ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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December 19, 2016

Andrew Slavitt
Acting Administrator, Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

Re: Final Rule for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, CMS-5517-FC

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the October 14, 2016 final rule for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). 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 the Centers for Medicare and Medicaid Services' (CMS) commitment to a successful implementation of MACRA. The final rule clearly involved a tremendous level of effort by CMS and the Department of Health and Human Services (HHS) to propose a Quality Payment Program (QPP) that fulfills Congress' goals to:

- End the Sustainable Growth Rate (SGR) formula for determining Medicare payments for health care providers' services.
- Develop a new framework for rewarding health care providers for providing better rather than more care.
- Consolidate existing quality reporting programs into a single system.

ASN considers the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (AAPMs) to be a significant improvement over the SGR formula and commends the Agency for the policy principles that shape the QPP. ASN appreciates the opportunity to provide comments about the final rule; the society hopes that the comments in this letter are helpful to CMS as it implements this important new program.

- **Transition Year**
  The creation of a transition year for 2017 was greatly appreciated by ASN and is a strong indication that CMS listened to the comments ASN and others provided regarding the ability of all participating clinicians to be ready by January 1, 2017. Allowing participants to "pick their pace" and affording flexibility on what to report in the transition year is a welcome approach. ASN appreciates and thanks CMS for the decision.

- **Transition Year Reporting and Scoring**
  ASN appreciates the flexibility CMS created for MIPS participants to both pick their pace and reporting details, within limits, in the transition year. The general reduction in reporting requirements in the QPP and, to an even larger degree, in the transition year in Quality, Improvement Activities, and Advancing Care Information was also positive, as is the weighting of the MIPS cost reporting category in the transition year at zero. ASN thanks CMS for listening to its and other stakeholder recommendations to move away from the "all-or-nothing" approach to scoring in MIPS. These changes allow all participants flexibility and an opportunity to "try out" the new reimbursement system. ASN appreciates these decisions.

- **ESRD Seamless Care Organizations (ESCOs)**
  CMS' decision to count both non-LDO and LDO ESCOs as Advanced APMs provides nephrologists more flexibility and opportunity to participate in both ESCOs and Advanced APMs. Clearly, CMS heard ASN's and other stakeholders' request to provide more access to Advanced APMs specifically and to provide more space in the new QPP generally for nephrologists. ASN appreciates the decision and believes that greater access to participation in ESCOs will lead to better outcomes for patients and facilitate nephrologists' involvement in more coordinated models of care.

- **Higher Participation Threshold**
  Setting the participation threshold of the QPP at above $30,000 in Medicare Part B allowed charges and more than 100 Medicare Part B beneficiaries is evidence that CMS heard the concerns of ASN and others regarding the burden of participating in the QPP for clinicians with very low levels of Medicare beneficiaries and charges. ASN appreciates the decision.

- **Robust Outreach/Website**
  ASN encouraged CMS to "develop a robust outreach and education strategy to help clinicians understand the new payment system, decide which payment pathway makes the most sense for them, and prepare their practice to participate successfully in that pathway." ASN believes that CMS understood the society's concern, and that of other commenters, and responded in a robust manner. Allowances for a transition year and lower reporting and scoring requirements indicate that CMS wants clinicians to succeed in the new program. CMS' commitment to success was reinforced by the allocation of $100 million in educational outreach over the next five years and by the development of the www.qpp.cms.gov website. The website is fresh, easy to navigate, and easy to read and understand. ASN encourages CMS to maintain this much more transparent and approachable style of communicating as the QPP matures. ASN appreciates this development.

- **Risk Adjustment**
  Because patients with kidney disease tend to be sicker on average and nephrology providers tend to have riskier patient panels with smaller numbers of patients, ASN believes that appropriate risk adjustment is vital to accurately assessing the quality and cost of nephrology care. That is why ASN applauds CMS's efforts to study the feasibility of including sociodemographic data into risk adjustment models for both quality and cost measures. We believe that CMS's work with the National Quality Forum (NQF) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in studying sociodemographic factors is vital to the MIPS' success. ASN welcomes future opportunities to study how the ASPE's and NQF's findings can be applicable to patients with kidney disease and nephrology providers.

- **Financial Risk for AAPMs**
  CMS made meaningful changes to the methodology for determining AAPM risk thresholds as well as to the level of financial risk that APM entities must assume in order to qualify as AAPMs. The society appreciated the Agency's modifications, which will make it both easier for potential participants to assess participation and to assume the risk necessary to transition their practices and systems into AAPMs that will ultimately deliver more coordinated, patient-centered care. As noted below, ASN has further recommendations in this vein for CMS' consideration but the society appreciates the inroads that the Agency has made in terms of simplification and some risk reduction.

ASN's overall position regarding the final rule of the QPP is positive and applauds CMS for its willingness to review comments and adjust program details when appropriate and possible. With such a massive transformation of the Medicare physician reimbursement system, however, there are bound to be areas of further refinement and adjustment. ASN recognizes the inevitability of the need for refinement in the QPP and would like to work with CMS on a limited number of issues for which refining and adjusting are a priority for ASN.

- **Nephrology-specific Quality Measures**
  There are currently far too few meaningful nephrology-specific measures that are not facility based. ASN is concerned that nephrologists in MIPS will be challenged by a lack of meaningful quality measures; therefore, ASN pledges to work with CMS to develop nephrology-specific quality measures. These measures should also be patient-centered and account for the heterogeneity of the population of patients with kidney diseases. As CMS examines the challenges of the QPP in its transition year, ASN requests that it makes collaboration with the society to develop quality measures for nephrology providers a priority.

- **Reporting from Multiple Settings**
  ASN commented repeatedly in its June 27, 2016 comment letter on the proposed rule that nephrologists have unique challenges when it comes to reporting from

multiple care delivery sites. The average nephrologists may see patients in their office, in a hospital, in a transplant center, and in five to six dialysis facilities at any given time. While they often have no control over the electronic health records (EHR) systems used at those facilities as CMS has acknowledged, they also often have no input or control over costs and clinical practices as well. ASN appreciates the exception that CMS made for this dilemma in the Advancing Care Information portion of the final rule; however, the society maintains there will be similar reporting challenges for some nephrologists in these other categories as well. ASN requests that CMS monitor this situation and the society will apprise the Agency as it learns of examples of these challenges.

- **Value-based Modifier Case Load**
  ASN notes that, with the proposed application of the Value-based Modifier to individual clinicians in 2017, it is imperative to develop adequate within-disease adjustment, to account for the tremendous heterogeneity in patients with kidney diseases. The final rule maintains that measures are reliable with a minimum case size of 20. ASN is uncertain that this is the case across measures, and notes that, within the dialysis realm, ICH-CAHPS, requires a minimum of 30 patient responses. ASN is concerned that 20 is likely to be insufficient given heterogeneity of CKD/ESRD patients and that CMS should model the number of responses necessary for a valid response.

- **EHR Interoperability**
  For EHRs to achieve their potential in advancing care for patients in the context of MIPS (as well as in AAPMs), physicians and other health professionals need solutions that permit disparate EHRs to interface and provide genuine interoperability. Until EHR technologies achieve better interoperability than currently available, any EHR adoption requirements for health professionals participating in MIPS or APMS will be relatively ineffective at driving improved patient outcomes. ASN does agree that opportunities exist to use EHRs to improve care for patients with kidney disease, but ASN strongly encourages the Secretary of Health and Human Services to work with the technology community to develop the seamless interoperability that health professionals need and patients deserve.

- **Nephrology-specific Episodes**
  ASN concurs with CMS's decision to delay using cost performance measures during the transition year. We would like to reiterate the importance of having nephrology-specific episodes that meaningfully reflect the cost of nephrology care. Patients with kidney disease represent a heterogeneous and complex group. The care provided to patients with kidney diseases varies substantially with disease severity and form of ESRD therapy, as does the type of provider primarily involved in delivering care. We would like to stress the importance that episode-based cost-measures adequately reflect this heterogeneity. ASN welcomes all opportunities to provide feedback in the construction of these episodes. We also would like to emphasize the importance of having

parsimonious episodes of care in the context of other nephrology-based cost-measures that are outside the scope of the QPP (e.g., the ESRD prospective payment system). ASN looks forward to providing input as these episodes move closer to being operationalized.

- **Alternative Payment Models**
  As previously noted, ASN is grateful for CMS' responsiveness to the society's input and other commenters' recommendations to create a non-LDO ESCO track that qualifies as an AAPM. ASN recognizes that implementation of MACRA will be an ongoing process, and in future years urges CMS to test significantly more models than at present in order to facilitate the goal of creating as many options as possible for clinicians to participate in APMs and AAPMs. In setting future financial benchmarks for the assumption of risk, ASN also encourages CMS to focus on how entities that can assume those risk levels may influence the independence of the patient-physician relationship and clinician latitude to individualize patient care. These elements must be preserved and should be an important consideration in the design and selection of APMs. ASN also encourages CMS to consider how alternative definitions of financial risk might broaden the scope of providers and institutions able to participate in AAPMs.

  ASN maintains that the development of a comprehensive nephrology care delivery model that is broader than the ESCO program—encompassing kidney patients from advanced CKD through transplant or other kidney replacement therapy and end-of-life—would be an ideal such APM or AAPM. By uniting the elements of care in a kidney patient's journey that are currently siloed (CKD care, kidney replacement therapy including transplantation and dialysis, and end-of-life and comprehensive conservative care), such a nephrologist-led model would provide continuity of care, optimize transitions as kidney disease progresses, and yield cost-savings through greater pre-emptive transplantation, slowing of CKD progression, and superior preparation for and transition to kidney replacement therapy.

Again, thank you for the opportunity to comment on this final rule. ASN appreciates CMS's commitment to a robust, quality-driven physician reimbursement system and the Agency's efforts to engage the society and other stakeholders in the QPP implementation. ASN would be pleased to discuss these comments with CMS if it would be helpful and stands ready to assist in any way; please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

Raymond C. Harris, MD, FASN
President