ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

1510 H Street NW • Suite 800 • Washington, DC 20005
p 202.640.4660 • f 202.637.9793 • www.asn-online.org

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

Re: Proposed Rule for Medicare Program; CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the June 20, 2017, proposed rule for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for performance year 2018. ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality chronic kidney disease (CKD) and end-stage renal disease (ESRD) care and the integrity of the patient-physician relationship.

ASN appreciates CMS's commitment to a thoughtful and transparent transition from the Sustainable Growth Rate (SGR) formula for determining Medicare payments for health care providers' services to the new Quality Payment Program (QPP) created to implement MACRA. The creation of a 2017 transition year for the first performance year has been instrumental to helping clinicians understand and prepare for full participation in the QPP.

The proposed rule clearly involved a tremendous level of effort and thought by CMS and HHS to propose updates in three primary areas:

- Making participation easier for small (and possibly rural) practices,
- Easing clinicians into reporting requirements, and
- Recognizing the diversity of practices, practice settings, patients, and care models.

ASN appreciates the opportunity to provide comments about the proposed rule; the society hopes that the recommendations in this letter, summarized below, are helpful to

CMS as it continues to implement and update this important and evolving program. ASN:

- Welcomes the proposal to create a complex patient bonus and stands ready to work with CMS to make the proposal both more robust and more closely aligned with the patient population served by nephrologists.
- Recommends CMS further refine its approach to topped-out measures to ensure they are identified and expeditiously removed.
- Supports maintaining the weighting of costs at 0 percent in 2018 and urges CMS to use the time between now and December 31, 2018 to transparently develop episode measures applicable to nephrology caregivers.
- Remains concerned that too few APMs—and particularly, too few Advanced APMs—exist as options for specialists, including nephrologists. CMS should utilize every lever available to expand APM and Advanced APM opportunities, including considering modifications to reduce the level of required risk for physician-focused models.
- Maintains that the independence of the patient-physician relationship, and clinician latitude to individualize patient care should be an important consideration in the design, selection and implementation of APMs, episode groups and quality measures.

The Quality Payment Program (QPP)

In 2016, the society encouraged "CMS to develop a robust outreach, education and feedback strategy to help clinicians understand the new payment system…." The society would like to thank CMS for doing exactly that. The creation of the Quality Payment Program website is a welcome tool that contributed to that effort – as well CMS's timely and clear notification to clinicians identifying whether the clinician or practice was included within MIPS or AAPMs.

ASN further thanks CMS for the creation of a 2017 transition year that included a "Pick Your Pace" structure for MIPS and weighted the costs category at 0 percent along with other modifications designed to ease clinicians into the QPP.

CMS has proposed to raise the low-volume threshold in MIPS in 2018. Clinicians would be excluded from MIPS if they do not bill over $90,000 in Medicare Part B allowed charges or do not have over 200 Part B beneficiaries. ASN appreciates CMS's decision to proceed cautiously in implementing the QPP and taking extra steps to protect small practices or ones with lower levels of Part B allowable charges.

Merit-based Incentive Payment System (MIPS)

<u>Facility-Based Measurement</u>
CMS has proposed an optional, voluntary facility-based scoring mechanism based on the Hospital Value Based Purchasing Program. The proposal contains a thoughtful discussion of issues relating to the timing of providing the necessary information to facility-based (specifically, hospital-based) MIPS clinicians. The focus of that discussion

centers on efforts to ensure that by providing this information at certain points in the year it does not give these clinicians an unfair advantage over non-facility-based clinicians.

ASN urges CMS to move cautiously and measure the reaction to this proposal carefully as this move could harbor several unintended consequences that would place the non-facility-based clinicians at a disadvantage. ASN notes that the typical nephrology practice involves work at multiple facilities, often seeing patients at several hospitals, multiple dialysis units and at least one outpatient clinic. The impact of this mechanism on nephrology practices is uncertain, and ASN would be pleased to discuss this further with CMS.

Hierarchical Conditions Category Bonus

CMS proposes to add a complex patient bonus, limited to three points, to the final score for the 2020 MIPS payment year for MIPS eligible clinicians that submit data for at least one performance category. CMS proposes to calculate the average Hierarchical Condition Category (HCC) risk score for a clinician or group by averaging HCC risk scores for beneficiaries cared for by the clinician or clinicians in the group during the second 12-month segment of the eligibility period, which spans from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year (September 1, 2017 to August 31, 2018 for the 2018 MIPS performance period). The proposed rule also contains an alternative proposal, in which CMS would apply a complex patient bonus based on the ratio of patients who are dual eligible.

The society thanks CMS for focusing on this important topic and welcomes this discussion. Patients with kidney diseases are among the most complex in clinical practice. These patients usually have multiple severe comorbid conditions – especially those with kidney failure treated with dialysis or transplant – and require high levels of care and monitoring. CMS succinctly and accurately identifies the issues involved and the need for balance in the QPP when it wrote in the proposed rule that “[t]he overall goal when considering a bonus for complex patients is two-fold: (1) to protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage….” ASN concurs with this statement.

There are several aspects of this important proposal that need further refinement. The point bonus does not appear robust enough nor does the proposed process sufficiently consider patient population size, as smaller patient populations are statistically problematic. As seen in Table 36 of the rule, the average HCC Risk Score for nephrology is 3.05 and the dual eligibility ratio is 33 percent. That is the highest HCC Risk Score of any specialty and one of the highest dual eligibility ratios as well. ASN is concerned that the proposed HCC risk scoring could be cumbersome and, while the alternative proposal is simpler, the proposed rule does not provide a sufficiently detailed discussion of the pros and cons of the alternative to properly compare the proposals. ASN stresses that, reflecting the complicated patient population, nephrology providers

have relatively small numbers of patients they care for; this combination of high severity and low numbers requires a robust system to adequately account for illness severity and complexity.

ASN welcomes CMS's interest in this issue and hopes CMS will further refine this proposal to better accommodate the complexity of care involved and the potential for smaller patient populations – as well as developing a more robust comparison of the possible methods for calculating the HCC risk score. ASN would welcome the opportunity to work with CMS as this effort moves forward.

Topped-Out Quality Measures

In 2019 and beyond, CMS proposes that any measure that is identified as topped-out for two consecutive years would not provide more than six measure achievement points in the second consecutive year it is identified as being topped-out. After three years of being identified as topped-out, the measure would be considered for removal through the rulemaking process. ASN does not object to this proposal.

The statistical definition CMS uses to define topped out measures is exceedingly difficult to reach given the high numbers as, with large populations or numbers of facilities, clinically insignificant differences can be statistically significant. Nephrology's experience with the Quality Incentive Program (the first mandatory pay-for-performance program within Medicare, implemented in 2010) suggests that even if a measure does not meet CMS's statistical definition of being topped-out, there are many circumstances, particularly given the relatively low numbers of patients at each dialysis facility in relation to the much larger number of facilities, where measures are 'clinically' topped out. When this occurs, the measure may no longer achieve the goal of incentivizing and rewarding quality care but rather prevents individualized patient-centered care.

This concept has important implications across quality payment programs, including for the MIPS. Quality can be defined as the right care for the right patient at the right time. Inherent in this definition is the ability to individualize care and the recognition that there are both medical reasons and patient-choice reasons why a treatment that is optimal for most patients may not be optimal for a specific patient. As such, ASN supports a robust process to evaluate and remove topped-out measures to ensure optimal patient care and success of the QPP and emphasizes that assessment of whether a measure is 'clinically' topped out is essential for all metrics. This evaluation should include statistical assessment but also requires clinical input and evaluation.

Performance Threshold

ASN appreciates CMS's efforts to adjust the performance threshold with care within the constraints of the statute – especially regarding small practices. CMS indicates that payment year 2021 will be either based on the mean or the median of the proceeding performance year. Since the 2017 transition year set the performance threshold at 3, CMS proposes to set the 2018 performance threshold at 15 to prepare clinicians and groups for a potentially more stringent threshold set by the HHS Secretary based on the mean or median in the future.

Since 2020 with be the year that is used for the mean or median calculations in performance year 2021, CMS discusses setting the 2020 performance threshold at 15 again or at an alternative of 6 to allow for a greater number of clinicians to exceed the mean or the median and protect smaller practices. CMS also suggests another alternative of 33 with the goal of encouraging more robust participation. Setting a threshold of 6 could be met by submitting two quality measures with required data completeness or one high-weighted improvement activity. Setting the performance threshold at 33 points would require full participation both in improvement activities and in the quality performance category and would represent a significant increase in performance requirements.

In general, ASN would prefer to evaluate the threshold results for 2018 before determining the performance threshold for 2020. However, if CMS is planning now, ASN recommends either keeping the 15-point threshold or adjusting downward to allow practitioners greater room for success.

Additionally, CMS proposes to award 5 bonus points to the final scores of small practices less than or equal to 15 clinicians. CMS does not propose to extend the same bonus points to rural practices now, but will monitor rural practices for signs those practices should also receive similar bonus points even though CMS notes that rural and non-rural practices are only separated on average by one point at this time. ASN appreciates CMS's concerns regarding small and rural practices, but, in this case, the society urges caution in this area because it has concerns that CMS may be signaling that quality standards for rural patients need not be as robust as for non-rural patients.

Costs

CMS has proposed to weight costs at 0 percent for performance year 2018 as it did in transition year 2017. ASN concurs with CMS's recognition of the fact that, with limited episode groups developed, implementation of this category will be difficult—or even impossible—for certain eligible clinicians, including nephrologists. The society thanks CMS for proposing to weight this category at 0 percent and strongly supports this direction for 2018.

CMS is also soliciting comment on an alternative proposal of weighing costs at 10 percent in 2018. The rationale presented for the alternative proposal is that, by statute, costs must be set at 30 percent in performance year 2019 (payment year 2021) and that going from 0 percent to 30 percent could be too abrupt an increase. While ASN recognizes that CMS is statutorily obligated to comply by performance year 2019, the society believes that it would be best to focus efforts in 2018 on developing episode groups in partnership with the medical community and building buy-in for their use starting in 2019.

ASN is concerned that, to date, no Technical Expert Panel has been announced for work on episode groups pertaining to nephrology. Episode groups are complex, and are key to calculating costs in the QPP; therefore, ASN does not believe it is wise to weight

costs above 0 percent without a sufficient set of episode groups in place for both primary care and specialties. ASN recommends using calendar year 2018 to give CMS, its contractors, and TEPS additional time to further develop episode groups. ASN is concerned about what appears to be a lack of information or transparency surrounding the development of episode groups and is concerned about the prospect of entering 2019 with no nephrology specific episode groups. ASN recommends that CMS use the final rule to delineate its timeline and process for the development of episode groups for each specialty.

Opt-In

Starting in 2019, CMS proposes to let clinicians and groups opt-in to MIPS if they exceed only one of the two threshold requirements but meet another identified requirement such as Part B items and services. ASN is not opposed to this approach but shares CMS's concern about what to do if particularly small practices or solo practitioners with low Part B beneficiary volumes opt-in, as such clinicians may lack sufficient sample size to be scored on many quality measures, especially measures that do not apply to all patients in a clinician's practice. Since ASN could imagine this might be the case at times in nephrology, it encourages CMS to move carefully and to maintain this as a strictly *voluntary* approach only.

Continuing Medical Education

CMS has included language in Table F to explicitly recognize Continuing Medical Education (CME) as an Improvement Activity (IA) in MIPS. ASN welcomes the inclusion of CME in this category to support better health care and provide flexibility for health professionals as well as incentivize clinicians and groups to participate in CME activities that improve their practice.

Virtual Groups

In 2016, ASN urged CMS to create virtual groups for performance year 2017. ASN is glad to see CMS moving forward on virtual groups for 2018 and hopes this will be a helpful path for solo practitioners and small practices.

Data Completeness

CMS proposes that clinicians who report on measures that do not meet data completeness standards will receive one point as opposed to three points currently although small practices will continue to receive three points. Recognizing that the QPP is a young, evolving program, ASN urges CMS to not make this change and maintain the current formula so clinicians will have the opportunity to learn how to interact optimally with this developing program.

Data Submission

CMS proposes to allow clinicians and groups to report measures and activities through multiple submission mechanisms within a performance category. ASN enthusiastically welcomes this change.

Certified Electronic Health Record Technology (CEHRT)

Under the proposed rule, the Advancing Care Information category would allow both the 2014 and 2015 Edition of CEHRT. ASN welcomes any changes, such as this proposed modification, that allow clinicians to use existing products instead of acquiring new ones.

ASN believes that significant opportunities exist to leverage EHRs to improve nephrology care, and hopes that their increased adoption will meaningfully improve patient outcomes in the future. However, the society continues to advise against requiring high adoption levels of participation in MIPS (or in APMs) until there are greater levels of interoperability in the EHR technology. Until EHR technologies achieve better interoperability than currently available, increasing the stringency of EHR adoption requirements for health professionals participating in MIPS or APMS will be relatively ineffective at driving improved patient outcomes. This is particularly true for nephrologists, reflecting the multitude of locations in which they practice, the lack of integrated EHR technologies in many of those environments, the lack of control over the selection of technologies, and the lack of interoperability of these systems.

Advanced Alternative Payment Model (AAPM)

ASN supports the creation of AAPMs and the transition to a more truly integrated and value-based care system. As with MIPS, CMS has taken great care to build a solid foundation upon which to base this growing and valuable pathway for clinicians to practice and expand upon.

As noted in last year's comments, ASN remains concerned about the relatively small number of Advanced Alternative Payment Models (AAPM) available for clinicians, particularly for clinicians who care for patients in multiple settings without focusing on dialysis. While the ESRD Seamless Care Organization program offers one option to nephrologists, it remains limited to dialysis care, thereby excluding the nearly 40 million Americans with CKD not yet on dialysis as well the hundreds of thousands who have received kidney transplants who could benefit from integrated care. By definition, this substantially impacts the ability of the clinicians who care for these patients to participate in AAPMs. The society urges CMS to use every available mechanism to foster the development of AAPMs to provide physicians and patients a path forward to the future of care delivery, including models that span rather than silo stages of kidney diseases and incentivize optimal transitions across care settings.

ASN particularly appreciates the work of Physician-Focused Payment Model (PFPM) Technical Advisory Committee (PTAC) in considering and recommending new models to the Sectary for consideration, but the small number of AAPM proposals submitted to the PTAC demonstrate how early in development this path in the QPP remains. As the recommendations from the PTAC to test new PFPM models increases, the society hopes that the Secretary will act favorably and consider testing these models that are recommended.

<u>Nominal Risk</u>

CMS proposes the definition of nominal risk be just the 8 percent revenue standard – 8 percent of the average total Medicare Parts A and B for an entity – and eliminating the 3 percent of expected expenditures. ASN appreciates CMS's efforts to provide a more achievable risk standard for those groups/entities trying to create an AAPM. However, ASN maintains that 8 percent is still high and could serve as a barrier to increasing the number of AAPMs – particularly Physician-Focused Payment Model (PFPM) AAPMs.

As ASN stated in 2016, the society recommends several alternative options for less stringent risk structures for AAPM for CMS's consideration. The society particularly recommends that CMS consider these alternatives as pathways to AAPM designation for PFPMs, as truly physician-led care delivery models will typically have substantially fewer resources with which to take on risk.

- Limiting risk on using revenues received by a practice as a metric instead of a percent of total expenditures for patients (at least in some models).
- Not requiring payments back to CMS if the APM entity falls short of its anticipated revenues, as calculated by the physicians, for at least the first 2 years. Simply not receiving a bonus may be sufficient incentive for improving the ability to calculate risk, as physicians learn how to work within this new paradigm.
- Allowing certain APMs to operate for a pre-specified time period as one-sided risk (long enough to test whether a new care delivery model is promising in terms of cost and outcomes) but with the expectation that it would transition into two-sided risk if it were to be expanded/extended.

The society continues to maintain that, because of the level of risk in a full capitation model, it is unlikely that many, if any, independent physician practices could assume this level of risk and remain independent. Because nephrologists care for a very vulnerable patient population with high rates of complication and mortality, full capitation would be an extremely challenging business model in the absence of significant financial resources. Partnerships with entities with significant revenue and reserves would likely be necessary to support full capitation. However, ASN cautions that permitting an over-abundance of full capitation models will restrict the diversity of practice types in the future and contribute to further consolidation in the already consolidated kidney care marketplace.

<u>All-Payer Models</u>

CMS has provided a great deal of guidance on the many aspects of the all-payer combination option and other payer issues that clearly outlines the process to be followed. CMS has recommended numerous provisions to provide the clinician every possible opportunity to perform well in the AAPM. The support proposed for the clinician and the transparency provided are both greatly appreciated by the society.

The process CMS recommends in the proposed rule will benefit patients with kidney diseases. It would encourage care and attention before a patient reaches ESRD and better align incentives across payers. This approach is welcomed by ASN given its

potential to improve patient outcomes and system efficiencies. For example, the proposed structure could facilitate timely placement of dialysis arteriovenous fistulas, increased utilization of home dialysis and non-dialysis comprehensive conservative care, higher pre-emptive transplant rates, and greater continuity of care – all of which would benefit patients with kidney diseases.

When designing the reporting mechanism to clinicians to denote their participation in an all-payer model, ASN urges CMS to utilize caution to keep the mechanism from becoming onerous.

ASN is pleased with the approach that CMS is taking in the second year of implementation of the QPP. In the 2016 final rule, CMS stressed that it saw the QPP as an evolving system that would need input and participation from all sectors of healthcare, and ASN welcomes that continued approach.

Again, thank you for the opportunity to provide comment on this proposed rule. ASN would be pleased to discuss these comments with CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

Eleanor D. Lederer, MD, FASN

President