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 2, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1612-P: Proposed Rule that updates payment policies and payments rates for services furnished under the Medicare Physician Fee Schedule (PFS) for calendar year 2015.

Dear Ms. Tavenner:

The American Society of Nephrology (ASN) represents nearly 15,000 physicians, scientists, nurses, and other health professionals who improve the lives of patients with kidney disease every day. ASN appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule that updates payment policies and payments rates for services furnished under the Medicare Physician Fee Schedule (PFS) for calendar year 2015. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN'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 CMS to:

1. Finalize its proposal to modify the billing rules to allow nephrologists to bill the full month of care when a home dialysis patient has been hospitalized during that month.
2. Permit billing for both ESRD services and complex chronic care management (CCM) services during the same 90 days and clarify that nephrologists may utilize the proposed CCM services billing codes for patients with CKD.
3. Consider the potential benefits of adding the monthly capitation payment (MCP) services for home dialysis patients to the Medicare telehealth list as federal statute regarding "originating telehealth sites" evolves.
4. Maintain the existing exception for reporting of payments for accredited and certified CME under the Open Payments program for faculty and attendees.

Payments for Physicians and Practitioners Managing Patients on Home Dialysis

ASN commends CMS for its recommendation to address a discrepancy in the way it reimburses nephrologists caring for home dialysis patients who are hospitalized. The society strongly supports the proposed change to "allow the MCP physician or practitioner to bill for the age appropriate home dialysis MCP service (as described by

HCPCS codes 90963 through 90966) scenario if the MCP physician or practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face visit." This proposed change would bring physician payment for home dialysis care into alignment with the existing physician payment for when in-center dialysis patients are is hospitalized.

Home dialysis—in the form of peritoneal dialysis (PD) or home hemodialysis (HHD)—is an important treatment option that, for some patients, offers significant clinical and quality of life advantages. ASN believes that patients should, in consultation with their nephrology care team, have flexibility in selecting the dialysis modality and environment of their choice, including home dialysis.

Under current policy—in contrast to in-center hemodialysis patients—nephrologists must separate out the time their home dialysis patients spend in the hospital and bill for the outpatient services provided to patients at a daily rate instead of the full capitated payment for the month the patients are hospitalized. This discrepancy may create a barrier to equitable patient access to home dialysis as a therapy option. ASN believes that properly aligning physician payments for home dialysis services with may enable more patients to consider dialyzing at home, when appropriate.

This proposed correction aligns with the continued recognition by both Congress and CMS that ensuring people with ESRD have access to home dialysis. ASN appreciates CMS' acknowledgment of concerns regarding this payment discrepancy raised by the society and recommends that CMS finalize the proposed correction.

Chronic Care Management Codes

ASN applauds CMS for establishing payment codes recognizing that coordinated care management is a critical component contributing to better health for individuals and reduced expenditures to the Medicare program. These new complex chronic care management (CCM) codes help account for the non-face-to-face care management work that is frequently involved in or would improve the care of certain types of beneficiaries with complex medical needs—including patients with kidney disease.

ASN strongly recommends that CMS issue explicit clarification that nephrologists may utilize the proposed CCM services billing codes for patients with CKD and encourages CMS to permit nephrologists to bill separately for the proposed CCM services billing codes for patients who are also receiving ESRD services (CPT 90951-90970) during the same 90 days.

Importance of CCM services for patients with CKD

Patients with kidney disease typically have multiple other serious chronic co-morbidities, including diabetes, peripheral vascular and cardiovascular disorders. Nephrologists are specifically trained to manage these multiple co-morbidities, develop appropriate care plans, and coordinate treatment for them in the context of kidney disease. Effective management of these 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 advancement of co-morbidities that are caused or worsened by kidney disease, such as hypertension. Nephrologists are also best positioned to coordinate patients' access to the multitude of other providers necessary to optimally prepare those patients with CKD who will progress to kidney failure for initiating dialysis. In patients with CKD altered drug

metabolism also increases the risk of inappropriate drug prescribing or adverse events from polypharmacy.

Given the importance of managing chronic kidney disease as early as possible in its progression, ASN strongly recommends that CMS issue explicit clarification that nephrologists, who often serve a role as the primary care provider, are permitted to utilize the proposed CCM services billing codes for patients with CKD.

Importance of CCM services for patients with ESRD

ASN urges CMS to reconsider its decision to disallow use of the CCM codes if ESRD services are billed during the same 90 days, and recommends that CMS permit billing for both ESRD services and CCM services during the same period. Currently, nephrologists caring for patients with ESRD often serve as a primary care provider, and it would be particularly important for these clinicians to be permitted to provide CCM services.

Given that a preponderance of patients with ESRD on dialysis have multiple other serious chronic co-morbidities, these complex patients are among the most likely to benefit from more coordinated, comprehensive care. Importantly, the scope and requirements of the CCM codes vastly exceed the scope and requirements that either dialysis units (under the Conditions for Coverage) or nephrologists (as per Monthly Capitated Payments) are currently required to provide. Allowing eligible professionals to bill for CCM services for their patients on dialysis would improve the care of one of the most complex, vulnerable patient populations. Currently, the time taken to provide such care often precludes nephrologists from taking on the role of care coordinator, beyond the time already required to care for dialysis patients and ensure attention to dialysis quality. This leaves the patient without a physician advocate or requires an additional physician visit.

Furthermore, ASN questions the logic of making one life-sustaining benefit—ESRD services to treat kidney failure—mutually exclusive of another service that would provide a coordinated, comprehensive plan of care for and management of all health issues. ASN urges CMS to permit billing for both ESRD services and CCM services during the same 90 days.

Telehealth services

ASN commends CMS for maintaining individual and group Kidney Disease Education (KDE) services on the list of approved telehealth services. The society believes that the KDE program helps to provide patients in all geographic regions the essential educational and counseling services necessary to help them manage their chronic kidney disease (CKD). Important in helping patients understand their treatment options, these services also support the ability of patients to participate in the decision making process as they manage their long term care and, when appropriate, prepare for an optimal transition to dialysis.

In general, ASN is supportive of policies that increase patient access to telehealth care services. Advances in communications technology have the potential to improve the way healthcare is delivered, and Americans stand to benefit from technologies that connect patients and healthcare professionals virtually, facilitating ongoing care and treatment.

One such patient population that may benefit in particular from telehealth services is the home dialysis patient population. While home dialysis therapy is not an appropriate option for every dialysis patient, ASN believes it offers substantial benefit to certain candidates. One major reason that patients select home dialysis is to minimize visits to dialysis centers—a goal that telehealth services could help many patients safely achieve. The society encourages CMS to consider adding the monthly capitation payment (MCP) service for home dialysis patients to the Medicare telehealth list so that a telehealth visit could fulfill the home dialysis face-to-face requirement in the future. For some patients, a telehealth visit to substitute for a face-to-face interaction would enhance the benefits of home dialysis, especially for those who are relatively healthy or who have to travel long distances to see their nephrology health professional.

ASN recognizes that in order to support this recommendation, Congress would first have to establish the home as an originating site for the provision of dialysis. That said, the society encourages CMS to consider the potential benefits of home dialysis telehealth services in subsequent iterations of rulemaking and as federal statute regarding "originating telehealth sites" continues to evolve.

Sunshine Act and Open Payments

In previous iterations of the Final Physician Fee Schedule Rule, CMS has maintained an exclusion for the reporting of payments associated with certain continuing education events (§403.904(g)(1), and ASN is concerned that CMS has now proposed to eliminate this important exclusion. Physician faculty and attendees at accredited and certified CME events should not become reportable under the Open Payments program. ASN contends that this is simply not needed due to the profession's strict adherence to the firewall created by the ACCME Standards for Commercial Support.

ASN joins numerous other providers of continuing medical education in urging that CMS maintain the following recognition of accredited CME providers, faculty and attendees with respect to Open Payments program reporting requirements:

1. **Accredited CME:** The Open Payments program currently—and importantly—distinguishes between accredited CME, which is offered by accredited CME providers offering credit certified by the CME credit systems in medicine, and the promotional education of physicians, which is offered by companies. All providers of accredited CME strictly adhere to firewalls established through the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, promulgated by the Accreditation Council for Continuing Medical Education (ACCME), as revised in 2004, and universally implemented in accredited and certified CME.

2. **Accredited CME Faculty:** Faculty at accredited and certified CME programs are currently not subject to reporting under the Open Payments program. These faculty relationships are with the accredited and certified CME provider, not with any company which might grant commercial support to the CME provider. Grants to CME providers establish a relationship between the company and the CME provider, but not with the independent faculty.

3. **Accredited CME Attendees**: Attendees at accredited and certified CME programs are not subject to reporting under the Open Payments program as

attendees have no relationship with any company which might grant commercial support to the CME provider.

ASN urges CMS and the Open Payments program to retain these exceptions for reporting of payments for accredited and certified CME under the Open Payments program.

Accredited and certified CME differs from other types of promotional educational programming offered directly by pharmaceutical and device manufacturers because accredited and certified CME contains safeguards specifically designed to protect against commercial influence. To avoid the introduction of commercial influence into education which is not accredited and certified and therefore not adherent to the firewall created by the ACCME Standards for Commercial Support, CMS must maintain the distinction between accredited and certified CME versus promotional education to physicians.

CMS also suggests that the current exclusions may warrant repeal based on whether sponsors are aware of the faculty presenting at certified, accredited CME events—either before or after the event. This proposal is flawed for three reasons:

1. CME programs are planned years in advance, and the names of faculty are typically promoted months in advance. It is not realistic, nor would it be perceived as transparent, if faculty names were hidden until the day of the program, nor would physicians attend such programs. Companies providing commercial support to CME providers will potentially learn the names of the faculty, usually before the program, and certainly after the program, through publicly available program promotion. The names of faculty at CME programing cannot and should not be hidden, and establishing a reporting policy based on when a company learns of these names is unreasonable and arbitrary.
2. CMS has agreed that a grant from a company to an accredited and certified CME provider does not establish a relationship with the faculty, due to the firewall established by strict universal adherence in accredited and certified CME to the ACCME Standards for Commercial Support. Therefore, it is should not be necessary to eliminate the exception for reporting of payments for accredited and certified CME under the Open Payments program.
3. CMS has always recognized that attendees have no relationship with companies which might choose to provide grants of commercial support to CME providers for accredited and certified CME. Therefore, it is not necessary to establish an arbitrary timing proxy for attendees. Attending accredited and certified CME does not establish a reportable relationship with any supporting companies.

For these reasons, ASN strongly encourages CMS to maintain the existing exception for reporting of payments for accredited and certified CME under the Open Payments program.

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

Recategorizing measures (Table 23)
CMS proposes to re-categorize two measures relevant to kidney disease in the PQRS measure set for CY 2015 and beyond into a different National Quality Strategy domain:

- Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months. (Re-categorizing from Communication and Care Coordination Domain to Effective Clinical Care Domain)

- Care of Patients with Specific Comorbid Conditions: Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition**.** (Re-categorizing from Effective Clinical Care Domain to Communication and Care Coordination Domain)

ASN supports the proposed re-categorization of the two above measures to different domains.

Removing measures (Table 24)
In addition to the measures CMS proposes re-categorize, CMS also proposes, in Table 24, to remove three measures from the PQRS measure set for CY 2015 and beyond. ASN supports the removal of two of these three measures.

- Adult Kidney Disease: Patients on Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL.

  ASN supports the removal of this measure, which the society has previously opposed due to clinical importance reasons.

- Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months.

  Although monitoring kidney function in patients with hypertension is an important element of care for many patients, no validated data exists regarding optimal testing frequency. ASN supports the removal of this measure but emphasizes the need to screen certain high-risk individuals—such as people with hypertension or diabetes and those who have a first degree relative with advanced kidney disease before old age.

ASN recommends that CMS not finalize its proposal to eliminate the following measure from the PQRS measure set for CY 2015 and beyond.

- Hypertension: Urine Protein Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months.

  Screening for kidney disease is important in high risk individuals, as is identifying people with proteinuria, information that will help identify the first line blood

pressure agent. While recognizing that this is a somewhat flawed measure, ASN believes the benefits of identifying individuals with hypertension and proteinuria is important enough that CMS should not eliminate this measure from the PQRS measure set.

Pediatric measures (removing claims reporting option) Table 23
CMS also proposes to remove the claims reporting option for two pediatric kidney disease measures, Pediatric Kidney Disease: Adequacy of Volume Management and Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL. ASN offers no comment on the administrative changes to the reporting option, but observes that insufficient data exist to support these measures. ASN would support the removal of these measures with the overarching goal that data to support meaningful, robust measures for children with kidney failure should be developed.

CKD Measures Group (Table 29)

Table 29 of the proposed rule lists the measures that CMS recommends including in the CKD Measures Group for 2015 and beyond. ASN commends CMS for creating and maintaining a CKD measures group, but offers some suggestions for improvement on the measure set proposed for inclusion in 2015 and beyond:

- **#122 Adult Kidney Disease: Blood Pressure Management:** ASN concurs with CMS that blood pressure management is a crucial component of care for patients with kidney disease but opposes inclusion of #122 in the measure set. At present, there is insufficient evidence to suggest that reducing blood pressure below 140/90 mmHg does in fact attenuate progression to CKD or provide any cardiovascular benefits to patients with kidney disease. The Action to Control Cardiovascular Risk in Diabetes (ACCORD), African American Study of Kidney Disease and Hypertension (AASK), and other data sources support the same conclusion regarding the lack of evidence. Indeed, recent evidence suggests that less aggressive overall blood pressure control, particularly diastolic blood pressure control, may actually produce better outcomes for patients with CKD. The forthcoming results of the SPRINT trial may provide better evidence to substantiate a blood pressure management measure for this population.

- **#1668/121 Adult Kidney Disease: Laboratory Testing (Lipid Profile):** ASN opposes this inclusion of this measure in the CKD Measures Group given that it is not consistent with the current Kidney Disease Improving Global Outcomes (KDIGO) guideline statement.

- **#0041/110 Preventive Care and Screening: Influenza Immunization:** ASN supports this measure, but recommends that CMS edit it to definitively include those who refused immunization or those who have a contraindication to immunization. NQF #0041 does have these denominator exclusions, but the statement included in the proposed rule differs from NQF #0041 and is more closely aligned to PQRS #110, which divides out the numerators between given, previously given, not given for a good reason, and not given for no particular reason. The dates for the exclusion period should also be modified based on availability of vaccine.

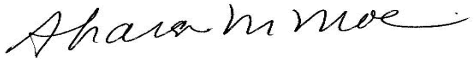
Physician Compare website
CMS proposes to continue expanding physician compare website to reflect new PQRS measures and PQRS reporting from more physicians. The agency also proposes that Physician Compare will present only reliable, valid data that is meaningful from a patient perspective, specifically including:

- Publishing only measures that are statistically valid and reliable and therefore most likely to help consumers make informed decisions about the Medicare professionals they choose to meet their health care needs
- Publishing only measures that are based on reliable and valid data elements to be useful to consumers
- Performing consumer testing and soliciting stakeholder feedback to determine specifically which measures are published on profile pages on the website.

ASN supports these "principles" regarding the quality and usability of the data reported via the Physician Compare website. The society believes these concepts are particularly important to uphold considering the limited number of PQRS measures that are directly applicable to the nephrology community.

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,



Sharon M. Moe, MD, FASN
President