ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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November 17, 2015

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: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the September 2015 "Request for Information (RFI) for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)." ASN represents nearly 16,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of patients. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. 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.

In summary, ASN encourages Centers for Medicare and Medicaid Services (CMS) to:

- Encourage physicians to report on a smaller number of outcomes-based measures (instead of a greater number of process-based measures)
- Create as many mechanisms as possible for interested physicians to participate in Alternative Payment Models new payment and care delivery models
- Facilitate the development of Physician Focused Payment Models and allow as many of these models as possible to qualify as Alternative Payment Models
- Prioritize the creation of a "comprehensive CKD care delivery model" to optimize kidney patient outcomes and quality of life throughout the spectrum of kidney disease
- Continue to collaborate with ASN and other stakeholders in the MACRA implementation process

Merit-Based Incentive Payment System

ASN commends the MIPS program's goal to better align physician reimbursement with quality and value. The society appreciates that a single program—MIPS—will replace three separate programs—EHR Meaningful Use (MU), the Value-Based Modifier (VM), and the Physician Quality Reporting System (PQRS). ASN offers comments on the four MIPS program categories

and looks forward to continuing to work with the Agency as it shapes the details of this new program moving forward.

MIPS Category #1: Quality

ASN recommends that CMS maintain all PQRS reporting mechanisms noted above under MIPS. The current PQRS reporting mechanisms provide physicians with choice and flexibility to report in the manner best-suited to their particular practice environment. Moreover, maintaining the current mechanisms will avoid the administrative and financial hardships of implementing and learning a new reporting system. While ASN recognizes that there are advantages and disadvantages to each of the current PQRS reporting mechanisms, the disadvantages are far outweighed by the benefits associated with maintaining the current system. The society would be pleased to work with CMS to identify weak points in the existing PQRS reporting system and conceptualize improvements that could be implemented in the new MIPS program.

Under the current PQRS, CMS requires physicians to report on 9 or more measures; in the new MIPS system, ASN urges CMS to consider reducing that number and to emphasize on outcomes measures as opposed to process measures. By limiting the reporting requirement to 9—or fewer—measures, physicians will be encouraged to focus on the most meaningful aspects of care most likely to improve patients outcomes.

ASN also recommends that CMS encourage physicians to report predominantly on outcomes-based measures, directly reflecting the quality of care their patients actually receive. To do so, the society suggests CMS permit physicians who report on outcomes measures to report on fewer measures than physicians who report on more process measures. That said, the society believes that all physicians should be required to report on a minimum number of outcomes-based measures. Over time, CMS could potentially increase this number, such as to three and then to five measures over a span of several years. Ultimately, reporting on a maximum of five outcomes-based measures should constitute success within the Quality aspect of the MIPS program.

The society also observes that outcomes-based measures would address every domain within the National Quality Strategy. Thus, physicians reporting all or predominantly outcomes-based measures should not be required to report on measures that cover a specified number of National Quality Strategy domains. For physicians reporting predominantly process measures, it would be appropriate to require them to cover three of the six National Quality Strategy domains. To incentivize physicians to focus on outcomes instead of processes, ASN recommends CMS offer the option of not requiring a specific number of National Quality Strategy domains if the measures reported are outcome-based.

As CMS selects outcomes measures for inclusion in the MIPS program, ASN encourages the Agency to prioritize measures that are applicable to both specialists and primary care providers. Outcomes measures should be cross-cutting and not subject to change as “best practices” evolve over time. Examples would include outcomes measures such as mortality, hospital admissions, patient safety outcomes, and access to high acuity care (ER).

ASN believes it would be helpful for CMS to require that reporting mechanisms include the ability to stratify the data by demographic characteristics noted in the RFI, such as race, ethnicity, and gender. The society also recommends that CMS add age to the list of characteristics. Assessing social determinants of health that influence people’s ability to manage their chronic disease (and which physicians have no control over), such as behavioral

health issues, would be an interesting aspect for CMS to explore in the context of the Quality category.

CMS inquires what potential barriers may exist to meeting the "Quality" category of MIPS successfully? As noted elsewhere in this comment letter, a proliferation of quality measures, particularly less-meaningful process measures, would add significant administrative burden and distract from more meaningful aspects of practice. ASN strongly encourages parsimony in measure reporting requirements and an emphasis on fewer, outcomes-based measures. The society also urges CMS to identify mechanisms to reduce the two-year time lag between when care is provided and physicians receive payment adjustments. The significant gap in time reduces the utility of the program and makes it harder for physicians to make meaningful alterations in practice based on the quality program information.

Finally, ASN notes that the diversity of patient populations—with different degrees of comorbidities and health status changes—will make it difficult for all providers, especially those who treat the sickest and most disadvantaged patients, to succeed. CMS should identify ways to ensure that the new system does not unintentionally create disincentives to provide care to the most vulnerable patients, and ASN would be pleased to work with the Agency in this effort.

MIPS Category #2: Resource Use

Of the four existing components of the VM, ASN believes that the "per beneficiary" spending assessment is the most useful evaluation. The society does not have recommendations of other cost or resource use measures at this time, but observes that the baseline for the component "per beneficiary – with specific conditions" will change over time as best practices evolve.

ASN participated in the development of the Choosing Wisely recommendations and strongly supports their use in helping physicians and their patients in making informed, individualized recommendations. However, the society does not recommend that CMS attempt to incorporate these recommendations into the MIPS program. Not only is it possible that some of the Choosing Wisely recommendations will be modified over time as knowledge of "best practices" evolve, the recommendations are not intended to apply to all patients or be used in every situation. As such, ASN believes it would be inappropriate to integrate Choosing Wisely into the MIPS program.

At present, primary care providers and community-based measures are the peer group/benchmarks in the VM program. As CMS implements MIPS, ASN strongly encourages the Agency to compare subspecialists to subspecialists, and to use measures that best reflect that subspecialty. Collecting and disseminating data regarding how peers in the same subspecialty perform in terms of resource utilization would be a helpful and motivating practice for physicians nationwide. ASN would be pleased to provide additional input regarding measures specific to the practice of nephrology and encourages CMS to seek input from the society, nephrologists, and other kidney community stakeholders.

MIPS Category #3: Clinical Practice Improvement Activities

ASN believes that the "subcategory" areas outlined—expanded practice access, population management, care coordination, beneficiary engagement, and patient safety and practice assessment—are appropriate areas of focus to achieve the MIPS program's goals of focusing on value- and outcomes-based payment as opposed to quantity-based payment.

At present, nephrologists and other health professionals engage in a wide variety of focused, documented activities that aim to improve the efficiency and effectives of their practice, enhance patient access, and deliver better outcomes. Broadly speaking, the society would encourage CMS to allow as many of these activities as possible to qualify for participation in the MIPS program. For example, nephrologists routinely conduct Quality Assurance (QA) and Performance Improvement (PI) activities in dialysis units and health systems. Frequently, these QAPI and other clinical practice improvement activities are designed specifically to address the local patient population needs. Consequently, there is significant—and necessary—variation across institution and geographic regions. ASN hopes that CMS will structure the MIPS program in a way that reflects and embraces the multitude of clinical practice improvement activities that meet the needs of diverse patient populations nationwide.

In terms of patient safety and practice assessment, ASN recommends that the program also permit any and all activities that health professionals participate in as part of Maintenance of Certification activities—from any accrediting body—to qualify towards participation in the MIPS program. Further, ASN suggests that CMS permit patient safety and practice assessment-related activities developed by nationally recognized professional societies in their area of expertise also count towards MIPS participation. Similarly, the society observes that many patient safety and practice assessment activities are only successful to the degree that they aim to achieve high quality, evidence-based quality metrics. ASN recognizes that MACRA made available funding to develop such metrics, and encourages CMS to prioritize clinical practice improvement activities designed to help clinicians achieve such metrics developed by professional societies for MIPS eligibility.

The society also believes that the most effective types of clinical practice improvement activities include utilization of composite score on multiple aspects of care over time, as opposed to a single aspect of care. Utilizing a composite score can be a helpful approach not only to encourage focus on multiple aspects of patients' well-being at once, but also to ensure latitude to individualize patient care without concern for deleterious effects on a metric assessing a single aspect of care. For physicians caring for smaller numbers of patients, or those with very complex conditions and differential care goals, preserving this flexibility is especially important. For instance, in nephrology care, a potential MIPS-qualifying clinical practice improvement activity could be tracking progress over time on achieving patient-meaningful measures, in a composite score, such as:

- Catheter rates at dialysis initiation
- Nutritional benchmarks
- Percent of patients who receive transplantation
- Percent of patients who resume work (full or part time)
- Rehospitalization rates
- Vaccination rates

Accordingly, ASN suggests that CMS prioritize clinical practice improvement activities that involve composite scores for MIPS eligibility.

Overall, ASN views thoughtful and appropriate expansion of telehealth and related technologies as an integral piece of the transition from fee-for-service care to more comprehensive, alternative payment models. Accordingly, the society also strongly endorses the concept of permitting telemedicine to also qualify as part of the MIPS program. ASN encourages CMS to allow health professionals who are implementing telemedicine and remote patient monitoring to

count as part of their successful participation in the MIPS program. Telemedicine will be a key tool for many health professionals to provide more comprehensive, timely, and coordinated care and should be included among the MIPS-qualifying options, such as under clinical practice improvement subcategories of care coordination and patient engagement, and under the categories of resource utilization and quality. ASN would also support waiver of the existing limitations on what qualifies as an originating site, geographic, and other limitations currently restricting the provision of telehealth or remote patient monitoring services.

MIPS Category #4: EHR Meaningful Use

As explained in greater detail in this comment letter (please refer to comments regarding EHR utilization requirements for PFPMs) ASN is entirely supportive of the shift to EHR systems but believes HHS should focus more on elevating the standards for which types of technology/interoperability meet "certified" criteria than on imposing stringent adoption requirements on health professionals. As such, the society generally advises CMS to implement policies and methodologies that make it as feasible as possible for physicians to fulfill this aspect of the MIPS program, at least at this time, and until EHR technologies are advanced such that they consistently provide the interoperability to support meaningfully improved patient care.

Alternative Payment Models

ASN is enthusiastic regarding the transition towards payment and care delivery models that shift towards a more coordinated, value-based system. The society looks forward to working collaboratively with CMS to conceptualize and develop APMs as well as PFPMs in the coming months and years. ASN hopes these preliminary comments—which focus around the theme of creating as many mechanisms as possible for interested physicians to participate in these new payment and care delivery models—are helpful to CMS and looks forward to continued opportunities for dialogue.

As noted in the RFI, MACRA defines eligible APMs (EAPMs) as:

- A Centers for Medicare and Medicaid Innovation (CMMI) model
- Medicare Shared Savings Program Accountable Care Organizations
- A Health Care Quality Demonstration Program (under section 1866C); or demonstrations required by Federal law

CMS inquires how it should define "services furnished under this part through an EAPM entity" and the society encourages CMS to adopt a definition as broad as possible to maximize physician participation and opportunities for patients to receive value-based care. The society recognizes and commends CMS for permitting patient choice in current ACOs and CMMI demonstration projects. In a similar vein, ASN also encourages CMS to consider more flexible approaches to allowing physicians to provide care that counts towards participation in an APM.

CMS also asks for input regarding the appropriate level of financial risk "in excess of a nominal amount." The society again encourages CMS to define nominal risk to permit broad participation by physician practices of different sizes and types. While supportive of the shift to these new types of care delivery models, the society also believes CMS should work to ensure that smaller physician practices are not imperiled or eliminated during this transition. The definition of "nominal" will vary largely by the size of a given practice; for instance, for a practice of three physicians, a risk interval of three percent could be a prohibitive barrier to APM participation.

Practices will need to invest in new staff and technologies to become a successful APM, adding the financial risk of APM participation. In fact, allowing APMs to "count" start-up infrastructure costs in risk level definition will generate more APMs. CMS may wish to consider a sliding scale of risk levels, as well as caps on losses. The society also suggests that the agency consider permitting risk to remain one-sided (i.e. eligible for shared savings but not shared losses) for a number of years, particularly for smaller practices.

CMS invites comment concerning which entities should be eligible to participate in EAPMs; ASN again emphasize the importance of defining EAPMs broadly to encourage participation in and acceptance of these new care delivery models. The three basic criteria for an APM—nominal financial risk, quality measures that are comparable to MIPS measures, and use of certified EHR technology with payment based on quality performance—are clearly criteria for EAPM design. In addition, ASN also stresses the importance of a leadership role for physicians—not only in PFPMs but also in APMs. As discussed elsewhere in this letter, ASN also strongly urges the agency to allow PFPMs to count as APMs—and to support the development and testing of a wide variety of PFPMs.

Use of certified EHR technology is a baseline criterion for APMs, and CMS requests input regarding what specific EHR components should be required, including whether the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs is appropriate.

ASN believes that significant opportunities exist to leverage EHRs to improve nephrology care, and hopes that APMs incentivize more widespread adoption and use of EHR systems to meaningfully improve patient outcomes. However, in order for EHRs to achieve their potential in advancing care for patients in the context of APMs, physicians and other health professionals need solutions that permit disparate EHRs to interface and provide genuine interoperability.

As noted in a 2015 article by Drawz et al in the *Clinical Journal of the American Society of Nephrology*, opportunities exist to use EHRs to improve care for patients with kidney disease and 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.

For instance, in order to make seamless care transitions and optimal care coordination a reality, it is critically important that EHRs used in hospitals and in nephrology practices effectively and easily interface with and incorporate data from the dialysis providers. Currently, it is burdensome to access EHR data from the dialysis units and vice versa. ASN encourages HHS to pursue solutions that have the disparate EHRs develop interfaces for interoperability.

Until EHR technologies achieve better interoperability than currently available, any EHR adoption requirements for health professionals participating in APMS will be relatively ineffective at driving improved patient outcomes. As such, ASN recommends that certified EHR technology criteria for APM be separate from current Meaningful Use definitions. ASN is entirely supportive of the shift to EHR systems but believes HHS should shift focus toward development of standards for technology/interoperability that meet "certified" criteria by facilitating seamless care.

Physician-Focused Payment Models

ASN encourages CMS to be broad in its selection process and create as many opportunities as possible for societies, practices, and other stakeholders to propose new APMs that could be tested or operated through the Center for Medicare and Medicaid Innovation (CMMI) or other "selected Medicare demonstrations." On principle, PFPMs Models should be led by, and centered on payments to, physicians and physician-led entities (not facilities or other provider types).

As noted in the RFI, MACRA requires CMS to establish an independent PFPM Technical Advisory Committee that will evaluate potential models and make recommendations to the Secretary, and that while PFPMs do not necessarily have to meet the criteria to be considered APMs, ASN joins CMS in encouraging model proposals that would "count" towards physicians' participation in APMs. The society believes structuring the PFPM Committee and criteria in a way that allows as many possible PFPMs to qualify as APMs is a vitally important goal towards the success of the MACRA law. CMS should encourage a wide variety of PFPMs, promoting innovation in care delivery as opposed to a single model for a patient or provider type. Heterogeneity among PFPM models should be encouraged, allowing for physicians in disparate regions caring for unique patient populations to devise and test new and better ways of delivering care. Importantly, ASN encourages CMS to assess PFPM's effectiveness in improving both patient outcomes and patient satisfaction.

CMS proposes that special consideration may be given to creating PFPMs for specialists not eligible to participate in current APMs; ASN opposes this proposal for several reasons. First, this construct potentially implies the approval of just a limited number of PFPMs (for example, this could imply that the CMMI Oncology Care Model is the only PFPM available to oncologists). Such consideration would seem counter to MACRA's objective to help as many physicians as possible move into APMs. Second, ASN observes that some existing CMMI models involving specialists—such as the ESRD Seamless Care Organization (ESCO) program—involve only a fraction of the scope of practice of a group of specialists (in the case of the ESCO, dialysis). ASN hopes that CMS facilitates the development of alternative models based on the wide variety of patient conditions, stages of diseases, and needs—including needs that extend to the period before kidney failure.

That ESCO program, which focuses on the care of patients with ESRD, is an important and worthwhile experiment in care delivery. But ASN believes that more avenues should be available to test physician-focused models that provide care to patients with kidney disease throughout the *continuum* of kidney disease. Among patients with more rapidly progressing kidney disease and patients with advanced chronic kidney disease (CKD), including but not limited to those treated with dialysis and transplantation, ASN notes that nephrologist care is critical to optimizing treatment of nearly all health issues in this population. As CMS is aware, the current system is fragmented, with multiple providers often providing less than seamless care and frequent sharp demarcations at times of transition, including at development of kidney failure.

ASN believes that the establishment and testing of multiple PFPMs in kidney care would generate novel models of care for these chronically ill patients with multiple co-morbidities, leading to better outcomes and reduced costs in the Medicare program. Given the complexity of CKD patients, CMS should allow a range of kidney PFPMs to be evaluated in order to have a rich dataset in order to take the best possible models to scale.

APMs: Potential Comprehensive CKD Care Model

One such APM, for instance, could be a "comprehensive CKD care delivery model." This care delivery paradigm would be similar to the ESCO, but broader, as it would include patients with advanced CKD, including kidney transplant recipients, coordinating transitions across kidney disease states, and managing and slowing the progress of kidney disease and other complex chronic conditions that are common in patients with advanced kidney disease. Including transplant patients within the scope of this model would create inherent incentives to promote transplantation for the greatest number of patients possible who are candidates.

MACRA's enactment opens the door to developing a specialized CKD care delivery model to address the unique and significant unmet needs of this patient population. As noted earlier, more than 20 million Americans have CKD, a condition that disproportionally affects underrepresented minorities. Patients with advanced kidney diseases suffer from multiple other serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disease, and heart failure, and commonly receive care from multiple specialists. More than 50% of patients with CKD have 5 or more other co-morbid conditions, and CKD care for patients age 65 and older exceeded $50 billion in 2013—representing 20% of all Medicare spending in this age group. A "comprehensive CKD care delivery model" would present a unique opportunity to provide better cost-effective, patient-centered care that is not possible under the current delivery system.

Such a pilot model would build upon and borrow from many of the same concepts in the ESCO model, but expand the target patient population. Spearheading the care coordination efforts, a nephrologist would serve as the care leader for a population of patients from the time of their diagnosis of advanced CKD and would assume responsibility for their care—in coordination with other providers, including physicians, heart failure and palliative care specialists, and dialysis organizations—through the transition periods of dialysis initiation, transplantation or end-of-life care.

Nephrologists are specifically trained to manage patients with multiple co-morbid conditions and, in a "comprehensive CKD care delivery model," the nephrologist and nephrology practice would assume primary responsibility of managing related comorbidities and coordinating patients' access to the multitude of other specialists needed to manage their complex conditions—with an option to form partnerships with other providers as appropriate. Effective management of co-morbid conditions is especially important for patients with earlier stages of CKD, during which proper care coordination by a nephrologist can help slow the progression of kidney disease towards ESRD, reduce provision of unsafe medications to CKD patients for whom many medications either require dose reduction or should be avoided, and help prevent the worsening of co-morbidities that are caused or exacerbated by kidney diseases, such as hypertension and heart disease. Public accountability for quality and cost of services delivered, and a common financial system or shared financial goals across all sites of care included in the model would contribute to more patient-centered, cost-efficient care for those with the complexity of illness associated with advanced CKD.

As patients progress towards kidney failure, a "comprehensive CKD care delivery model" would inherently incentivize care coordination that improves outcomes and reduce costs, including:

- Facilitating timely, optimal preparation and education for the preferred forms of kidney replacement therapy, including all aspects and options of kidney transplantation, exposure to home therapy modalities, and vascular access planning and procedures.
- Focusing on slowing the progression of kidney disease, including patient education and incorporation of various innovative methods of disease-monitoring to enhance self-care.
- Eliminating the fragmentation that often characterizes the transitions of care from CKD to dialysis to transplantation.
- Allowing for thorough discussions of goals of care with patients and their families and allowing transitions to palliative care for those individuals who decline renal replacement therapies.

Besides improving the transitions of care though advancing CKD stages to ESRD, ASN anticipates that a "comprehensive CKD care delivery model" would facilitate best practices. ASN would also support inclusion of telemedicine services—as well as remote patient monitoring—as a tool that should be available to health professionals participating in a CKD, or other, APM. Used appropriately and judiciously these services in the context of a new payment model may give nephrologists flexibility to manage co-morbidities and coordinate care for people with all stages of kidney disease more effectively.

Many important details of this or any other kidney-focused PFPM would need to be considered at length. For example, most nephrology practices today have relatively small patient populations with high comorbidity (and morbidity), making case-mix adjustment difficult and presenting a barrier to establishing sufficient volume such that one adverse event does not overly affect performance. ASN would welcome the opportunity to continue discussions and provide more detail regarding how the society envisions a "comprehensive CKD care delivery model" APM could improve patient outcomes and reduce costs to the Medicare system.

PFPM Criteria

CMS puts forward five criteria (listed below) that it is considering for possible use by the PFPM Committee. With the exception of bullet number one—for which ASN's concerns are described elsewhere in this letter—the society believes that these are reasonable criteria

- We are considering that proposed PFPMs should primarily be focused on the inclusion of participants in their design who have not had the opportunity to participate in another PFPM with CMS because such a model has not been designed to include their specialty. **[Oppose]**
- Proposals would state why the proposed model should be given priority, and why a model is needed to test the approach. **[Support]**
- Proposals would include a framework for the proposed payment methodology, how it differs from the current Medicare payment methodology, and how it promotes delivery system reforms. **[Support]**
- If a similar model has been tested or researched previously, either by CMS or in the private sector, the stakeholder would include background information and assessments on the performance of the similar model. **[Support]**
- Proposed models would aim to directly solve a current issue in payment policy that CMS is not already addressing in another model or program. **[Support]**

Recognizing that it is likely that providers will come forward with many potential models that achieve these criteria, ASN suggests that CMS consider a mechanism to fast-track evaluation of PFPM proposals through the Innovation Center. The society also hopes that CMS will collaborate with ASN and other specialty societies to provide feedback on drafts and upfront data, ensuring that CMMI receives high-quality proposals that have been thought through by multiple stakeholders. Finally, ASN requests that CMMI provide feedback to applicants whose PFPM proposals are not selected so that they can revise accordingly.

Again, thank you for the opportunity to provide comment on this RFI. ASN would be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Associate 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