August 21, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare Program; CY 2018 Updates to the Quality Payment Program

Dear Administrator Verma:

The American Urological Association (AUA) is a globally-engaged organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy. The AUA welcomes the opportunity to submit comments in response to the Quality Payment Program proposed rule for calendar year (CY) 2018. We support many of CMS’ efforts to reduce burdens and provide flexibilities for eligible clinicians participating in the Merit-based Incentive Payment System (MIPS) by proposing less stringent reporting requirements, and standardizing Alternative Payment Models (APMs) to stabilize financial risk. Our comments are limited to the sections of the proposed rule that are most applicable to AUA members.

MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

Low-Volume Threshold
The AUA supports the proposal to raise the low-volume threshold for CY 2018 to exempt from MIPS reporting requirements clinicians who bill $90,000 or less in Medicare Part B charges annually or treat 200 or fewer Medicare patients. We agree that increasing the low-volume threshold will ease the burden on small and rural practices challenged by workforce shortages and smaller patient populations. We also are supportive of allowing clinicians the flexibility to opt-in to MIPS in 2019 if they exceed one but not both of the low-volume exclusionary determinations.
Performance Period
The AUA supports the proposal to maintain the continuous 90-day performance period for the MIPS Improvement Activities and Advancing Care Information performance categories for CY 2018, and urge CMS to extend the same flexibility to the Quality performance category. For the 2017 transition year, CMS allowed clinicians to choose from three flexible options to participate in the first year of MIPS at a pace most convenient for their practice. Currently, clinicians are allowed to test MIPS by submitting a minimum amount of data, partial year data or report data for the full year. In the previous final rule, CMS acknowledged that the MIPS learning and development period would last longer than the first year, and therefore, “envisioned CY 2018 to also be transitional in nature to provide a ramp-up of the program and the performance thresholds.” Therefore, for the Quality performance category it would be appropriate for CMS to allow clinicians the option to submit data for a minimum period of 90 continuous days during the second year of MIPS to avoid a negative payment adjustment in 2020. To facilitate successful participation in MIPS, the performance periods should be consistent across-the-board during the transition period.

Performance Threshold
For CY 2018, CMS proposes to increase the existing MIPS performance threshold from 3 points to 15 points. The current MIPS performance threshold essentially allows clinicians to submit one Quality measure or one Improvement Activity or the required Advancing Care Information base measures to avoid a downward payment adjustment in 2019. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) permits the Secretary of the Department of Health and Human Services to determine the performance threshold for the first two years of MIPS. We understand CMS’ concern that setting the performance threshold too low for next year may create a steep jump for the third year of MIPS. However, we are concerned that increasing the performance threshold from 3 points to 15 points one year later would be too steep of an increase and potentially create a margin for failure. Many clinicians will still be adjusting to MIPS reporting in 2018 and will need a lower hurdle for successful participation. For this reason, the AUA recommends CMS set the performance threshold at 6 points for CY 2018, as a smaller increment in the performance threshold next year will provide extended time needed for clinicians to adapt to MIPS reporting requirements and become better prepared for a higher reporting standard the following year.

Data Submission
Last year, CMS finalized use of multiple mechanisms for submission of performance data, but only one mechanism per performance category. For 2018, CMS proposes to allow individual and group clinicians to submit data using more than one submission mechanism for a single performance category. While the AUA appreciates CMS’ efforts to ease data reporting, for qualified clinical data registries (QCDRs), such as the AUA’s AQUA registry, the use of multiple mechanisms will make it difficult to discuss MIPS performance and estimate best scoring strategies for AUA participants. We are concerned that this proposal,
if adopted, would make it difficult to assess performance category improvements from year to year. Furthermore, CMS admits that it does not have the ability to aggregate data across multiple mechanisms for the same measure. **Therefore, we oppose allowing use of multiple submission mechanisms for a single performance category, as we believe it will further complicate an already complex scoring system and may increase cost of reporting measures for some physicians.**

**Quality Performance Category**
The AUA supports the proposal to retract the previously finalized policy to reweight the Quality performance category to 50 percent, and instead, maintain the 60 percent weight, contingent upon finalization of the proposal to reweight the Cost performance category to zero. We also appreciate and support the proposal to incorporate 11 additional quality measures into the Urology measure set for CY 2018. Through creating a larger measure set, urologists will be able to demonstrate a high level of performance by reporting quality measures that are most meaningful to their practice.

CMS is proposing to implement a 4-year lifecycle to discontinue topped out measures by applying a 6-point cap on a measure if it exceeds 95 percent for two consecutive years and then removing it from reporting after it has been identified as topped out for three consecutive years. CMS considers a measure topped out if 100 percent of those reporting it score about 95 percent. While the AUA supports using a phased-in approach to identify topped out measures, we disagree with CMS' rationale for determining when a measure is topped out because all applicable users may not report on the measure in question. CMS' determination pertains only to those clinicians reporting the measures, which may be a fraction of the total number of applicable MIPS clinicians. For example, if 100 out of 15,000 urologists report on a specific measure and score well, CMS would consider the measure to be topped out within a few years, despite the fact that the number of users is not an accurate reflection of the total population of applicable MIPS clinicians. In order for a measure to truly be considered topped out, we suggest it should be reported by 75 percent or more of applicable MIPS clinicians. The same logic would apply whether the measure is general or specialty-specific.

We also discourage CMS from retiring measures considered to be topped out. Instead, we suggest that CMS maintain those measures and assign them a lower point value. Several urology process measures are topped out and many other specialties and subspecialties already have limited applicable measures. Furthermore, some urologists with highly subspecialized practices may only have sufficient patients to report in a limited subset of the AQUA registry measures. We believe process measures continue to serve a purpose and retiring them would disadvantage certain clinicians from successfully meeting the reporting requirements for the Quality performance category. Equally, if not more important, quality measurement is critical to identifying gaps in care. CMS has already removed a significant number of measures under MIPS based solely on benchmark data, without consideration of clinical factors, scientific evidence, and the importance of a
measure. There is valid concern that if specialty-specific quality measures are removed from inventory, there will be no mechanism to track performance of certain activities, which could inadvertently affect patient outcomes. If a measure is minimized in point value rather than retired, it would be easier to increase the point value again without having to go through various stages to reinstate it in the event gaps in care reemerge.

The AUA is opposed to CMS’ case minimum requirements and the scoring methodology of assigning 3 points for measures that do not have a benchmark. We realize that a certain number of clinicians must report a measure in order to obtain a benchmark, and CMS has adopted 20 as the threshold for this purpose. Therefore, if 20 or more practitioners use a measure, they may obtain between 3-10 points depending on how well they score. Conversely, if less than 20 clinicians use a measure, then the measure will be scored unfairly, and fewer clinicians will be inclined to use new measures because only 3 points will be granted. The scoring methodology also creates an unlevel playing field for measures developed for QCDR use, such as the AQUA registry. The AUA has invested significant resources into developing quality measures for AQUA; however, the measures are only able to earn urologists 3 points because they are new. To encourage use of new measures, we suggest CMS consider raising the point value, particularly for specialty-specific measures (or for measures with a highly variable performance rate that are not nearly topped out). This approach would allow a benchmark to be scored after the first year a measure is approved for use and potentially avoid a vicious cycle of clinicians choosing not to report new measures capped at 3 points, and instead, selecting to report random measures that may not align with their specialty, but are worth up to 10 points.

**Improvement Activities Performance Category**

In response to the call for submission of Improvement Activities for CY 2018, the AUA submitted an application for inclusion of the AUA Symptom Index (AUA-SI), also known as the International Prostate Symptom Score (IPSS), to increase patient engagement in quantifying lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). CMS recently announced a proposal to include the AUA-SI in the MIPS Improvement Activities inventory for CY 2018 as a new activity or incorporate it into an existing activity. As CMS has acknowledged, maintaining copies of the AUA-SI in the patient’s medical record will serve as validation that the patient completed the symptom score and discussed it with the clinician to determine together appropriate treatment based on patient preferences, and thereby qualify as an Improvement Activity for the Beneficiary Engagement subcategory. Although the proposal to include the AUA-SI was not stated in the proposed rule, we strongly support it and urge CMS to finalize the proposal as a high weight activity for the Improvement Activities performance category.

The AUA also supports inclusion of the Peri-Operative Surgical Home model as an Improvement Activity for CY 2018. We firmly believe participation in the Peri-Operative Surgical Home model will allow urologists to improve efficiencies, decrease resource
utilization, reduce length of stay and readmission, and decrease complications. **We urge CMS to finalize the proposal for the Peri-Operative Surgical Home model; however, we recommend doing so as a high weight rather than a medium weight activity for the Improvement Activities performance category.**

In addition, we encourage CMS to further clarify published guidance on the data validation criteria for Improvement Activities, specifically, for documentation requirements to sufficiently prove the activity was completed, in a consistent and meaningful manner, in the event of an audit.

**Advancing Care Information Performance Category**

Again, the AUA commends CMS for proposing to extend a continuous 90-day reporting period for the Advancing Care Information performance category in the third year of MIPS. CMS previously acknowledged that physicians will require additional time to update their certified electronic health record technology (CEHRT), and therefore, designated a 90-day reporting period for the first and second year of MIPS. The proposal to extend the provision is a clear indication that a 365-day reporting period will be overly burdensome for clinicians in 2019. We are concerned that having to attest to a full year EHR reporting period will limit the time that clinicians spend on providing high quality patient care. Also, physicians typically need several months to test new software updates after installation to ensure system changes are operating properly. In such cases, a full year reporting period may force many clinicians to seek a hardship exception, whereas a shorter 90-day reporting period would allow clinicians to familiarize themselves with new EHR installations and still be able to meet the reporting period compliance requirement. The fact that increased use of EHRs recently has been reported as worsening physician burnout is another concern with EHR reporting for a full year. We also would like to point out that the Meaningful Use program has operated on a 90-day reporting period, rather than a full calendar year since 2014, to accommodate ongoing issues with the program. **Therefore, the AUA recommends that CMS establish a continuous 90-day reporting period for the Advancing Care Information performance category as a permanent provision of MIPS instead of a temporary stipulation.**

We also appreciate CMS proposing to modify current law to allow clinicians to use either the 2014 or 2015 Edition CEHRT, or a combination of the two, for CY 2018. While we understand CMS’ desire to influence increased use of the 2015 Edition CEHRT by offering a one-time 10 point bonus applied to the final score for the Advancing Care Information performance category, clinicians will likely need additional time to transition to the updated version, given that not all vendor products may be available on the market by the end of 2019. Smaller health IT vendors are still upgrading their products and will need additional time to meet the 2015 certification criteria required for approval by the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program. **Thus, we encourage CMS to continue to offer bonus points for end-to-end use of the 2015 Edition CEHRT as long as it remains a voluntary option for the Advancing Care Information performance category.**
We agree that the Advancing Care Information performance category should be re-weighted to zero for clinicians that demonstrate a significant hardship, and support hardship exceptions for hospital-based clinicians, ambulatory surgical center-based clinicians, small group practices and clinicians using decertified EHR technology through no fault of their own. We also agree that clinicians that write fewer than 100 permissible prescriptions during the performance period should be excluded from the Electronic Prescribing objective and measures in CY 2018. Finally, we support the proposed exclusion from the Health Information Exchange objective and measures for clinicians that transfer or refer patients to another setting, or receive transition of care or referrals, or have less than 100 new patient encounters during the performance period.

The AUA strongly urges CMS to establish an alternative pathway to achieve credit for the Advancing Care Information performance category. Specifically, clinicians that use CEHRT to participate in a QCDR should be granted full credit for the Advancing Care Information performance category. By doing so, CMS will further incentivize EHR adoption and participation in clinical data registries. The statute defining Meaningful Use states that the meaningful use of CEHRT includes electronic exchange of health information to improve the quality of health care, and reporting on quality measures. Both of these objectives can be achieved by using CEHRT to participate in a QCDR. MACRA also provides the Secretary with substantial discretion to modify Meaningful Use requirements for incorporation into the Advancing Care Information component of MIPS to ensure that the application of the Meaningful Use requirements is “consistent with the provisions of” MIPS.

Cost Performance Category
CMS proposes to again weight the Cost performance category at zero percent of the total MIPS performance score, but is concerned that the weight increase to 30 percent in the third year of the Quality Payment Program, as required by statute, will create a sharp increase. CMS further proposes not to use the 10 episode-based measures that were adopted for the 2017 MIPS performance period, and instead, develop new episode-based measures and provide feedback on the new measures in the fall, along with a list of care episode and patient condition groups in December 2017. In the proposed rule, CMS also states that feedback on the Medicare Spending per Beneficiary (MSPB) measure and total per capita costs measure will be provided in July 2018.

While the AUA supports a zero weight for the Cost performance category and development of new episode-based measures, we believe the proposed timeline to overhaul the measures is overly ambitious. We believe it is highly unlikely that an extra year will allow adequate time to develop and test the validity and reliability of the new measures, and provide clinicians with much needed education to help them understand their quality and cost assessments. Thus, we urge CMS to refrain from implementing new episode-based measures prior to thorough testing, and to provide more tools and educational resources, so that clinicians are able to show marked improvement in quality and resource use efficiencies in preparation for the percentage increase in CY 2019.
MIPS APMs
The AUA supports the addition of the bone density measure for patients with prostate cancer receiving androgen deprivation therapy to the Oncology Care Model for MIPS APMs in CY 2018. We also agree that the varying scoring weights for the Advancing Care Information performance category should be aligned across all MIPS APMs. CMS previously finalized the Advancing Care Information performance category would account for 75 percent of the total performance score for MIPS APMs in CY 2018, but only account for 30 percent for APMs under the Medicare Shared Savings Program and Next Generation ACO model APMs. For CY 2018, CMS proposes a standardized weight of 30 percent for the Advancing Care Information performance category for all MIPS APMs. The AUA supports this proposal.

QCDRs and other Third-Party Intermediaries
The AUA supports CMS’ proposal to simplify the self-nomination process for QCDRs and qualified registries in good standing by eliminating the email submission method and adopting a web-based tool for performance periods occurring in CY 2018. For the 2019 performance period, QCDRs and qualified registries in good standing may continue participating in MIPS by attesting that their approved data validation plan, cost, approved QCDR measures, MIPS quality measures, activities, services, and performance categories offered in the previous year’s performance period have no changes. We fully support streamlining the process, as we believe it will reduce the burden for existing QCDRs that have participated in MIPS in prior years, and allow CMS more time to focus on data submission determinations.

CMS also proposes to modify the title for QCDR related Improvement Activity (IA_AHE_3) to, "Promote Use of Patient-Reported Outcome Tools." Additionally, the activity weight would be increased to high, and eligible for an Advancing Care Information bonus. The AUA supports these changes, as proposed, as they would enable QCDR participants to enhance their MIPS performance score and potentially earn bonus points.

CMS further proposes for CY 2018 that clinicians may achieve credit for a specialized registry only if they reach the “active engagement option 3: production” phase, meaning they have completed testing and validation of the electronic submission and are submitting production data to the public health agency or clinical data registry. A provider should still be able to receive credit for the specialized registry measure if they chose to share data with the registry, and make every effort to do so, but for some reason were unable to fully advance to production. We believe that clinicians who attempt to participate with a specialized registry should continue to receive credit for the measure. Therefore, the AUA strongly encourages CMS to withdraw this proposal as it can take several months to reach the most robust stage of engagement, and instead, maintain the current policy that allows clinicians the option to demonstrate active engagement through completed registration to submit data, testing and validation, or production.
In the previous final rule, CMS required QCDRs to provide performance feedback on MIPS categories at least four times a year. CMS is now proposing QCDRs, and other third party intermediaries provide “real time” feedback as soon as technically feasible, however, CMS has not defined what “real time” means or whether the data transmissions would have to be active or passive. The AUA urges CMS to continue to seek comments on the definition of “real time” data and clarify the type of feedback that would be required, so we can better determine how quickly the information could be supplied to our QCDR participants.

ALTERNATIVE PAYMENT MODELS (APMS)

Financial Risk Standard Amount for Advanced APMs
The AUA appreciates CMS’ proposal to extend the revenue-based nominal amount standard of 8 percent until the 2020 performance year, and address the standard amount thereafter through subsequent rulemaking. However, we support the American Medical Association’s recommendation that CMS phase-in the 8 percent standard for Advanced APMs over a specified period of time to provide a sufficient period of financial stability. The recommendation calls for the revenue-based nominal risk amount to be reduced to four percent for 2018, increased to six percent in 2019 and 2020, and set at 8 percent in 2021 and subsequent years. This rationale is based on interpretation of the MACRA statute that mandates that the APM participation threshold increase from 25 percent in the first two performance periods of the Quality Payment Program up to 75 percent in the fourth performance period and thereafter, which indicates that Congress intended for clinicians’ exposure to APM-related financial risk would also be phased in over time.

We also urge CMS to set the revenue-based nominal amount standard for small and rural practices participating in Advanced APMs at either the same or a lower amount as the medical home models, which is proposed at decrease from 2.5 percent to 2 percent for CY 2018 and increase an additional 1 percent each year until the standard amount reaches 5 percent in performance year 2021.

Physician-Focused Payment Models
The AUA fully supports the proposal to broaden the definition for Physician-Focused Payment Models (PFPMs) to allow PFPMs to include payment arrangements with Medicare, Medicaid or CHIP, or any combination of these payers. Expanding the definition and criteria may provide a pathway for more specialty-specific APMs to qualify as Advanced APMs, which would provide more opportunities for specialists to participate and determine the most cost-effective model for their practice.

In conclusion, we appreciate the opportunity to provide comments on the proposals for the second year of the Quality Payment Program. If you have any questions or wish to discuss our comments, please contact Lisa Miller-Jones at (202) 403-8501 or ltmiller@auanet.org.
Sincerely,

Chris M. Gonzalez, MD, MBA
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