American Urological Association

BOARD OF DIRECTORS
Officers
William W. Bohnert, MD
President

William F. Gee, MD
President-elect

Pramod C. Sogani, MD
Immediate Past President

Gopal H. Badlani, MD
Secretary

Manoj Monga, MD
Secretary-elect

Steven M. Schlossberg, MD, MBA
Treasurer

Section Representatives
Craig A. Peters, MD
Mid-Atlantic

Kevin R. Loughlin, MD, MBA
New England

Muhammad S. Choudhury, MD
New York

Stephen Y. Nakada, MD
North Central

John D. Denstedt, MD
Northeastern

Randall B. Meacham, MD
South Central

Thomas F. Stringer, MD
Southeastern

Jeffrey E. Kaufman, MD
Western

Headquarters
Michael T. Sheppard, CPA, CAE
Executive Director

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

August 29, 2014 ***Submitted electronically***

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services,
Attention: CMS-1612-P,
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 [CMS-1612-P]

Dear Administrator Tavenner:

The American Urological Association (AUA), representing more than 90 percent of practicing urologists in the United States, welcomes the opportunity to submit comments in response to the above proposed rule. The long-standing mission of the AUA is to promote the highest standards of clinical urological care through education, research, and formulation of health care policy. Our comments will address the areas of the proposed rule that are of most concern to our members. We appreciate your attention to the concerns of America's urologists.

II. PROVISIONS OF THE PROPOSED RULE FOR PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

Changes to Direct PE Inputs for Specific Services

RUC Recommendation for Monitoring Time following Moderate Sedation

CMS is proposing to accept, without refinement, the RUC recommendation to adjust the clinical labor minutes for post-procedure moderate sedation monitoring and post-procedure monitoring. **The AUA supports this decision, as the proposed change would add 15 minutes of RN time for one hour of post-procedure moderate sedation and post-procedure monitoring.** As a result, clinical labor minutes for CPT codes 50593 (Ablation, renal tumor(s), unilateral, percutaneous,

cryotherapy) would be increased from 30 to 60 minutes and CPT code 50200 (Renal biopsy; percutaneous, by trocar or needle) would be increased from 15 to 60 minutes, which is a more accurate reflection of the monitoring time for this procedure.

Radiation Treatment Vault

For 2015, CMS proposes to remove the radiation treatment vault as a direct PE input from radiation treatment delivery CPT code 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLS, per treatment session). CMS believes that the requirements for the vault reflect building and infrastructure costs (indirect PE), rather than medical equipment costs (direct PE).

This proposed shift in PE policy comes just before CMS will unveil wholesale changes to the radiation treatment delivery code set in the 2015 Physician Fee Schedule final rule. We believe it is premature for the agency to make a determination on removing the vault as a direct PE when the agency is scheduled to introduce significant payment rate changes to the radiation treatment delivery code set in the final rule, and the new and revised codes are published in the 2015 CPT book. **Due to the potential enormity of the payment changes for CPT code 77418, the AUA urges CMS to reconsider the proposed radiation treatment vault policy change and delay any final decisions until after the radiation oncology coding changes are implemented.**

Updates to Price for Existing Direct Inputs

In the proposed rule, the Centers for Medicare & Medicaid Services (CMS) seeks stakeholder input on the best approach to use sample invoices to ensure the rate setting process to update equipment and supply prices remains transparent. The AUA appreciates CMS' willingness to maintain an open and transparent process for pricing direct inputs. **To ease the difficulty in obtaining accurate pricing information, we suggest that a sample of paid invoices collected from practices be obtained and submitted with the practice expense (PE) materials to the AMA/Specialty Society Relative Value Scale Update Committee (RUC), or submitted directly to CMS.** The costs associated with the equipment and supplies should then be averaged and utilized in the direct PE to determine a "typical" price.

Using OPPS and ASC Rates in Developing PE RVUs

In the proposed rule, CMS is soliciting comments on the possible uses of the Medicare hospital outpatient cost data in potential revisions of the PE methodology for the Physician Fee Schedule. CMS notes that the resulting fee schedule payment amounts would not necessarily conform to outpatient payment amounts since outpatient payments are grouped into APCs, while fee schedule payments would continue to be valued individually and would remain subject to the relativity inherent in establishing PE RVUs, budget neutrality adjustments, and fee schedule updates. CMS is particularly interested in comments that compare such possibilities to other broad-based, auditable, mechanisms for data collection, a wide range of options for gathering and using the data, including using the data to validate or set resource assumptions for only a subset of fee schedule services, or as a base amount to be adjusted by code or specialty-level recommended adjustments, or other potential uses.

The AUA commends CMS for the decision to delay use of outpatient hospital rates to develop PE payment rates for physician services, and for recognizing that hospital cost data are not an appropriate proxy with which to establish PE RVUs, as these data would result in inaccurate estimates of physician PE. In the hospital setting, APC rates result in payments that exceed hospital costs for some procedures and which are below hospital costs for other procedures. Because hospitals offer a broad range of services, they can more easily leverage cost shortfalls against cost gains. By contrast, physician practices billing under the fee schedule typically do not provide a broad range of services and, therefore, would be incentivized to drop procedures where payments fall below costs.

As stated in our comments on the 2014 Physician Fee Schedule proposed rule, the statutorily mandated Resource-Based Relative Value Scale (RVRVS) system, is intended to capture direct and indirect resource costs for physician services on a line-by-line item basis supported by invoices to reflect actual cost. Using hospital data would not meet the statutory requirement to determine physician practice costs. **For the most accurate source of physician practice costs, we recommend CMS continue working with the RUC to gather survey data of specific procedures.** The AUA believes this is the most stringent and effective way to appropriately value supplies and equipment used by physician practices.

Starting January 1, 2015, CMS proposes to collect data across two different payment systems through use of a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on both the CMS-1500 claim form for physician services and the UB-04 (CMS form 1450) for hospital outpatient claims. CMS is seeking comments on whether a code modifier is the best mechanism for collecting this service-level information.

We believe a code modifier is not the best mechanism for collecting this level of service data for off-campus provider-based outpatient departments. With the reporting requirements to satisfactorily participate in PQRS and other quality initiatives, required use of a code modifier would be an additional burden for physician practices. We urge CMS to be cognizant of the need to reduce physician reporting burden. While we do not support CMS' proposal to require physician practices to use a code modifier, if CMS can modify their system to automatically append the modifier, then this may be an effective method for collecting PE data. If it is not possible for CMS to make the adjustment to their system, then the agency should consider creating a new site of service code instead of a modifier, or execute this effort as a demonstration project under the Center for Medicare and Medicaid Innovation (CMMI).

B. Potentially Misvalued Services Under the Physician Fee Schedule

Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More

In 2015, CMS intends to review approximately 65 codes, as part of the ongoing effort to identify potentially misvalued services. Specifically, CMS proposes to review a subset of potentially misvalued codes under a newly established statutory category, "codes that account for the

majority of spending under the physician fee schedule." To capture such services for this new category, CMS has looked at high expenditure services by specialty that exceeds $10 million in allowed charges. Included in this subset are CPT codes 51720 (Bladder instillation of anticarcinogenic agent (including retention time)), 51728 (Complex cystometrogram (ie, calibrated electronic equipment); with voiding pressure studies (ie, bladder voiding pressure), any technique), 51798 (Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging), 52000 (Cystourethroscopy (separate procedure)) and (55700 Biopsy, prostate; needle or punch, single or multiple, any approach).

The AUA supports CMS' efforts to ensure appropriate valuation of codes and is committed to ensuring the accuracy of the services flagged for review. CPT code 51720 is widely used by urologists in the management of bladder cancer and to reduce the risk of cancer recurrence. Although CPT code 52000 is identified as a high expenditure, the procedure has not changed in time, work or PE since it was reviewed during the third Five-Year Review in 2005. CMS must recognize that cystourethoroscopy is an essential diagnostic tool in the urologists' armamentarium. Without it, a major spectrum of urologic conditions, such as bladder cancer, urinary tract stones, hyperplasia of the prostate, and other urethra and urinary tract disorders, cannot be properly diagnosed. In both cases, high utilization for these services is inevitable, but that should not be interpreted as inappropriately valued.

The AUA understands CMS' attention to services that account for the majority of spending under the physician fee schedule. Action Plans have been submitted to the RUC for review of the codes at the September 2014 meeting. While we fully support CMS' continued effort to identify potentially misvalued codes, we recommend the agency continue to work with the RUC to ensure the content of the misvalued screens are accurate and appropriate. **With the RUC meeting fast approaching, we respectfully urge CMS to defer any action on CPT codes 51720, 51728, 51798, 52000 and 55700 until after the RUC has completed its review and issued recommendations for the relative values.**

CMS has been vigorously engaged in the misvalued code initiative for several years now. The ACA initially directed CMS to periodically review and identify potentially misvalued codes and make appropriate adjustments to the relative values in 7 categories. CMS also recently combined the misvalued code initiative and the Five-Year Review into an annual rolling review process. In addition, CMS has ongoing contracts with the RAND Corporation and the Urban Institute to develop validation models for RVUs. Most recently, the Protecting Access to Medicare Act of 2014 (PAMA) further expanded the categories of misvalued codes to examine by adding 9 additional categories. Collectively, CMS has 16 existing misvalued screens, and is proposing to add another "new" screen to the review process.

Specific requirements in law compounded by CMS' interpretive requirements have led to excessive and overlapping regulatory efforts to identify and revise potentially misvalued codes. The continued issuance of code reviews has resulted in numerous screens. Specialty societies invest a significant amount of time and resources to analyze data for service reviewed by the RUC. The extreme and competing efforts to identifying misvalued codes continuously imposes

undue financial hardship on specialty societies because the codes often have to be re-surveyed without any added benefit to the ultimate goal of appropriately valuing codes

We believe it is possible to lessen the burden of additional review screens without compromising the agency's ability to accomplish its goals and successfully maintain the intent of the law. **We encourage CMS to assess their approach to identifying and reviewing potentially misvalued codes and the timeliness of this effort. The effectiveness of the overzealous direction of the misvalued code initiative needs to be evaluated to determine whether it is having the desired impact.**

Prostate Biopsy Codes – HCPCS codes G0416, G0417, G0418, and G0419

In 2015, CMS proposes further changes to the HCPCS codes for prostate biopsy pathology services. Specifically, the agency proposes to revise the descriptor for G0416, which is currently used to report the gross and microscopic examination using any method for 10-20 prostate needle biopsy specimens, and to delete codes G0417, G0418, and G0419 to eliminate possible confusion caused by the coding. CMS also proposes to use existing values for G0416 for CY 2015. In addition, CMS has identified G0416 as a potentially misvalued service and is therefore seeking public comment on the appropriate work RVUs, work time, and direct PE inputs for G0416.

The AUA disagrees with the agency's conclusion that to establish "straightforward coding and maintain accurate payment", it would be appropriate to use only one "G" code to report prostate biopsy pathology services regardless of the number of specimens. If fact, we are certain that another coding change in the code descriptors for the G codes - the second revision within a two year period - would only create further confusion for physicians and their administrative staff, who have not had time to adapt to the coding changes implemented this year.

In the 2014 Physician Fee Schedule final rule, CMS implemented a change to HCPCS codes G0416, G0417, G0418 and G0419 to revise the descriptors by deleting the phrase "saturation biopsy sampling" and replacing it with "biopsies, any method." This substantive change in reporting the surgical pathology gross and microscopic examination and prostate needle biopsies was done in final rulemaking without a proposed rule with a comment period. Further change at this point would not create greater clarity.

Further, since the creation of HCPCS codes G0416, G0417, G0418 and G0419, CPT code 88305 has already been revalued as part of CMS' misvalued code initiative. **The AUA recommends that CMS withdraw its proposal to utilize HCPCS code G0416 for the pathology of all prostate specimens.** We believe the most accurate coding structure to best define this service and capture accurate payment is to utilize CPT code 88305. In addition, we further request that CMS defer review of HCPCS code G0416 as potentially misvalued. We also encourage the agency to provide education for the public on appropriate selection and application of the current coding structure through a Medicare Learning Network® (MLN) article.

Improving the Valuation and Coding of the Global Package

Under the misvalued code initiative, CMS also proposes to transition all 10-day and 90-day global codes to 0-day global codes. The transition for 10-day global periods would start in 2017 and the transition for 90-day global periods would start in 2018. Medically necessary pre- and post-operative services would be billed separately during the pre- and post-operative periods outside of the day of the surgical procedure.

At the present time the AUA believes the proposal to transition all global surgical codes is premature. Although the concept has merit, there are too many issues and concerns that must be addressed before support can be garnered for this proposal. While we believe there are some prospects for comprehensive reform of the global surgical packages, we are far more concerned that the negative consequences would outweigh the benefits. We agree with several of the complications that CMS acknowledges in the proposed rule with attempting to adjust RVUs for global services, particularly with regard to typical resource use, site of service assumptions, and changes to the number of post-surgery visits.

The PE for post-operative visits in the current 10 and 90 day surgical packages is a prime example because they contain unique supplies for the post-operative care (staple removers, gauze pads, perineal pads, scissors, syringes and hundreds of other supplies), that are not part of the PE for E&M codes. Another major concern is the proposal to "blend" the higher PE costs and malpractice risk of surgeons with the costs of all providers of E&M services. We believe this would result in a significant discount in the value of E&M services when billed separately. Surgeons better at managing their patients will be penalized by reduced fees, whereas surgeons less skilled will be rewarded with higher payments because they will be incentivized to keep patients in the hospital longer and require more post-operative office care. The current global system equalizes this discrepancy by using the "typical" patient to establish resource use.

Private payers will most likely continue to use the global period concept, which would make billing for procedures unimaginably complex. CMS admittedly does not have accurate information regarding the true value of the E&M services now contained in the global period and would, therefore have to collect data for all 4,246 affected codes, for more accurate estimates of the number and kind of visits included in the post-operative periods at the time of survey. If all of the surgical codes are to be reviewed again, specialty societies should not bear the expense in time, labor and money to re-survey.

Conversion to a 0-day global policy would also adversely impact Medicare patients with co-pays. E&M visits for post-operative services such as removal of staples, stiches, catheters, stents and drains would require separate co-pays for each visit. This will increase the financial burden for Medicare patients, many of whom are already living on a fixed income, thus making them less likely to comply with follow-up care.

The global period was initially developed to address the issues of fee-splitting and itinerant surgery. With so many health care reforms advancing towards bundled payments, eliminating

the global structure would reverse this progress and add confusion to an already overly complex coding system. **Rather than deconstruct the current global payment structure, the AUA recommends CMS develop a more effective mechanism to increase accuracy of physician fee schedule payments within the global structure.**

E. Medicare Telehealth Services

In 2015, CMS is proposing to expand the list of covered telehealth services to include coverage for psychotherapy services, prolonged services, and annual wellness visits. **The AUA supports the expansion of telehealth services to include the prolonged service CPT codes (99354-5). We further support broadening the definition of "originating sites" to include more geographic locations.**

F. Valuing New, Revised and Potentially Misvalued Codes

CMS is proposing a new process for establishing payment rates for new, revised, and potentially misvalued codes that would ensure by CY 2016 that all revisions to payment inputs are effective only after CMS has responded to public comment. By using the proposed process for new, revised, and potentially misvalued codes, CMS is proposing to eliminate the Refinement Panel process.

Currently, CMS publishes RVU changes for new and revised codes in an interim final rule typically issued in early November and effective on January 1 the following year. This means that any changes will be in place for a full year before any modifications are possible. The timing and publishing of RVU changes are the chief complaints across medical societies because the current process does not allow for opportunity to comment or educate members about changes before they are implemented. The current process also does not allow physician practices ample time to make practice changes to account for reduced values.

The AUA appreciates CMS' effort to create a more transparent process for rate setting; however, we disagree with the proposed timeline to implement this change in 2016, as it would impact code changes already underway. In order for CMS to accomplish the proposed timeline, all RUC recommendations must be submitted by January 15th of each year. This would exclude value recommendations made during the May and January /February RUC meetings for the 2016 cycle, which CMS proposes to create temporary G codes to value codes approved during those meetings. The proposal also would extend the time required to generate a code or relative value from 22 months to 30 months.

Alternatively, the AMA has proposed a modified timeline that would accommodate the review of commonly performed services for the May CPT and October RUC meetings, and the October CPT and January RUC meetings. Under the AMA's proposal, the February CPT meeting would predominantly address editorial changes, clinical lab payment schedule services, and new technology services, with expected low volume. The April RUC meeting would replace the formerly lighter September RUC meeting agenda and would be utilized to review the low volume new technology services and discuss methodological and process issues. **The AUA**

supports the AMA's alternative recommendation to modify the timeline for the CPT 2017 cycle and the 2017 Medicare Physician Fee Schedule.

For years, the Refinement Panel has played an important role in the ability for specialty societies to appeal decisions made by CMS. Recent changes in the process have made it more restrictive; however, we believe with improvements the Refinement Panel could once again be an effective process. If CMS is successful in implementing the valuation of codes in the proposed rule, the Refinement Panel can still play a significant role in correcting any misconceptions about code values. **We support the AMA's recommendations that instead of eliminating the Refinement Panel process, CMS should create a fair, objective, and consistently applied appeals process that would be open to any commenting organization.**

III. OTHER PROVISIONS OF THE PROPOSED REGULATIONS

I. Reports of Payments or Other Transfers of Value to Covered Recipients

Continuing Education Exclusion (§403.904(g)(1))
In the proposed rule, CMS puts forth several changes to the existing Sunshine Act, including the reporting exclusion for continuing medical education (CME) activities, which would remove the language in §403.904(g)(1) in its entirety, due in large part to requests from other accrediting bodies that they be added to the list of exempt organizations covered by the exclusion. CMS also declares the exclusion is redundant with the exclusion in §403.904(i)(1), which exempts indirect payments or other transfers of value where the applicable manufacturer is unaware of, or does not know the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

The AUA understands that CMS' intent may be to simplify the Open Payments rule and to protect the government from pressure to add to a list of continuing education accreditors and standards, when it is not the government's role to adjudicate such requests. However, we are concerned that eliminating the existing exclusion for accredited and certified CME under the Open Payments program would have an unintended outcome, as it would open the door for unapproved standards that are not part of the universally accepted CME accreditation system.

Accredited and certified CME contains safeguards specifically designed to protect against commercial influence. Therefore, it is critical that CMS maintain certain firewalls that distinguish between independent, accredited and certified CME, and other types of promotional education to physicians. **We therefore recommend that CMS retain the exclusion detailed at §403.904(g)(1) of the Open Payments program which includes the limited number of accreditors and credit systems, and the standards they all follow.**

J. Physician Compare Website

Proposals for Public Data Disclosure on Physician Compare in 2015 and 2016

CMS is proposing to expand public reporting of group-level measures by making all 2015 PQRS GRPO web interface, registry, and EHR measures for group practices of 2 or more eligible professionals (EPs) and ACOs available for public reporting on Physician Compare in 2016. The data would need to meet the minimum sample size of 20 patients and prove to be statistically valid and reliable. In addition, CMS would expand measures for individual EPs by making all 2015 PQRS individual measures collected via registry, EHR, or claims available for public reporting on Physician Compare in late 2016, if technically feasible. CMS states it will only publish on Physician Compare measures that are statistically valid, reliable and most likely to help consumers make informed decisions about the Medicare professionals they choose to meet their health care needs.

While CMS has made efforts to try to improve the physician information available on Physician Compare by verifying PECOS data with Medicare data, the system is still riddled with errors and inconsistencies. Early this year, the AUA polled members about their information on Physician Compare. The results of the poll indicate the following problems still exist:

- Providers are not listed despite notifying CMS about the issue several times,
- Misspelling of names and practice addresses,
- 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 and languages spoken.

The AUA supports CMS' logic that if the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate on that measure will not be publicly reported. Nonetheless, we strongly urge the agency to focus on correcting the glitches in Physician Compare before taking on the addition of more data. In addition to the errors, the AUA's overarching concern about a lack of meaningful urology measures is again relevant here. The measures that would be listed on Physician Compare are not applicable to the practice of urology and will not provide useful information to consumers trying to compare providers and make an informed decision. Moreover, we remain concerned that physicians need more than a 30-day preview period to review their data and resolve discrepancies to ensure an accurate portrayal of their performance.

CMS is also seeking comment on the option of linking from Physician Compare to specialty society websites that publish non-PQRS measures. If adopted, the Quality Clinical Data Registry (QCDR) would be required to declare during their self-nomination if they plan to post data on their own website and allow Physician Compare to link to it, or if they will provide the data for public reporting. **We agree that the option to link Physician Compare to specialty society websites that publish non-PQRS measures should be voluntary and available only to those specialties choosing to participate.**

For CY 2016, CMS is proposing to provide patient experience data from 2015 for all group practices of 2 or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor. We believe CMS should include other patient surveys utilized by providers, such as Press Ganey. CG-CAHPS is not the only patient survey available, and thus the information it provides is probably not as complete as it could be if other survey data was added.

CMS also proposes to create composites and publish composite scores based on these grouped measures. The proposed composite groups are very narrow, as they only include 7 measure groups, and would impact a limited number of EPs. Unless CMS makes note of this limitation on Physician Compare, we are concerned that the information may be misleading and cause patients to question why some physicians have composite scores and others do not. Thus, we suggest CMS analyze the component measures that make up the 7 measure groups to see if a statistically viable composite can be constructed with the data reported for 2015. If so, we recommend that CMS post a statement on Physician Compare clarifying that composite groups are not readily available at this time for all measure groups.

In addition, CMS proposes to make available on Physician Compare the 2015 QCDR measure data collected at the individual measure level or aggregated to a higher level of the QCDR's choosing, if technically feasible. If CMS wishes to make QCDR measure data available, it should be at the aggregate (group practice) level. QCDRs are new and struggling to recruit members; publishing data at the individual level may discourage participation and endanger the livelihood of many QCDRs. The data produced at the aggregate level would still be useful to the public, and CMS would still have access to the data at a more granular level, but we do not recommend it be available to the public at this level.

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

Requirements for the PQRS Reporting Mechanisms

CMS proposes that EPs who do not satisfactorily report in PQRS through 1 of the reporting mechanisms in 2015 will receive a 2 percent penalty to the fee schedule amount in 2017. If an individual EP reports through claims or a registry they must report 9 measures, covering 3 national quality strategy (NQS) domains, and include at least 2 measures in the newly proposed PQRS cross-cutting measure set. For 2015, CMS proposes that for at least 50 percent of the EP's applicable patients, an EP must report at least 9 measures under the QCDR covering at least 3 of the NQS domains.

CMS must not overlook the fact that many EPs are still not able to report on 9 measures. While they want to participate in PQRS and improve the care they provide their patients, they often do not possess the resources (staff, electronic health records, time, etc.) which enable them to report on more than 3 measures. Since these providers are making a good faith effort to participate in PQRS, CMS should recognize the effort and continue to keep the option to report on 3 measures in order to avoid the PQRS penalty. Granted these participants would be penalized for the

Value-Based Payment Modifier, but they would avoid being penalized for both PQRS and the Value-Based Payment Modifier.

The AUA appreciates CMS' willingness to align PQRS quality reporting requirements with other quality reporting programs, such as the Medicare EHR Incentive Program, Physician Value-Based Payment Modifier, and the Medicare Shared Savings Program, to the extent appropriate and feasible, to reduce the burden on physicians.

While we support the proposal to extend the deadline for qualified registries to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period, we urge CMS to go a step further and extend the submission deadline for all reporting mechanisms. We also appreciate the increase of non-PQRS measures from 20 to 30, as it would allow participating AUA members to gain more value from the program.

Proposed Criterion Individual EPs in a QCDR for the 2017 PQRS Payment Adjustment
Within a QCDR, "satisfactory participation" is a new standard under the PQRS and is a substitute for the underlying standard of "satisfactory reporting" data on covered professional services that EPs must meet to avoid the PQRS payment adjustment. We believe this concept will encourage more providers to participate in the collection of data and in quality improvement efforts to ultimately improve healthcare quality in the United States.

CG-CAHPS and S-CAHPS for PQRS Survey Measures
Beginning in 2015, CMS declares it will no longer be feasible to continue to bear the cost for group practices of 100 or more EPs to report the CG-CAHPS for PQRS survey measures, and therefore proposes that CAHPS for PQRS would be optional for groups of 2-24 and 25-99 EPs. Group practices would be required to bear the cost of administering CG-CAHPS for PQRS survey measures. CMS is also proposing to not implement the reporting of the S-CAHPS survey measures for the 2017 PQRS payment adjustment.

We are discouraged to hear that CMS will not continue to pay the costs associated with operating the CG-CAHPS survey, as this alternative will be a burden to EPs who wish to participate in PQRS via this mechanism. However, if CMS believes payment is the only feasible way to offer the patient survey option, CMS should include other patient surveys which they are paying for, such as Press Ganey to provide more robust information. In this way, the EP would be able to select the patient survey which would be most appropriate for his or her practice and which would offer the most useful feedback.

We also are disappointed to see that CMS will not include S-CAHPS in PQRS due to a lack of vendors. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which CMS considers important from the patient's perspective, and for which the patient is the best source of information. If participants are to pay to utilize such features for PQRS reporting, it seems likely that a vendor(s) could be secured to implement the reporting survey. S-CAHPS has been endorsed by National Quality Forum (NQF) and, therefore, should be available to

providers, as it will more accurately reflect care provided in a surgical setting. We realize the required structure would not be implemented in time to begin in 2015, but we believe it is feasible for CMS to have it in place by January 2016.

Proposed Changes to the Requirements for the QCDR
CMS is proposing that an entity must meet the following requirements to serve as a QCDR under the PQRS for reporting periods beginning in 2015:

- The entity makes available to the public the quality measures data for which its eligible professionals report.
- The title and description of the measures that a QCDR reports for purposes of PQRS, as well as the performance results for each measure the QCDR reports, be available on a continuous basis and be continuously updated as the measures undergo changes in title and description, as well as when new performance results are calculated.

CMS will defer to the QCDR as to the method it chooses to use for reporting, and to determine whether to report performance results at the individual level or aggregate level for EPs in the same practice.

The AUA appreciates CMS' willingness to allow the QCDR to select the method and level of reporting. We recently began the process of developing and piloting the AUA Quality (AQUA) Registry, which will be capable of reporting data at the aggregate level. The AQUA Registry will be the only specialty-wide, urologic disease focused registry in the United States and will be designed to measure and report health care quality and patient outcomes. Through the aggregation and organization of both clinician and patient reported data on diagnostic and therapeutic interventions, clinical and patient-reported outcomes and resource utilization, AQUA will provide the urologic community with a definitive resource for informing and advancing urology on a national scale. **The AUA strongly supports reporting QCDR data at the aggregate level.**

Proposed Criteria for the Satisfactory Reporting for Individual EPs for the 2017 PQRS Payment Adjustment
For the 12-month reporting period for the 2017 PQRS payment adjustment, the EP would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the EP's applicable patients. Of these measures, the EP would report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures - resource use, patient experience of care, or efficiency/appropriate use. A 50 percent threshold would force physicians to report on their entire patient population, which is more than the requirement for traditional PQRS reporting. This requirement represents a significant reporting burden for physicians with busy practices. It should be sufficient for physicians to satisfy QCDR reporting requirements by reporting on a statistically valid sample of patients. **The AUA urges CMS to provide more flexibility by allowing physicians participating in**

QCDRs to provide CMS with data on a statistically valid sample of patients, rather than on 50 percent of their patients. Moreover, reporting on 1-3 outcomes measures is exceedingly difficult for urology, as well as other surgical specialties, as strong evidence on outcomes is often lacking. **There should be recognition that process measures can serve an important role in quality improvement.**

Proposed PQRS Quality Measures

In an effort to aid EPs and group practices to determine what measures best fit their practice, and in collaboration with specialty societies, CMS is beginning to propose measure sets available for reporting according to specialty. In addition to grouping measures according to specialty, CMS also plans to have a subset of measures that specifically addresses multiple chronic conditions. The AUA supports this suggestion because we believe that it underscores the point we have been noting for many years that there are insufficient specialty-based measures. In 2014, there are only 5 measures directly related to urology. In 2015, 1 of the measures will be retired and 3 of them will be registry-only options. Thus, the list of applicable measures dwindles to 1 measure for those who report via claims (which is the majority of urologists), or to 4 measures for those choosing to report via registry.

The AUA, and many other specialties, have worked to draft measures only to have them denied through the NQF endorsement process. For example, the AUA developed a measure set on prostate cancer several years ago. Created under the auspices of the Physician Consortium for Performance Improvement (PCPI), this measure set was submitted to the NQF, but only a subset of the measures was ultimately endorsed by the NQF Board of Directors. In addition, the AUA recently devoted more than 2 years' effort to the development of its female stress urinary incontinence measures. These measures were developed under the independent measure development process of PCPI and relied on the expertise of a multi-disciplinary workgroup that included the specialties of urology, urogynecology, geriatrics, family medicine, nursing and federal organizations. Despite this rigorous and inclusive process and a tremendous investment of resources, only one of the five measure concepts was approved by NQF for further development.

Additionally, the current measure endorsement process provides limited opportunity for specialties due to NQF's interest in certain "priority" populations and conditions. For example, NQF may not be interested in non-cancer urologic topics despite their importance to urologists and the impact on the quality of life of urologic patients. AUA's experience with the current measure endorsement process has been frustrating, yet not unique. Many specialty societies are hesitant to invest significant resources in measure development, only to have their measures rejected by NQF.

Although non-NQF endorsed measures can be included in federal quality reporting programs, the pathway is not completely independent of the NQF process and is difficult for surgical specialties, thus limiting the use of these measures. Additionally, the emphasis on outcomes measures rather than process measures can be a challenge for specialty society measures. **The agency must recognize that only specialty societies can develop clinically meaningful and**

scientifically sound measures for their members to report on in quality programs. We therefore recommend that CMS adopt a new measure approval process independent of NQF and focused on specialty measures.

PQRS Measures Groups

CMS is proposing to retire Measure #49 (Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65), and remove the claims reporting option for Measures #50 - Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older, Measure #102 - Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:, and Measure #104 - Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients:) which would make them available only through registry reporting in 2015. **The AUA firmly opposes discontinuation of Measure #49 and we urge CMS to make all PQRS measures available for all mechanisms.**

As previously stated, there are very few measures in PQRS directly applicable to urology. CMS is proposing to make 3 of them available only through registry reporting. We strongly oppose these changes because eliminating 1 of 5 applicable measures and limiting the reporting mechanism will place urologists at a disadvantage. Measure #49 is important because it impacts a large patient population, and is necessary to continue to improve care. We believe CMS should still be working to encourage participation, and limiting the applicable measures a specialty has at their disposal is discriminating. For various reasons, registry reporting is not an option for all EPs, and CMS must acknowledge this. It is not fair to participants that measures are being selected for one reporting mechanism over the other in a piecemeal fashion.

In addition, CMS is proposing to remove the perioperative care measures group because EPs consistently meet performance on this measure , suggesting there is no gap in care. In addition, CMS would add new measure groups for general surgery and oncology for 2015 and beyond. **The AUA strongly opposes removal of the perioperative care measures. Removal of this group will significantly impact AUA member's ability to successfully report, as the perioperative measures group is the only current measures group applicable to urologists.** Our members have found these measures to be meaningful in their practices; therefore, the AUA cannot support the removal of measures on which our members have successfully reported. Again this will disadvantage urologists and other specialties that do not have any specialty-specific measures groups. A high performance rate has been achieved for some of the measures but that does not lessen the importance of these measures in impacting quality of care. **Therefore, if CMS decides to eliminate this measure group, which we discourage, it should be phased out over a period of time but not before CMS adopts steps to implement more specialty-specific measures groups.**

Furthermore, the general surgery measure group is useless to many surgeons including urologists because 1 of the 7 measures included in the group is "Anastomotic Leak Intervention: Percentage of patients 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery." While urologists could report on the other 6 measures included in the measures group, they would always receive a zero on the anastomotic

leak intervention and thus fail. Similarly, the Oncology Measures Group is not useful to our members because it includes breast cancer and colon cancer measures; therefore, effectively eliminating this group as a viable option for an urologist. **We urge CMS to remove the "Anastomotic Leak Intervention" measure from the general surgery measures group in order to make the measures group viable to a greater number of EPs.** If the group were limited to 4 truly general surgery measures, our members would be able to satisfactorily report.

N. Value-Based Payment Modifier and Physician Feedback Program

CMS proposes to apply the Value-Based Payment Modifier (VM) beginning in CY 2017 to physicians in groups with 2 or more EPs and to physicians who are solo practitioners. In addition, the amount of payment at risk increases from 2 percent to 4 percent. CMS plans to distribute 2013 Quality and Resource Use Reports (QRURs) in late summer 2014 noting that this will provide sufficient time to understand how the VM works and how to participate in the PQRS.

Despite the best efforts of CMS and other organizations like the AUA to publicize and educate members about the VM, most EPs do not understand the program and thus would not understand why they are being penalized to such a degree. Even though practices with fewer than 10 EPs will not be affected, the proposed penalty increase to 4 percent seems overly stringent. The AUA believes additional time is necessary for EPs to understand the VM program and how they might alter their practice to improve their PQRS participation. Before proceeding with plans to increase the VM penalty to 4 percent, CMS should consider the impact of such a penalty if combined with PQRS and electronic health record penalties, on top of sequestration cuts. **The AUA is very troubled that the increased penalty may leave some practices vulnerable to more than a 10 percent cut in total Medicare payments in 2017. Therefore, we strongly urge CMS to maintain the 2 percent level for at least another year and conduct a rigorous impact analysis of the VM framework.** We believe what little analysis has been conducted on the VM was based on a period when the PQRS program that underpins the VM was far less demanding than it is today, potentially underestimating the number of physicians who will face penalties under the current program.

Even if the QRURs will be amended to be more understandable and relevant to an EP's practice as CMS hopes, the VM program is very complex program which is not easily understood. Additionally, changing one's practice patterns is difficult; a mere matter of months most likely will not be sufficient for the amount of education and other resources that must be acquired. **For this reason, we urge CMS to allow more time for physicians to improve performance on the quality and cost measures that will be used to calculate the Value-Based Payment Modifier in CY 2017.**

In closing, the AUA is grateful for the opportunity to present our views to CMS on the proposed rule. If you have any questions or wish to discuss our comments, please contact Lisa Miller-Jones at (410) 689-3772 or lmiller@auanet.org.

American Urological Association

Sincerely,

David Penson, MD, MPH
Chair, Public Policy Council

J. Stuart Wolf, Jr., MD
Chair, Science & Quality Council