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

September 8, 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: CMS-1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the July 2015 "Proposed Rule: End-Stage Renal Disease Prospective Payment System and Quality Incentive Program." ASN represents nearly 15,000 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 are 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:

- Permit patients with ESRD to receive chronic care management services
- Finalize the proposal to cover advanced care planning services for all patients
- Finalize the proposal to add certain home dialysis services to the list of approved Medicare Telehealth Services
- Establish pathways to form of alternative payment models (APMs) that will lead to seamless patient-centered, high-quality and cost-effective healthcare delivery for patients with chronic kidney diseases
- Pre-specify the metrics/endpoints that define success of an APM and rigorously and transparently assess success in achieving these metrics
- Permit as many of the routine clinical practice improvement activities physicians conduct as part of day-to-day practice and as part of maintaining certification to qualify for participation in the Merit-Based Incentive Payment System (MIPS) program as possible

Chronic Care Management
ASN applauds CMS for establishing and continuing to assess the Chronic Care Management (CCM) payment codes; coordinated care management is a critical component contributing to more patient-centered care, better health for individuals, and reduced expenditures to the Medicare program.

Patients with advanced kidney diseases almost always have multiple other serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disorders, and heart failure, and commonly receive care from a multiple specialists. As such, they could especially benefit from the proactive, comprehensive care coordination that CCM services offer—providing them superior quality of life, fewer hospitalizations, and better long-term health. More than 50% of patients with chronic kidney disease have 5 or more other co-morbid conditions, and chronic kidney disease is included among 4 of the 5 most costly chronic condition combination triads in the Medicare program (CMS Office of Information Products and Data Analytics, August 2014). ASN strongly believes that patients with kidney disease deserve equitable access to CCM services.

Patients with kidney disease—particularly those with End-Stage Renal Disease (ESRD) who are on dialysis—often have a nephrologist serving as their principal care provider, overseeing and coordinating many other facets of their care beyond managing dialysis. Some patients with kidney disease on dialysis continue to have a general internist or family practitioner fill that role. Due to the high acuity of illness and substantial burden of serious chronic co-morbidities, all of these patients deserve access to CCMS care coordination and non-face-to-face care management benefits, regardless of which provider type delivers these services. ASN is concerned that because code 99490 cannot be billed during the same service period as CPT codes 90951–90970 (certain ESRD services), these patients are missing out on important benefits covered by CCM but not by these ESRD services. Patients with kidney disease on dialysis would benefit from, as examples, the following components of CCM services that are not directly related to their ESRD care:

- *Accessibility of care plan though certified EHR to patients and other care providers*: Care plans for patients on dialysis tend to be very unique and very important to patient safety. Granting patients as well as care providers access to this care plan via certified EHR would protect patient safety and ensure patients' individual care wishes are enacted.
- *Managing non-ESRD related care transitions*: Transitions of care are increasingly recognized as one of the most dangerous times in a patient's care—as well as one of the most costly. Patients with kidney disease are frequently hospitalized for a multitude of reasons, both kidney and non-kidney related, and their health and safety would be better ensured with the oversight of a health professional providing CCM services.
- *Coordinating non-ESRD related care among different providers*: Given their complexity, ESRD patients need a "captain" who can oversee and coordinate the procedures and medications to treat their multiple conditions. Certainly now, an individual health professional rarely serves that role.
- *Access to care (24/7 coverage), and enhanced communication capabilities between patients and providers*: 24/7 access to for care management services would provide ESRD patients with a means to make timely contact with the nephrology health professionals who have access to their comprehensive electronic care plan, enabling address their urgent chronic care needs, helping reduce hospitalizations and provide more timely care
- *Medication reconciliation*: Patients with kidney disease require a number of different medications prescribed by different specialist to manage their multiple co-morbidities and have altered drug metabolism, which increases the risk of untended drug interactions or adverse events. A health professional providing CCM services could

coordinate and oversee the patient's medications and reduce the risk of unintended adverse events.

Importantly, none of the above services are included under the scope of the Monthly Capitated Payment (MCP) that nephrologists receive. ASN believes that patients with ESRD should be eligible to receive these CCM services, whether from a nephrologist or other qualified health professional.

In the longer term, ASN anticipates that, by encouraging providers to focus on all aspects of a complex patient's care, new payment mechanisms such as CCM codes will encourage innovation and the development of more sophisticated APMs and healthcare systems that provide effective comprehensive and coordinated care. But until APMs are more widespread and our health care system has made more progress in the transition from fee-for-service reimbursement models, ASN believes that patients with kidney disease who are on dialysis should not be barred from receiving CCM services while receiving life-sustaining dialysis care.

CMS also requests comment on "ways to recognize the different resources, particularly in cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the codes that describe the broader range of E/M services." ASN observes that nephrologists often spend a significant amount of time consulting with patients with kidney disease and their families via telephone, as opposed to a face-to-face visit. Particularly when physicians already have a fully-scheduled day and their patients have a medically necessary inquiry, phone consultations can be of benefit to the patient—as well as save costs by preventing that patient from visiting an emergency room or other urgent care environment to address their health concern.

ASN recognizes that Medicare does not pay separately for physician telephone conversations with patients (or their families), but that these conversations may be taken into account when the physician is determining which level of evaluation and management (E/M) code to assign on the next claim for a face-to-face E/M visit. Nonetheless, ASN would support payment for medically necessary care provided by telephone, as described by AMA CPT Codes 99441, 99442, and 99443.

Ideally, as telemedicine services continue to expand, patients will have additional tools to remotely see their health professionals. As noted elsewhere in this letter, ASN strongly supports integration of telemedicine care into APMs. In the meantime, the society encourages CMS to consider improving patient access to timely care by providing reimbursement for phone consultations for medically necessary patient inquiries.

Advanced Care Planning Services
ASN commends the agency for proposing to activate the advanced care planning codes as described in the proposed rule, CPT code 99497 and CPT code 99498

This laudable addition to the suite of services available to Medicare beneficiaries will significantly improve patients' and families' experience of care and allow for more individualized, patient-centered care planning. ASN concurs with CMS that advanced care planning is essential for chronically ill patients, such as those with advanced kidney disease. Without access to these important services, patients would have less flexibility to direct care to best meet their needs.

In summary, society believes these advanced care planning codes will be advantageous to all patients, including those with CKD and ESRD, and encourages the agency to finalize this important proposal.

Telehealth Services
ASN commends CMS for its proposal to add the monthly capitation payment (MCP) services (CPT codes 90963, 90964, 90965, and 90966, the at least one face-to-face patient visit per month for the home dialysis MCP service) for home dialysis patients to the list of approved Medicare telehealth services. ASN and other stakeholders have previously advocated for this change and the society thanks CMS for its shared understanding regarding how this addition to the Medicare telehealth list will facilitate dialysis patient access, choice, and improved health outcomes.

Routine face-to-face interactions remains a cornerstone of high-quality care for all dialysis patients, and ASN supports at least one face-to-face interaction per month. However, permitting flexibility for home dialysis patients and their physicians to sometimes conduct their monthly interactions via approved telecommunications technologies (such as videoconferencing) will facilitate medically necessary patient-physician interaction—especially in rural or underserved areas—and will likely prompt more patients to consider home dialysis.

Again, the society thanks CMS for this proposal and encourages they agency to finalize its recommendation to add these MCP services to the list of approved Medicare telehealth services.

Proposed New Physician Quality Reporting System (PQRS) Measures Available for Reporting for 2016 and Beyond and Proposed Changes to Existing PQRS Measures

ASN offers comment regarding three proposed changes to the Physician Quality Reporting System (PQRS):

1. CMS proposes to add the measure "**Adult Kidney Disease: Referral to Hospice**." ASN believes access to hospice care is an important element of patient choice and, overall, supports the concept of this measure. ASN supports the addition of the measure but note notes that clarification is needed in defining 'withdrawal' as well as how inpatient (hospital level) vs outpatient and sub-acute facilities are accounted for in the denominator and numerator, respectively, before the measure is ready for use.

2. CMS proposes re-categorize the measure "**Adult Kidney Disease: Catheter Use for Greater than or Equal to 90 days**," from the "effective clinical care" domain to the "patient safety" domain. ASN opposes the re-categorization of this measure. While for most patients catheters are the least optimal vascular access—and do carry increased risks—catheters are not inherently unsafe for all patients. Indeed, for some patients, such as those with very limited life expectancy or damaged vasculature, catheters are the most appropriate vascular access option. As such, the goal should not be to eliminate catheter use altogether, as placing the measure in the patient safety category may imply.

3. CMS proposes to remove two measures, "**Adult Kidney Disease: Hemodialysis Adequacy: Solute measure**," and "**Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial (AV) Fistula**," on the

ground that there is no gap in care. Consistent with ASN's position that assessing a smaller number of measures that examine significant gaps in care is the best approach to drive quality improvement, the society supports the removal of these, and other, "topped out" measures.

Merit-Based Incentive Payment System (MIPS)

ASN appreciates the opportunity to provide input to the forthcoming MIPS program, specifically regarding the types of activities that should qualify as "clinical practice improvement activities." The society hopes the comments it offers on this aspect of the program are helpful, and looks forward to future opportunities to provide input on the other three components of the MIPS program—quality measures, electronic health record standards, and efficiency measures.

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, including QAPI activities certified through an appropriate oversight process, 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—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 metrics developed by professional societies for MIPS eligibility.

The society also believes that the most effective types of clinical practice improvement activities includes 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 achievement 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)
- Referral rates for kidney transplantation
- 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, 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 such as 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.

Alternative Payment Models (APMs)

ASN strongly supports formation of alternative payment models (APMs) that will lead to seamless patient-centered, high-quality and cost-effective healthcare delivery for patients with chronic kidney disease. The shift away from fee for service towards disease-focused, physician-driven value-based care models will result in more comprehensive delivery systems designed to achieve evidence-based standards of care. ASN appreciates the opportunity to provide feedback during this rulemaking cycle and looks forward to continuing to work with the agency during the forthcoming RFI period to shape and evaluate physician-focused payment models. The society also encourages CMS to make the APM development and selection process as open and transparent as possible, focusing on inclusion of patient and health professional input.

APMs: Financial Risk and Quality Assessment

The movement towards payment through APMs aligns with ASN's belief that we need to reshape reimbursement to promote care delivery that maximizes quality and optimizes outcomes for patients. Chief among the changes needed is a shift to more coordinated and comprehensive care. ASN believes there are likely numerous models of payment and care delivery that can help achieve this goal across specialties, and even within specialties.

All APM payment models will need to strike an appropriate balance of risk shared between payers and physicians. CMS should consider offering a range of risk levels for physicians to choose from, ranging from "nominal risk," to more significant risk/benefit opportunities.

Specifically, APM payment models for comprehensive CKD care will require CMS to carefully evaluate the allocation of risk between the payers and the nephrologist. As documented by CMS, CKD is a component in 4 of the 5 most costly diagnostic triads. If physicians and other providers bear too much financial burden, there will be a disincentive to pursue careers that provide care for advanced CKD patients. In addition, all APM models encourage and discourage different aspects of care; CMS must establish mechanisms that monitor quality and outcomes that are independent of APM administration. The goals of APMs, of course, are to deliver the "right" amount of care but the financial incentives are designed to reduce what is labeled unnecessary care. Independent monitors should evaluate the data to determine that care has not been reduced to unacceptable levels in order to maximize savings. In any shared-risk environment, it is imperative to maintain as close to real-time as possible monitoring of patient data to ensure quality standards and patient access are maintained.

In any APM, ASN recommends that CMS rigorously pre-specify the metrics that define success; these endpoints need to be transparent to the entire community before the initiation of the APM. The analytic plan for APM evaluation should be as detailed as possible, with comparable standards to a clinical trial. Such analyses will be important to distinguish between APMs that are truly bringing value-based, higher-quality care and those that have not truly "advanced" care for patients or provided value across the system.

In addition, the society also recommends that the quality measures selected for any APM be focused on outcomes that are meaningful from a patient perspective. A smaller number of high-impact quality measures will be more effective by promoting focus on improving the most important aspects of patients' outcomes and quality of life.

APMs: Qualifying Professionals

ASN believes all advanced practice professionals (APPs) should qualify, along with physicians, to participate in and be reimbursed through physician-focused payment models. APPs play an integral role in the nephrology care team, ensuring optimal and cost-effective care for patients through models of care delivery, which efficiently deliver care from the professional with the level of expertise needed for the clinical complaint. The partnership of APPs with nephrologists in APMs will be important for success. In summary, ASN supports payment models in which the right level of care by the right practitioner is paid for equitably. In some instances, that may mean greater roles for APPs in the care team.

APMs: Selection of APMs

ASN society 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." Given the complexity of CKD patients, CMS should allow a range of APMs to be evaluated in order to have a rich dataset in order to take the best possible APM(s) to scale.

For example, CMMI is currently developing an APM known as an ESRD Seamless Care Organization (ESCO) that focuses on the care of patients with ESRD. This is an important and

worthwhile experiment in care delivery, but more avenues should be available to test APMs that provide care to patients with kidney disease throughout the continuum of kidney disease. ASN believes that the establishment and testing of additional APMs would generate novel models of care for this chronically ill patients with multiple co-morbidities, which would lead to savings in the Medicare program

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 and focus on 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.

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, such 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-morbidities 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. Effective management of co-morbidities 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 as well as 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 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 allow 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 an APM may give nephrologists flexibility to more effectively manage co-morbidities and coordinate care for people with all stages of kidney disease.

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.

APMs: Electronic Health Record requirements

Finally, the agency requests information regarding electronic health record (EHR) use requirements. ASN believes that significant opportunities exist to leverage EHRs to improve nephrology care, and hopes that APMs are structured in a way to incentivize more widespread adoption and use of EHR systems to meaningfully improve patient outcomes and reduce the burden of CKD. As noted in the 2015 CJASN article by Drawz et al, it is also important to acknowledge some of the unintended consequences of EHRs—such as increased work tasks associated with computerized order entry, fragmentation of data, loss of communication, and clinical decision support that may be too rigid, include outdated content, and lead to alert fatigue—that need to be minimized by thoughtful design and implementation.

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.

The Drawz article makes several recommendations regarding how EHRs can be used or optimized 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. Right now, it is extremely burdensome to access EHR data from the dialysis units and vice versa. HHS needs to continue to pursue solutions that have the disparate EHRs develop interfaces for interoperability.

Until EHR technologies achieve far superior interoperability than currently available, any EHR adoption requirements for health professionals participating in APMs will be relatively ineffective at driving improved patient outcomes. 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.

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

Sincerely,

John R. Sedor, MD, FASN
Secretary-Treasurer
Chair, Public Policy Board