 51797 was revised as an add-on code. These new CPT codes were surveyed by urologists and gynecologists, and the RUC assigned work values using the base code plus the survey result RVUs. The final work values were determined by CMS.

CPT Codes 51728, 51729, 51797 are urodynamic diagnostic testing codes used to determine the cause of urinary incontinence/the loss of bladder control, which is a common and often embarrassing problem in the elderly population for both men and women. There are many types of urinary incontinence: stress, urge, overflow, functional and mixed. In order to determine the type of urinary incontinence for appropriate treatment, a urodynamics test is performed to evaluate the bladder and urethral pressure during the storing and voiding of urine from the bladder. Urodynamics is the most effective test urologists have to determine the cause of incontinence in the bladder and urethra.

CPT code 51728 was reviewed by the RUC in 2009 and bundled in 2010. This procedure is used very frequently by urologists, urogynecologists and gynecologists as a diagnostic tool to evaluate and diagnose urinary incontinence in patients. The results of the test help to determine the type of urinary incontinence experienced by the patient and the subsequent treatment options. Stress urinary incontinence, the most prevalent form of incontinence among women, affects an estimated 15 million adult women in the U.S. according to the National Association for Incontinence. CPT Code 51728 refers to complex pressure evaluation in the bladder during the filling phase of the cystometrogram and the urethral pressure profile (UPP) studies the measurement of urethral closure pressures done by any technique. This code was reviewed for CY 2010 and should be removed from the screen.

CPT code 51729 is a combination of the CMG, a voiding pressure study as well as urethral pressure profile studies. The cystometrogram refers to complex pressure evaluation in the bladder, the urethral pressure profile (UPP) study and the bladder pressure study monitors the voiding stage of the bladder. This code also was reviewed for CY 2010 and should be removed from the screen.

CPT code 51797 refers to intra-abdominal pressure monitoring by rectal catheter. This is an add-on code to be used in conjunction with CPT codes 51728 or 51729. This code should be removed from the screen as well, as it was reviewed for CY 2010 along with the other codes.
CPT code 51784 involves placing patch EMG electrodes around the urethral sphincter to measure the signals in the muscles involved in bladder function to assess any potential neurological disorder that may play a role in the patient's symptoms.

For several years, CMS and the RUC have worked in tandem to identify and address potentially misvalued codes. While government investigators and health policy researchers have unfairly criticized the ability of the RUC to appropriately value physician services, the AUA believes the RUC has been highly successful in refining the value of physician services. The RUC, through its own review of the 118 high expenditure services by specialty that exceed $10,000,000 in allowed charges, identified 21 services that do not fit the criteria of the screen and should be removed. Among the 118 codes, the RUC found 9 services that CMS either agreed with the values or established new values since CY 2010. **The AUA supports the RUC’s requests that CMS remove CPT codes 51728, 51729, 51797 and 51798 from the list as they do not fit the criteria for the high expenditure screen. The AUA also encourages CMS to continue working with the RUC to ensure that the high expenditure screen supports the stated goal of the misvalued code initiative.**

The AUA plans to resubmit Action Plans to the RUC for review of the services targeted in the high expenditure screen at an upcoming meeting. **Until the RUC has had a chance to review the codes and issue recommendations for relative values, the AUA respectfully ask CMS to defer any action on CPT codes 52000, 51720, 55700, 51700, 51702 and 51784 until after such time.**

We recognize that CMS is mandated under the Patient Protection and Affordable Care Act (ACA) to identify codes that account for the majority of spending under the physician fee schedule (PFS) as part of the misvalued codes initiative. The AUA shares CMS' commitment to preventing inappropriate spending under the PFS and will do our part to recommend appropriate values for urology services. In doing so, we ask that CMS acknowledge that high utilization is inevitable for some specialties, such as urology, and that sheer volume may not be the best indicator for detecting misvalued services. The AUA has nearly 15,000 members in the U.S. Therefore, high utilization of certain services is unavoidable, particularly for diagnostic utility to tailor patient care.

To better gauge the volume of services on the high utilization list that are actually billed by urologists, the AUA conducted a comparative analysis of allowed charges in the Physician Supplier Procedure Summary (PSPS) Master File for 2008 to 2012, and the Medicare Provider Utilization and Payment Data: Physician and Other Supplier file for 2013. (Refer to Addendums A and B). The findings show the allowed charges in 2013 for CPT codes 51700, 51702, 51720 and 51797 do not exceed $10,000,000 for those with a specialty of urology. The data also show a steady decline in CPT codes 51720, 51728, 51729 over the preceding years since 2009. There also has been a consistent decline in CPT code 55700 from 2008 to 2013 (with the exception of a marginal increase in 2011). **The AUA believes**
the above-mentioned codes are not misvalued and they should be removed from the screen. We strongly recommend that, instead of pursuing a review of codes where high utilization is expected, CMS should undertake a review when warranted by circumstances, such as new clinical practice guidelines or use of new technology. We believe this would be a better approach for the misvalued code initiative.

Refinement Panel
For CY 2016, CMS is proposing to permanently eliminate the refinement panel and instead publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. CMS intends to evaluate and respond to comments received in response to the interim values for CY 2016 in the CY 2017 PFS proposed rule. While we support publication of interim final codes in the proposed rule, we believe there is minimal merit to this approach as a substitute for the refinement panel. Refinement panels are a better way to initiate a dispute and vet stakeholder concerns.

The refinement panel, in its current format, plays a critical role in reaching consensus on final values for interim final codes that have been disputed. Broad multi-stakeholder input is needed to balance the interest of the specialty societies affected by interim final values adopted in the final rule. In an August 13, 2014 joint letter to CMS, the AUA along with the American Medical Association (AMA) and several other medical societies expressed concern that, if the refinement panel is completely eliminated, CMS will no longer seek the independent advice of contractor medical officers and practicing physicians, as required under the current process. Without the refinement panel, CMS will have sole discretion in determining whether a comment is compelling enough to modify a proposed value.

The AUA’s experience with the refinement panel suggests that it is a useful process. We believe there remains an opportunity to achieve greater efficiency in the review of interim final values. Rather than eradicating the refinement panel, we encourage CMS to retain it and continue to explore ways to address the stakeholder concerns about the need for a fair and objective appeal process.

Table 11: CY 2016 Proposed Work RVUs for New, Revised and Potentially Misvalued Codes
The AUA would like to request that CMS accept the RUC recommended values for CPT code 38570 Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple; and CPT code 5443B Replantation, penis, complete amputation including urethral repair. CPT codes 38570 and 5443B were reviewed at the January 2015 RUC meeting and the RUC recommended a physician work value of 9.34 and 24.5 respectively. CMS decreased the physician work RVUs for CPT code 38570 to 8.49 and for CPT code 5443B to 22.1. CPT code 5344B is a very difficult procedure to perform and requires delicate reattachment of blood vessels and tissue to obtain function of the male genital system. The AUA believes that the values proposed by the RUC are valid for these two codes and
respectfully request that CMS reconsider the proposed physician work value for these codes.

Although CPT code 5344B is done on an emergent basis, there are clinical tasks that must be performed after the admission with insurance companies. The RUC and CPT are considering procedures with emergent surgery implications and the AUA would request that CMS allow this issue to be reviewed in its entirety to determine standards for these procedures.

In reviewing Addendum B – Relative Value Units and Related Information Used in CY 2016 Proposed Rule, CMS reduced the current physician work RVU for CPT code 55866 Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed from 32.06 to 21.36. This is an extreme reduction in this work value of almost 10 RVUs. CPT Code 55866 was reviewed by the RUC during the April 2015 meeting and recommendations for work values were sent to CMS after that date. There is no explanation or rationale in the proposed rule for this significant reduction in work value for this CPT code and the AUA believes that the decrease in physician work RVU is not appropriate for the CY 2016. CMS should correct the Addendum B to show the 32.06 work RVU for CPT code 55866.

Advance Care Planning Services
In 2016, CMS is proposing to allow separate payment for advance care planning services. In 2015, the AMA CPT Editorial Panel created CPT code 99497 Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate; and CPT code 99498 Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure) to describe complex end-of-life health care services. To establish separate payment, CMS is proposing to adopt the RUC-recommended relative values for physician work, time, and direct PE inputs.

The AUA fully supports the proposal to reimburse physicians for advance care planning services under the CY 2016 PFS. We believe an effective treatment plan should encompass the full continuum of patient care and that includes end-of-life planning. Physicians and other health care professionals invest a significant amount of time in discussing complex medical decisions and developing treatment regimens to align with patient needs. We commend CMS for recognizing the importance of advance care planning. We believe that separate payment will not only promote the value of advance care planning, but also enhance service delivery though better coordination of patient care.
Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

In 2016, CMS proposes to amend the current “incident to” policy by removing language that states the ordering and supervising physician does not have to be the same and instead, stipulate that the billing physician or practitioner also must be the supervising physician or practitioner. It is unclear whether the proposed amendment would mean that a physician in a group practice would not be permitted to directly supervise auxiliary personnel services resulting from the professional services of a physician within the same group practice, or if the proposal is intended to simply clarify that the billing physician for “incident to” services must be the same physician who supervises the services. Modifying the current regulatory language could have a profound impact on office-based services. Sometimes due to surgical scheduling, the physician who develops the treatment plan may be different from the physician overseeing the auxiliary personnel that administers the services outlined in the treatment plan. This is common when the ordering physician is on vacation, there are surgical schedule conflicts, or when a physician is called away to a hospital for an emergency. If the current language is amended as proposed, it may be difficult for group practices to correctly interpret the new policy. The AUA strongly encourages CMS to retain the current ‘incident to” policy language until the intent of the proposed amendment is clarified.

Medicare Telehealth Services

Beginning in 2016, CMS proposes to expand the Medicare list of telehealth services under the PFS to cover prolonged service in the inpatient observation setting that would require additional unit or floor time beyond the scope of usual care (CPT codes 99356 and 99357) equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

In a variety of fields, telemedicine has been used to bring healthcare services to patients in distant locations. Telemedicine programs are thought to improve patient access to care by allowing physicians and health care facilities to expand their reach beyond their own offices and connect with patients in new ways. Given provider shortages in urology that are being seen in both rural and urban areas, it is anticipated that telemedicine will be critically important in the delivery of urologic health care in the future. The AUA supports the expansion of telehealth services to cover prolonged services in the inpatient observation setting.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (PAMA) directs CMS to establish, by November 15, 2015, a program to promote use of appropriate use criteria (AUC) for advanced diagnostic imaging services defined to include diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine (including positron emission tomography (PET)); and other diagnostic imaging services specified by the Secretary in consultation with physician specialty organizations and other stakeholders.
The PAMA stipulates that applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities.

**The AUA firmly supports use of AUC developed by medical professional societies.** We believe that AUC has the ability to reduce cost through the elimination of unnecessary tests and procedures when supported by clinical evidence that protect patients and ensure high quality of care. The AUA has developed a technology assessment for imaging of ureteral calculi and encourages physicians to follow guidelines and appropriateness criteria for many tests and procedures.

Many of the AUA’s clinical practice guidelines focus on issues of overuse/overutilization with a significant emphasis placed on the importance of shared-decision making. The guidelines also recommend against screenings at health fairs that do not include shared-decision making. Given that not all specialties have developed AUCs, largely due to a limited evidence base, we believe that physicians should have freedom to choose which medical society’s AUC would be most relevant to their practice, particularly in cases where there are competing recommendations.

To implement the Medicare AUC program, CMS is proposing to define “provider-led entity” to include national professional medical specialty societies or an organization that is comprised primarily of providers, and is actively engaged in the practice and delivery of health care, such as a hospital or health system. The AUA firmly believes that in order for a hospital or health system to qualify as a provider-led entity, it should not be affiliated with an insurance company. Private insurers often employ Radiology Benefit Management (RBM) companies to control utilization of imaging services. In a March 18, 2015 AMA joint comment letter, the AUA and other stakeholders expressed concern that RBM-developed AUC will focus primarily on the reduction of utilization of tests from a resource perspective and will not properly take into account the medical necessity of tests on a patient-by-patient basis. Denial of medical services solely based on the cost of a procedure runs counter to the underlying goal of the PAMA policy.

The PAMA further mandates that physicians use clinical decision support (CDS) tools to order advanced imaging exams by 2017 or face financial penalties. The AUA has long been a supporter of CDS tools. We believe CDS tools will encourage adherence to AUC. The AUA created the benign prostatic hyperplasia (BPH) Symptom Score Index, although not a CDS tool, it is based on patient input and helps physicians quantify urinary symptoms associated with an enlarged prostate, which is critical to prostate cancer testing and treatment, as well as to non-life-threatening conditions that significantly impact quality of life, such as incontinence. The BPH Symptom Score Index also has been adopted worldwide and is known as the International Prostate Symptom Score (IPSS). The AUA believes that web-based portals and mobile applications should be recognized as applicable CDS tools.
While the AUA supports AUC and use of CDS tools, we find it extremely concerning that, starting in 2020, CMS will impose prior authorization requirements on physician outliers whose ordering practices are inconsistent as compared to their peers. Prior authorization programs are resource intensive, time consuming, and often hinder timely patient access to care. Instead of unfairly subjecting outliers to the double burden of prior authorization and CDS tools, CMS should put forth other efforts to influence adherence to AUC, such as educational and feedback programs. Ultimately, we believe over time, the overall number of outlier physicians will decline as physicians become more accustomed to using AUC and CDS tools and as technology advances to more easily incorporate CDS at the point of care. Like the AMA, we believe the trend will commence, and when it does, CMS should modify the Medicare AUC program and implement it in a manner that closely mirrors the intent of the PAMA, which is to manage imaging utilization through the use of evidence-based, physician specialty society developed AUC rather than a through use of prior authorization.

**Physician Compare Website**

**Public Reporting of Performance and Other Data**
The AUA appreciates the value of meaningful information on surgeon performance and agrees that patients should have access to this information. However, the AUA has concerns about presenting data to the public that is misleading. In order to truly provide valuable information to patients, there is a need for clinically validated data, novel and consistent methodologies, and a collective willingness by all stakeholders to collect and disseminate accurate information. We are committed to these efforts through the AUA Quality (AQUA) Registry, which has been designed to potentially provide all participating urologists in the U.S. with much deeper and more meaningful data on both clinical and patient-reported outcomes.

In accordance with the Patient Protection and Affordable Care Act (ACA), CMS plans to continue to publicly report physician performance information on Physician Compare. As the law is phased in, CMS will not publicly report a performance rate for a particular measure if the minimum threshold is not met, or the measure is otherwise deemed unsuitable for public reporting. CMS also will not publicly report first year measures, meaning new PQRS and non-PQRS measures that have been available for reporting for less than one year, regardless of reporting mechanism. In addition, CMS will continue to publicly report all measures submitted and reviewed, and found to be statistically valid and reliable in the Physician Compare downloadable file, and continue to reach out to stakeholders in the professional community, such as specialty societies, to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.

The AUA continues to support CMS’ position on the minimum threshold and public reporting of first year measures although one year may not be adequate for assessing measures. The AUA also supports the inclusion of statistically comparable measures on
Physician Compare and CMS' plan to solicit patient feedback on measures of interest to patients in plain language that are easy for Medicare beneficiaries to interpret. Additionally, the AUA agrees with exclusion of measurement data that is not consumer-friendly, and from exclusion of these data from the downloadable database. The AUA and appreciates CMS' commitment to reach out to specialty societies to ensure that measures under consideration for public reporting remain clinically relevant and accurate. We look forward to working with CMS on this effort.

As previously finalized, CMS will continue to allow a 30-day preview period for individual eligible professionals (EPs) and group practices to view their measures as they will appear on Physician Compare prior to the measures being published. The AUA repeatedly has stated that 30 days is insufficient time for physicians to review performance data collected from multiple quality programs before posted on Physician Compare. We recommend that CMS allow a minimum of a 45-day preview period for individual EPs and group practices to view their measures, as consistent with the Open Payments program 45-day review period.

Proposed Policies for Public Data Disclosure on Physician Compare
CMS is expanding public reporting on Physician Compare by continuing to make a broad set of quality measures available for publication on the website. As such, CMS is proposing to add new data elements to the individual EP and/or group practice profile pages.

Value Modifier
For the CY 2018 Value Modifier (VM), CMS is proposing to use a "green check mark" to denote individual EPs and group practices that participate in the Medicare quality program and received an upward adjustment for the VM. The 2018 VM would be based on 2016 data and included on the Physician Compare website no earlier than late 2017. The VM upward adjustment indicates that a physician or group has achieved one of the following: higher quality care at a lower cost; higher quality care at an average cost; or average quality care at a lower cost.

The AUA is opposed to CMS' proposal to include a green check mark beside the names of individual EPs and group practices who received an upward adjustment for the VM. The AUA believes CMS may be overestimating the significance of the VM information. Consumers in general, particularly elderly patients, define quality differently than CMS. The VM information is very technical and may not be as useful as CMS envisions. In fact, some consumers may find the VM information incomprehensible.

Also, we are confused as to which performance year data would be posted for the 2018 VM. The rule states that data will be posted on Physician Compare "no earlier than late 2017." Typically, there is a two-year time lag for CMS data. This statement implies that 2014 data would be published. In 2014 only practices of 100+ EPs were in the VM, and participation was voluntary in order to receive the positive incentive. We urge CMS to clarify which
performance year data will be published on Physician Compare to ensure the
information is accurately understood.

Individual EP PQRS Reporting
CMS also proposes to continue annual reporting of all PQRS measures across all individual
EP reporting mechanisms available the year following the year the measures are reported.
For individual EP measures, the measure performance rate would be represented on the
website.

The AUA cautions CMS against public reporting of all 2015 individual EP level data
on Physician Compare and advocates for a delay. In particular, reporting qualified
clinical data registry (QCDR) individual EP level data is premature, as QCDRs are still in
their early stages. QCDR reporting is less than two years old; additional time is needed for
medical societies to collect, test, and set accurate benchmarks for new measures before
public disclosure. Premature posting may be an incentive for providers with low quality
scores to not participate in a QCDR. It also may incentivize some specialty societies to focus
on “safe” measures that are easy to meet and will not get at the real questions of varying
quality. The AUA plans to self-nominate as a QCDR in January 2016. While a pilot project
currently is underway, no organization can foresee how a QCDR will fare once it is fully
enacted. Therefore, it would be beneficial to allow medical societies a full year or more of
operation before fully disclosing all information to the public.

Individual EP and Group Practice QCDR Measure Reporting
Starting with 2015 data, CMS decided to make individual EP level QCDR measures, both
PQRS and non-PQRS measures, available for public reporting. As mandated by the
Medicare and CHIP Reauthorization Act (MACRA), CMS is proposing to make group practice
level QCDR PQRS and non-PQRS measures that have been collected for at least a full year
available for public reporting the year following the year the measures are reported. To
facilitate this effort, CMS proposes, under the Physician Quality Reporting System (PQRS),
to expand QCDR data to be available to group practices as well. For both EP and group
level measures, the measure performance rate would be represented on the Physician
Compare website.

In addition, the QCDR would be required to declare during its self-nomination if it plans to
post data on its own website and allow Physician Compare to link to it, or if the QCDR will
provide data to CMS for public reporting on Physician Compare. After a QCDR declares a
public reporting method, that decision would be final for the reporting year. If a declaration
is not made, CMS would consider the data available for public reporting on Physician
Compare.

Reporting of quality measures through a QCDR has several advantages that will enable AUA
members to successfully participate in PQRS because they will have a broader set of
measures to select from and QCDR measures are more relevant to the practice of urology.
The AUA supports CMS' proposal to make group practice level QCDR PQRS and non-PQRS measures available for public reporting and the proposal to make the QCDR reporting mechanism available to those electing to participate in the PQRS via the Group Practice Reporting Option (GPRO).

**Benchmarking**

CMS is proposing to publicly report on Physician Compare an item or measure level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology, which is annually calculated based on current year PQRS performance rates. The benchmark would only be applied to those measures deemed valid and reliable and that are reported by enough EPs or group practices to produce a valid result. CMS also proposes to use the ABC™ methodology to generate a benchmark that can be used to systematically assign stars for the Physician Compare 5 star rating system.

The AUA appreciates that CMS went to great lengths to reach out to stakeholders to identify the best possible benchmark methodology for Physician Compare’s five-star rating system. We agree with CMS that a five-star rating would enable consumers to better compare both physician groups and individual physicians. Even though the ABC methodology may be a well-tested, data-driven methodology, as noted in the rule, it is not entirely clear whether the benchmark methodology will apply to Physician Compare. The concern with the ABC methodology is that it has not been well tested outside of the primary care settings and only applied to substantially smaller projects. **Until the ABC methodology is further tested to ensure that it is appropriate for Physician Compare, the AUA encourages CMS to maintain the current system to avoid future drawbacks.**

**Downloadable Database**

To further aid in transparency, CMS proposes to add to the Physician Compare downloadable database the VM tiers for cost and quality, based on the 2016 data, noting if the group practice or individual EP is high, low, or neutral on cost and quality; a notation of the payment adjustment received based on the cost and quality tiers; and an indication if the individual EP or group practice was eligible to report quality measures to CMS, but did not. In addition, CMS proposes to publicly report in the downloadable database utilization data for EPs. Because the downloadable database is geared toward health care professionals, industry insiders, and researchers, rather than Medicare beneficiaries, CMS is proposing to include the VM information in the downloadable database rather than the physician profile pages.

The AUA is firmly opposed to the inclusion of VM information on Physician Compare, regardless of the format. The recently published ProPublica Inc. Surgeon Score Card is a perfect example of well-intentioned third parties using data to draw conclusions that are inaccurate. If CMS does not choose to include data on a physician’s profile page, then that information should not be accessible to the general public via any other mechanism. Releasing the pertinent raw data to specialty societies would be of greater value than
making it available to the general public in a downloadable file. Societies can then work with providers to interpret the data and determine how it could be used to help improve their performance which is the ultimate goal of the federal quality reporting programs.

**Seeking Public Comment for Possible Future Rulemaking**

In future years, CMS will consider expanding public reporting on Physician Compare to include information on quality measures, Medicare Advantage, the VM, Open Payments and measure stratification based on race, ethnicity, sex, primary language and disability status, within each of the PQRS reporting mechanisms. **The AUA supports such stratification but remains concerned about the data collection burden on the provider as well as use of appropriate adjustment methodologies that must be fully tested.** The purpose of quality reporting, which is to improve care, should always be paramount. Consequently, CMS should weigh provider burden against value of the data collected and continually question how the information would enable a provider to change behavior to ultimately improve care.

**Quality Measures**

CMS acknowledges there are gaps in the measures currently available for public reporting on Physician Compare and is seeking feedback from stakeholders about the types of quality measures that will help fill the gaps and meet the needs of consumers and stakeholders. The AUA applauds CMS for seeking suggestions for additional quality measures to report on Physician Compare. There remains a lack of urology-specific measures relevant to AUA members upon which they can act to improve quality of care. Measures specific to the practice of urology will help guide consumers trying to compare providers and make informed decisions about their health care services.

**Value Modifier**

CMS is seeking comment on whether to include in future rulemaking an indicator for a downward and neutral VM adjustment on group practice and individual EP profile pages, along with VM quality composite or other VM quality performance data for individual EPs, groups and in the Physician Compare downloadable database. **As previously stated, the AUA is opposed to including VM information on Physician Compare.** We caution CMS against publishing negative information, out of concern that the information may contribute to confusion among consumers, and more importantly, may have negative consequences for physicians if the information is inaccurate.

**Open Payments Data**

CMS is seeking comment about including Open Payments data on Physician Compare; to the extent it is feasible and appropriate. **The AUA strongly advises against including Open Payments data on Physician Compare.** Open Payments data is full of errors attributed to inaccurate payment information submitted by drug and device manufacturers. As CMS points out, Open Payments data are already publicly available. This would be a redundant effort on the part of CMS.
The AUA recognizes the significant effort CMS has made to improve the physician information available on Physician Compare. Unfortunately, the system is still riddled with errors and inconsistencies. We would like to use this comment period to reiterate several concerns about Physician Compare. Previously, the AUA polled members about their information on Physician Compare. The results of the poll indicated the following problems still exist:

- Providers are not listed despite notifying CMS about the issue several times,
- Misspelling of names and practice addresses occur,
- Incorrect list of practices and/or hospital affiliations,
- Physicians who left a practice are still associated with that practice and/or location; and
- Incorrect medical school are listed along with incorrect languages spoken.

The information on Physician Compare must not only benefit Medicare beneficiaries. CMS also must ensure that the information is accurate to safeguard physicians from unintended negative consequences. Accuracy is the greatest challenge we see for CMS to successfully move forward with expansion of Physician Compare. The AUA strongly urges CMS to focus on correcting the inaccuracies in Physician Compare before taking on the addition of more data.

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

Proposed Changes to the Requirements for the QCDR

Who May Apply to Self-Nominate to Become a QCDR
CMS is changing the self-nomination requirements to require that QCDRs provide timely feedback, at least 4 times a year on the measures at the individual participant level on the EPs behalf for the purpose of satisfactory participation in the QCDR. The AUA supports the proposal to provide feedback multiple times per year as opposed to once a year. More frequent updates will allow for more accurate reporting and timely feedback facilitates improvement in quality.

Self-Nomination Period
Starting in 2016, CMS proposes to open the self-nomination period on December 1 for the following year to allow more time for entities to self-nominate. The AUA commends CMS for the clarification and additional month to self-nominate a QCDR. Previously, there was no guidance for when the QCDR self-nomination period opened.
Proposed Establishment of a QCDR Entity

Beginning in 2016, CMS proposes for an entity to become qualified for a given year, the entity must be in existence as of January 1 of the year it seeks to become a QCDR, as opposed to having to be in existence a year in advance. The AUA supports the proposal that entities wishing to become a QCDR no longer demonstrate that they were established for 1 full year prior to self-nomination.

Attestation Statements for QCDRs Submitting Quality Measures Data during Submission

Currently, a QCDR entity is required to submit to CMS, via email, written attestation that all data, including the numerator and denominator, are accurate and complete. For 2016, CMS is proposing to allow QCDRs to attest during the data submission period using a web-based check box mechanism. If the proposal is finalized, email will no longer be an option. In addition, CMS is proposing to change the submission deadline from March 31 to January 31 for all documents, including measure information, necessary to determine an entity’s qualification as a QCDR. Once the information is submitted, it cannot be changed. The AUA is opposed to changing the deadline to January 31, as a truncated deadline may cause challenges for entities self-nominating for the first time and would eliminate the amount of time that QCDRs would have to go back and make modifications if needed.

Proposed Criteria for Satisfactory Reporting on PQRS Quality Measures Via the GPRO Web Interface for the 2018 PQRS Payment Adjustment

For the 2018 payment adjustment, CMS is proposing to require the reporting of the CAHPS for PQRS survey for groups of 25 or more EPs who register to participate in PQRS GPRO and select the GPRO web interface as the reporting mechanism. In addition, those groups must pay to have the CAHPS for PQRS survey administered on their behalf. The AUA remains opposed to this requirement; we find it inappropriate for CMS to burden group practices with the cost of administering the CAHPS survey in order to use the GPRO web interface. Moreover, we do not find the CAHPS for PQRS survey to be an adequate survey for all providers, particularly specialists, and we advocate that CMS expand the survey options available to participants.

Proposed Criteria for Satisfactory Participation in a QCDR for Group Practices Registered To Participate in the GPRO via a QCDR for the 2018 PQRS Payment Adjustment

Also for the 2018 PQRS payment adjustment, CMS is proposing to use the same criterion for group practices as individual EPs to satisfactorily participate in a QCDR. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report at least 9 measures available for reporting under a QCDR covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice’s patients. Of these measures, the group practice would report on at least 2 outcome measures, or if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures – resource use, patient
experience of care, efficiency/appropriate use, or patient safety. The AUA supports group reporting via a QCDR. It is a disadvantage when all reporting mechanisms are not available options for all providers. Adding GPRO to QCDRs will enable many practices to successfully participate in PQRS.

Proposed New PQRS Measures Available for Reporting for 2016 and Beyond and Proposed Changes to Existing PQRS Measures

CMS is proposing to include in the PQRS measure set for CY 2016 and beyond 6 new measures developed by the American Urogynecologic Society for urology/urogynecology services. For many years, the AUA has noted the lack of urology-related measures in previous comment letters. The AUA appreciates CMS’ recognition of urology/urogynecology as an area in need of measures despite the lack of National Quality Forum endorsement of these measures. Even though these measures cannot be reported by all urologists, it is a step in the right direction to have these measures available.

Multiple Chronic Conditions Measures Group for 2016 and Beyond

CMS is proposing to add a new Multiple Chronic Conditions Measures Group for 2016 to recognize providers who treat patients with multiple chronic conditions. The AUA supports the addition of the Multiple Chronic Conditions Measures Group to address the complexity of care that is required for patients who may have multiple disease processes that require clinical management and treatment. Previously, the AUA has commented that there are not enough measures groups that may be reported by multiple specialties. With the addition of this new measures group, many specialties should be able to adapt their practice patterns to utilize this measures group; thus making it easier for many to successfully participate in the PQRS.

Medicare Shared Savings Program

Request for Comment Related to Use of Health Information Technology

CMS is seeking comments on a quality measure related to use of health information technology within an accountable care organization (ACO) and how the measure might evolve in the future to ensure the Agency is incentivizing and rewarding providers for continuing to adopt and use more advanced health information technology. Currently, quality measure ACO #11 - Percent of PCPs who Successfully Meet Meaningful Use Requirements under the Care Coordination/Patient Safety domain is applicable only to eligible primary care providers who adopt, implement, or upgrade EHR technology, in addition to those who received payment for meeting Meaningful Use requirements.

Since the initial EHR quality measure was finalized in 2011, the Electronic Health Record (EHR) Incentive Program and Meaningful Use requirements have shifted from an initial focus on technology adoption and data capture to interoperability to exchange of data across systems, and the use of more advanced health information technology functions to support care coordination and quality improvement. In June, CMS issued a final rule that
will enhance the ability for certain specialists, including urologists, to participate in multiple ACOs starting in 2016.

We appreciate CMS’ willingness to consider changes to the Medicare Shared Savings Program for ACOs that will recognize other physicians that successfully coordinate patient care and communicate with their primary care physician colleagues. In light of the recent EHR Incentive Program and ACO policy developments, we urge CMS to broaden the focus of the measure beyond primary care physicians to all physicians participating within an ACO, including specialists. We believe that expansion of the measure will encourage greater adoption and use of more advanced health information technology among ACO participants.

**Physician Value-Based Payment Modifier and Physician Feedback Program**

**Approach to Setting the VM Adjustment Based on PQRS Participation**

For the 2018 VM, CMS is proposing to change the criteria for groups to be included in Category 1. CMS would consider whether the 50 percent threshold has been met regardless of whether the group registers for the PQRS GPRO reporting option. That way, if a group registered for PQRS through GPRO fails to satisfactorily report, the quality data reported by the individual EPs in the group can be taken into account for the 2018 VM. The AUA supports this proposal.

For the CY 2018 payment adjustment period, CMS also proposes to apply full quality tiering methodology for all physicians. For groups with between 2 to 9 EPs and physician solo practitioners, CMS will begin both the upward and downward payment adjustments under the quality-tiering methodology for the 2018 VM and will disseminate QRURs in the fall of 2015. CMS believes this will be adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2018. CMS will continue to monitor the policy for anomalous effects. **Solo practitioners need additional time to transition to the VM program, therefore the AUA is firmly opposed to application of the quality-tiering methodology to all group and solo practitioners for the 2018 payment adjustment.**

While we appreciate CMS’ willingness to monitor the policy, however, we disagree that QRURs provide the best predictor for future performance. The purpose of the QRURs is to help physicians understand their performance and identify practice opportunities for improvement. Despite CMS’ efforts to improve the QRURs, our members continue to find the cost and quality score calculations confusing.

In addition, the AUA will continue to monitor CMS’ work on developing episode-based cost measures. We have begun work on episode-based groupers within urology but recognize the challenges that these measures represent for surgical specialties.
Application of the VM to Groups and Solo Practitioners Who Participate in Multiple Shared Savings Program ACOs

Beginning with the CY 2017 payment adjustment period, CMS is proposing that Tax Identification Number (TIN) that participates in multiple ACOs during the same performance period would receive the quality composite score of the ACO that has the highest numerical quality composite score. Given the recent ACO final rule that will permit urologists to participate in multiple ACOs starting in 2016, the AUA supports this proposal.

Application of the VM to Solo Practitioners and Groups with EPs Who Participate in the Comprehensive ESRD Care Initiative, Oncology Care Model, and the Next Generation ACO Model

For participants in the Oncology Care Model, the Pioneer ACO Model and other applicable alternative payment models, CMS is proposing to waive the VM to minimize conflicting incentives between programs with regard to the evaluation of quality of cost and care, beginning with the CY 2017 adjustment period. The AUA fully supports the proposal to waive application of the VM for solo practitioners and groups participating in the specified alternative payment models.

Benchmarks for eCQMs

Currently, the VM program uses quality of care measure benchmarks based on PQRS reporting mechanisms (claims, registries, EHR, or Web Interface). CMS has become aware that a given measure may be calculated differently when it is collected through an EHR, and therefore is proposing to change the policy to create separate eCQM benchmarks. The AUA supports the proposal to apply separately appropriate benchmarks for eCQMs.

Minimum Episode Count for the Medicare Spending Per Beneficiary (MSPB) Measure

CMS currently uses a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a TIN's cost composite. CMS acknowledges this number is reliable for non-specialists, but not for specialists. Therefore, CMS is proposing to increase the episode minimum from 20 to 100 episodes beginning with the 2017 payment adjustment period. CMS further notes that this change in policy could create a situation in which a group that would have performed well on this measure would no longer have this measure included in its cost composite, which could negatively impact their cost composite, and ultimately their VM adjustment. The AUA recommends that CMS change the method rather than increase the number of episodes if the methodology is not reliable for an accurate composite.

Physician Self-Referral Updates

New Exception: Non-Physician Practitioner (NPP) Recruitment and Retention Exception
Limitation to Primary Care Services Only
CMS is proposing a new exception for assistance to physicians to employ non-physician practitioners (NPPs), but limiting it in a manner that promotes the expansion of access to primary care services only. As proposed, this new exception would limit the type of NPPs who qualify for this exception and would require the NPPs to furnish only primary care services to the patients of the physician's practice. The AUA urges CMS to expand the exception to permit the recruitment of NPPs into urology practices to permit increased access to urology care.

Safeguards Against Program and Patient Abuse
CMS is proposing to include the same general safeguards included in the current physician recruitment and other exceptions to prevent program and patient abuse and is seeking comments as to whether additional safeguards are necessary for arrangements to assist NPP employment. The AUA submits that including only the general safeguards in the new NPP exception is sufficient, and any additional safeguards would unnecessarily restrict the availability of this new exception.

Time Limitations
As proposed, the new exception for assistance to employ a NPP would limit the period of time during which assistance may be provided to two years. The AUA considers such a limitation to be unnecessary and inconsistent with the exception for recruitment of physicians.

Writing, Term, and Holdover Provisions in Certain Exceptions and Other Regulations.

Writing Requirement
CMS has stated that a collection of documents may satisfy the writing requirement and that an arrangement does not have to be reflected in a formal, single, written agreement. Rather, a collection of documents, including contemporaneous documents evidencing a course of conduct between the parties, may satisfy the requirement that an arrangement be set out in writing. For this reason, CMS is proposing to remove the term "agreement" from certain compensation exceptions and the special rules on compensation (excluding from this proposal the exception for group practice arrangements with hospitals and the exceptions for electronic prescribing and electronic health records). The AUA endorses this clarification and recommends that CMS consider providing further guidance regarding what constitutes a "signed" written agreement. Specifically, CMS should include the clarification that certain signed documents (for example, signed time records, checks, electronic signatures, and/or approvals) would satisfy the requirement that the arrangement be set out in writing and signed by the parties.
Term for One Year
CMS has stated that for those exceptions requiring a term of at least one year, the term does not have to be established by a formal, written agreement. Rather, it is sufficient that the arrangement lasts "as a matter of fact" for at least one year and that the parties (1) have contemporaneous writings establishing that the arrangement lasted for at least one year, or (2) are able to demonstrate that the arrangement was terminated during the first year and that they did not enter into a new arrangement for the same space, equipment, or services during the first year. For this reason, CMS is proposing to remove the term "agreement" and other language the rental of office space exception, the rental of equipment exception, and the personal services arrangement exception. The AUA commends CMS in making this clarification and is fully supportive of this proposal.

Holdovers
For exceptions that permit holdovers, CMS has proposed to eliminate the time limitations for the holdover. Thus, an arrangement could holdover indefinitely if it continues on the same terms as the original arrangement and continues to comply with the requirements of the applicable exception. CMS has requested comments as to whether it should extend the holdover to a definite period of time (e.g., one-, two-, or three-year periods) or for a period of time equivalent to the immediately preceding arrangement. In addition, CMS has requested comments on "what additional safeguards, if any, are necessary to ensure that holdovers lasting longer than 6 months do not pose a risk of program or patient abuse." The AUA views the indefinite holdover period as providing flexibility without creating additional fraud and abuse risk. Further, requiring that the holdover be on the same terms and conditions as the immediately preceding arrangement, which already meets the requirements of the applicable exception, provides sufficient safeguards, and therefore, no additional safeguards are necessary.

Exceptions Permitting Holdovers/Fair Market Value Exception
There are currently three exceptions that permit holdovers: the rental of office space exception, the rental of equipment exception, and the personal services arrangements exception. The AUA believes that the fair market value exception is substantially similar in nature to these other exceptions, and for this reason, CMS should include holdovers in the fair market value exception. In the event that CMS decides not to apply holdovers to the fair market value exception, the AUA would support a revision to the fair market value exception permitting renewals for any length of time.

New Exception: Time Share Arrangements

Limiting the Exception to Arrangements in Rural and Underserved Areas
CMS has requested comments on whether the proposed exception should be limited to arrangements in rural and underserved areas. The AUA believes that such a limitation is unnecessary and would serve to diminish the positive impact that the exception
would afford beneficiaries in having greater choice of location where physicians choose to offer services in areas where they otherwise do not have a full-time office.

**Equipment Covered by the Arrangement/Use of Advanced Imaging**
CMS is proposing to exclude from the exception the licensing of certain equipment, including advanced imaging equipment, radiation therapy equipment, and clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests). **The AUA asserts that there should be no limitations on the types of services provided in a timeshare arrangement because patient access to care and immediate diagnoses would be hampered by such limitations.** For example, urologists often use CT scans for the purpose of immediately diagnosing kidney stones. Excluding such services would adversely affect patient care. Further, any services provided in timeshare arrangements would need to meet the in-office ancillary exception, and thus, there are already built-in safeguards to address potential risks of program and patient abuse.

**Equipment Covered by the Arrangement/Location of Equipment**
As proposed, the timeshare arrangement exception would require that the equipment covered by the arrangement be located in the office suite where the physician performs evaluation and management services. CMS has requested comments on “whether the equipment location requirement should be expanded to include equipment located in the same building as the licensed office suite or an off-site location, and whether [CMS] should prohibit the license of equipment in the absence of a corresponding license of office space.”

**The AUA views the use of the “same building” standard in the timeshare arrangement exception to be consistent with the in-office ancillary exception and therefore supports the expansion of the equipment location requirement accordingly.** As an additional safeguard, where there are two lease locations (one with evaluation and management services and the other with equipment and DSH services), CMS could require that the two locations be (1) included in a single arrangement, and (2) used on identical schedules.

**Temporary Non-Compliance with Signature Requirement**
CMS proposes to revise 42 C.F.R. §411.353(g) “to allow parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent.” **While the AUA is fully supportive of this proposed change, it requests that CMS not limit an entity to using this exception once every three years.** The AUA believes that this exception should apply regardless of previous use and that permitting its use without such a restriction would not increase the risk of program and patient abuse.

**Conclusion**
In closing, we appreciate this opportunity to share our comments on the Physician Fee Schedule proposed rule for CY 2016. Stakeholder input is vital to the development process
and we look forward to continuing to work with CMS as the rule progresses. If you have any questions or wish to discuss our comments, please contact Lisa Miller-Jones at (410) 689-3772 or lmiller@auanet.org.

Sincerely,

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