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Submitted electronically via:
http://www.regulations.gov

Andrew M. Slavitt
Acting Administrator
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Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, Final Rule [CMS-5517-FC]

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 commends CMS for its efforts to implement physician payment reform under the Medicare Access and CHIP Reauthorization Act (MACRA) and appreciates the opportunity to further comment on the final policies for the Merit-Based Incentive Payment System (MIPS), the Alternative Payment Model (APM) Incentive, and the criteria for Physician-Focused Payment Models (PFPM) under the new Quality Payment Program.

The AUA commends CMS for its efforts in addressing the many concerns raised by the physician community to decrease administrative burden and ease transition into the Quality Payment Program. We support several of the modifications in the final rule and we thank CMS for adopting many of the AUA's recommendations. The revised policies, we believe, will provide opportunities for urologists to succeed under the MIPS, but CMS must do more to guide physician success under Advanced APMs.

MIPS Program Details

The AUA supports the inclusion of telehealth services in the improvement activities performance subcategories, and as a patient-facing encounter for MIPS reporting.

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We agree that telehealth can transform health care delivery and community health; enhance the nation's health IT infrastructure; and advance person-centered and self-managed health care. We, therefore, encourage CMS to liberalize the use of telemedicine, not just for MIPS reporting, but also for APMs. In an at-risk model, such as an Advanced APM, the use of telehealth should be unfettered as a tool of efficiency and access. The use of telemedicine, without restriction based on geography, also will enhance patient (and caretaker) convenience and access to care. This is especially true in settings such as nursing homes, but also applies to beneficiaries in outpatient settings who must often coordinate several office visits with several clinicians.

MIPS Performance Period

The AUA is particularly pleased with the modifications to the MIPS performance period that will allow eligible clinicians to pick their pace of participation for calendar year (CY) 2017, the transition year of the Quality Payment Program. We agree that the flexible options for data submission will provide much-needed time for physicians to familiarize themselves with the new requirements and make the necessary modifications to their practices to accommodate reporting under the MIPS. We also appreciate CMS for allowing a continuous 90-day reporting period for the improvement activities and advancing care information performance categories for CY 2017 and 2018 to allow adequate time for physicians to transition their certified EHR technology (CEHRT) to the 2015 Edition.

Quality Data Submission Criteria

The AUA supports the final submission criteria for quality measures (excluding CMS Web Interface and CAHPS for MIPS) that will require reporting of at least six measures including at least one outcome measure if available (or a high priority measure if an outcome measure is not available). The AUA is very appreciative of the urology specialty measure set that may be reported as an alternative. In addition, we support CMS' decision to not require submission of a cross-cutting measure for the transition year.

Although participants are required to report an outcome measure, if applicable, CMS admits that many specialties do not have outcome measures and urology is one of them. In the urology specialty measure set finalized in the rule, only process measures are available. The urology measure set initially proposed, which the AUA supported, included an outcome measure (#357 *Surgical Site Infection*). CMS removed measure #357 stating that it "is not applicable to urology." We disagree with this statement and would like to remind CMS that urologists are also known as genitourinary surgeons. Although urologists manage non-surgical problems such as urinary tract infections and benign prostatic hyperplasia (BPH), they also manage surgical problems such as the surgical management of cancers, the correction of congenital abnormalities, and correcting stress incontinence.[1]

[1] American Board of Medical Specialties. https://www.abms.org /member-boards-contact-an-abms-member-board/American-board-of-urology.

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In the rule, CMS noted that many stakeholders face barriers in the development and use of meaningful outcome measures. Consequently, it may be a while before specialties like urology will have access to more applicable outcome measures. Even so, urologists find greater value in reporting on process measures relevant to their practice rather than shoehorning an unrelated outcome measure just for the sake of completing reporting requirements. Just as CMS did not see value in requiring reporting of a general cross-cutting measure just for the sake of reporting, likewise CMS should reconsider the value of reporting a general outcome measure. However, since physicians are required to report outcome measures in the MIPS, we ask that CMS put back measure #357 into the urology measure set to support reporting requirements.

CMS also stated that clinicians "should select their appropriate specialty-specific measure set, because that pre-defines which measures are applicable to their specialty and provides protections to them." The AUA agrees there is value in creating a specialty measure set and thanks CMS for using many of the measures recommended by the AUA. However, it is unreasonable for CMS to assume that all clinicians within a specialty may use such a measure set. For example, the urology measure set contains measures related to prostate cancer and female stress urinary incontinence. Many urologists specialize in treating female urology and thus the prostate cancer measures would be inapplicable for that patient population. The reverse is true for those specializing in prostate cancer. The AUA believes that sub-specialization is true of nearly every specialty, and thus the assumption that all in a specialty can use such a list should not be made.

We noticed that CMS has included measure #402 (Tobacco Use and Help with Quitting Among Adolescents) in the urology measure set. The AUA questions this decision since the measure was not indicated in the urology measure set in the proposed rule. While we believe the goal of the measure is exemplary, we are concerned that urology may not be the proper specialty to report on this measure. The typical urologic patient population is not 12 to 20 years of age, with the exception of pediatric urologists, who likely do not participate in Medicare. We also question the value of reporting data on an age group that is not Medicare eligible and seek clarification on why this measure was added to the urology measure set.

CMS further noted that the measures group option under MIPS was not proposed because very few clinicians utilized that option under PQRS, and with the new specialty-specific measure sets, there is no need for continuation of measures groups. We disagree with this assumption. As CMS continues to assess the Quality Payment Program for enhancements in future rulemaking, we encourage CMS to reevaluate the decision to eliminate measures groups. For MIPS participants, the combined reporting requirements will be onerous even with the assistance that CMS is generously providing. When PQRS was first introduced, advancing physicians into value-based reporting was much more manageable when they

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were only responsible for reporting on 20 patients. Urology did not have a designated measures group in PQRS, yet many of our members chose this option in order to ease into the program and learn more about it. We believe a similar stepping stone would be invaluable to new MIPS participants and others who are facing challenges from the added responsibilities.

Submission Criteria for Quality Measures for Groups Reporting via the CMS Web Interface

Under the MIPS, only registered groups with 25 or more eligible clinicians are allowed to submit data on quality measures via the CMS Web Interface because CMS believes that practices with fewer than 25 clinicians will not have an adequate amount of Medicare Part B patients to report using this mechanism. Specialties such as urology see a significant amount of Medicare Part B patients; so, even smaller practices would likely meet the 248 patient sample size required to use the CMS Web Interface. We believe it is inappropriate for CMS to restrict a reporting mechanism that might be an easier alternative for some group practices. In the future, we urge CMS to extend the CMS Web Interface reporting option to all MIPS participants who attest that they are able to meet the patient threshold and data submission requirements, so that smaller groups or individuals have the same conveniences as larger groups.

Performance Criteria for Quality Measures for Groups Electing to Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

For the transition year of MIPS, CMS will allow groups to elect to participate in the CAHPS for MIPS survey. Although participation is voluntary, the CAHPS for MIPS survey is included under the quality performance category, as well as the improvement activities performance category as a high weighted activity in the Patient Safety and Practice Assessment subcategory. In the final rule, CMS acknowledged that certain specialties, such as surgeons, may not have patients to who the CAHPS for MIPS survey could be administered and therefore, are unable to receive any bonus points for patient experience.

The AUA agrees that patient experience measures are important and is among the numerous specialties that have urged CMS to adopt a patient experience survey for specialists, particularly surgeons, to ensure that they have the same opportunity to succeed in the MIPS as primary care providers. As CMS explores possible revisions to the CAHPS for MIPS survey, we hope that CMS will give serious consideration to developing a patient experience survey applicable to all specialties so they are able to achieve points in both performance categories in future years.

Data Completeness Criteria

The AUA appreciates that CMS agreed with our recommendations to not proceed with increasing the data completeness criteria to 80 percent via claims and 90 percent via EHR, clinical registry, QCDR or CMS Web Interface for non-Medicare and Medicare patients. We

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commend CMS for listening to the concerns of the physician community who stated that reporting on 80 percent of Medicare patients or 90 percent of all patients is too onerous. Instead, for the transition year, CMS will maintain the 50 percent data completeness threshold and increase it to 60 percent in 2018.

In the rule, CMS admitted that it does not "currently have the optimal capability to validate data completeness for all-payer-data" under the quality performance category. If this is the case, we question why CMS is determined to move forward with increasing the threshold in 2018 without absolute operational certainty. Before proceeding, we suggest that the 50 percent threshold for non-Medicare and Medicare patient data be maintained, regardless of the reporting mechanisms, until CMS has had time to learn from and improve the ability to validate all-payer data beyond a reasonable degree of certainty.

Call for Quality Measures

CMS confirms that process measures will continue to play an important role in quality measurement; however, in the list of considerations for submitting future quality measures, CMS is requesting "outcome based rather than clinical process measures." Yet, CMS repeatedly notes that process and structural measures will have a role in the MIPS especially where there may be measure gaps. This sends a mixed message to potential measure developers. We ask that CMS clarify in future rulemaking, to what extent, process measures will be accepted and which topics may be appropriate.

The AUA reiterates its comments on the proposed rule urging CMS to proceed with great caution when considering quality measure recommendations from the United States Preventive Services Task Force (USPSTF) until the USPSTF process for developing recommendations is substantially reformed to include meaningful contributions from medical specialists. CMS' vague response to our comments is cause for serious concern given that the 2012 USPSTF recommendation against prostate-specific antigen (PSA) screening for prostate cancer for all men was made without soliciting input or consultation from urologists, medical oncologists or radiation oncologists who are primarily responsible for the treatment of prostate cancer. The problem is not just that the USPSTF excluded specialist input. The problem is that *by* excluding specialist input (including cancer epidemiologists as well as all cancer clinicians) they excluded all bona fide experts on PSA and prostate cancer. As a direct result, they released a guideline that makes multiple, critical mistakes in its interpretation of the evidence. In addition to its decision on PSA-based prostate cancer testing, the USPSTF has in recent years issued multiple other controversial ratings on a variety of health care services, including screening for breast cancer, children's vision services, screening for skin cancer, and dementia screening in older Americans. Although the USPSTF plans to re-review the PSA guidelines, this type of unstable recommendation is a clear reason for CMS to use caution when considering quality measure recommendations from the USPSTF.

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Improvement Activities Performance Category

The AUA applauds CMS' decision to reduce the number of required improvement activities and extend the shorter, 90-day performance period for the second year of MIPS. We also appreciate that physicians will be able to achieve a bonus in the advancing care information performance category when they use functions included in CEHRT to complete certain improvement activities. The improvement activities performance category is a completely new concept under the MIPS, and reducing the reporting burden will allow physicians to become accustomed to reporting on the new activities before more stringent requirements are implemented.

In the final rule, CMS stated that MIPS eligible clinicians may retain any documentation that is consistent with the actions they took to perform each activity. This guidance is too vague. CMS further noted that more information about documentation expectations for the transition year will be provided in subregulatory guidance, but does not specify when that information will be available. MIPS participants need clear guidance before the MIPS performance period gets underway. Particularly, since what a clinician may view as sufficient documentation may vary substantially from what CMS considers to be sufficient documentation. With less than 60 days until the start of CY 2017, we urge CMS to provide explicit guidance on documentation expectations for the improvement activities performance category without further delay.

The AUA would like for CMS to reconsider making additional changes to the improvement activities performance category. In the proposed rule comments, we asked CMS to assign high weights (20 points) to more registry-related clinical practice improvement activities. In the final rule, CMS noted that assignment of a high-weight improvement activity is based on whether an activity is critical for supporting certified patient-centered medical homes. However, many of the improvement activities assigned high weights do not appear to be critical for supporting certified patient-centered medical homes. If the basic premise of MIPS is to link physician payment to quality of care through reporting measures, we believe that assigning a high weight to more registry-related improvement activities will increase QCDR participation and thereby accomplish this goal. For these reasons, we encourage CMS to assign all registry-related improvement activities a high weight.

Advancing Care Information Performance Category

We also commend CMS for reducing the number of required measures for the base score under the advancing care information performance category. For the transition year, CMS has provided two measure set options available for reporting depending on the version of CEHRT a physician chooses to use. We also appreciate the increase in the bonus score from one to five points for Public Health Registry Reporting and Clinical Data Registry Reporting measures. Finally, we appreciate the extended 90-day performance period for CY 2018 in recognition of the time physicians may need to transition from the 2014 Edition of CEHRT to the 2015 Edition. We believe the flexibilities that CMS has built into the advancing care

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information performance category will encourage more robust use of EHR technology under the MIPS.

Quality Measure Benchmarks
CMS has long held the belief that a measure may be topped out if performance is so high that meaningful distinctions and improvement in performance can no longer be made. In implementing the scoring for the quality performance category, CMS stated that the benchmark methodology for topped out measures will not be modified and a limit will not be placed on the number of topped out measures that a clinician can submit for the 2017 performance period, as proposed. CMS will instead create a separate scoring system for topped out measures beginning with the 2018 performance period, provided that it is the second year the measures have been identified as topped out.

The AUA supports CMS' decision to delay modification of the benchmark methodology for topped out measures and not confine the number of measures that can be reported, but we disagree with the assumption that improvement in performance can no longer be made if reporting of a measure is identified as consistently high for two consecutive years. We do not consider two years to be enough time to make a fair assessment whether a measure is topped out especially when the number of providers is expected to grow through Quality Payment Program participation. When evaluating the benchmarks, we encourage CMS to ensure that they do not impact various specialties differently, and refine as needed if a difference is shown.

Episode-Based Measures Proposed for the MIPS Cost Performance Category
The AUA supports use of episode-based measures for specific disease focused areas for the cost performance category. For the transition year, CMS reduced the weight of the cost performance category to zero and finalized a limited number of episode-based measures. While we are grateful that transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH) is on the list of approved episode-based measures for the CY 2017 performance period, we believe that the prostatectomy for prostate cancer episode-based measure is an even more appropriate indicator of urologists' resource use management. According to CMS, although the prostatectomy for prostate cancer episode-based measure is present in the PQRS program and was included in the 2014 QRUR, it did not meet the reliability threshold (at least 0.4) for a minimum case size of 20 episodes.

We find it hard to believe that the prostatectomy for prostate cancer episode-based measure did not meet the reliability threshold and question if the current standard is appropriate to establish a minimum case volume for specialists to be scored on a cost measure. We urge CMS to explore other methods to ensure reliability of episode-based measures before the start of the CY 2018 performance period, when the cost performance category will account for 10 percent of a clinician's total performance.

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MIPS APMs Other than the Shared Savings Program and Next Generation ACO Model – Improvement Activities and Advancing Care Information Performance Category Scoring under the APM Scoring Standard

We appreciate the recent announcement of additional APM opportunities and support CMS' strategy to reopen certain APMs for additional application rounds, amend the design of certain APMs so that they meet the Advanced APM criteria, and engage in development of potentially Advanced APMs based on recommendations from the PTAC. In doing so, CMS will need to better guide physicians to success under these models. That starts with improving policies for physicians reporting through MIPS APMs. For example, weight components, such as the advancing care information performance category, under the MIPS APM scoring system vary for different types of APMs. Specifically, under the Medicare Shared Savings Program or Next Generation ACO Model, the advancing care information performance category is weighted at 30 percent, as opposed to 75 percent for other APMs. More flexibility is needed in the structure of MIPS APMs to allow more specialists (in particular surgeons) to participate in Advanced APMs. Surgical care accounts for a significant amount of health care expenditures, yet CMS anticipates that it will be difficult for surgeons to find Advanced APMs to participate in in the early years of the Quality Payment Program. The credits under the improvement activities performance category is another concern. CMS needs to provide stability for MIPS APMs receiving full credit so that they do not have to adjust their activities on an annual basis.

Advanced APM Nominal Amount Standard

The AUA is encouraged by CMS' efforts to establish a realistic standard for what constitutes the more than nominal risk amount that an Advanced APM must bear by lowering the proposed marginal risk and minimum lost rate (MLR) requirements. We commend CMS for recognizing that a marginal risk of at least 30 percent was too high, and when combined with a four percent MLR and a four percent total cost of care benchmark, could amount to a significant fraction of an APM entity's revenue. We agree that a revenue-based standard is a better alternative for certain practices. A requisite total risk of eight percent of total Medicare Part A and B revenues, or three percent of total Medicare expenditures for an Advanced APM is a far more reasonable amount of risk to assume.

To ensure that the total amount of risk does not supersede incentives for improving efficiency, we urge CMS to create a period of stability and predictability for Advanced APMs by maintaining the eight percent nominal risk standard amount for the performance periods of the full six years (2019-2024) that the five percent incentive bonus payment is available, rather than just for the 2017 and 2018 performance periods. CMS also should allow the same Advanced APM financial risk structure to be used by all payers, rather than having different standards for Medicare APMs and Other Payer APMs. In addition, CMS should exclude the costs of Part B drugs from calculations of Advanced APM financial risk, since physicians have no control over the prices they must pay for Part B drugs. Setting the more than nominal risk standard for Advanced APMs at eight percent of total Medicare

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Parts A and B revenues will require APM entities whose physicians administer Part B drugs to accept substantial amounts of risk for costs they cannot influence or control.

Timing of Group Identification for Eligible Clinicians

We support the final policy to use a series of snapshots throughout the year to determine if an eligible clinician meets the qualifying participant (QP) criteria for an Advanced APM, instead of waiting until December 31 of the performance period. The first snapshot will be on March 31 of the performance period, the second snapshot will be on June 30 of the performance period, and the third snapshot will be on August 31, which will be the last day of the performance period. We agree that this approach will let eligible clinicians know their QP status well in advance of the MIPS data submission period and whether they need to report to MIPS for the applicable year.

Conclusion

Again, the AUA would like to thank CMS for incorporating many of our recommendations on the proposed rule into the Quality Payment Program. If you have any questions regarding our comments, please contact Lisa Miller-Jones at (410) 689-3772 or by email at lmiller@auanet.org.

Sincerely,

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Chair, Public Policy Council

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