

September 6, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1600-P: Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

Dear Administrator Tavenner:

The American Society of Nephrology (ASN) represents more than 14,000 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 for Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's concerns is the preservation of equitable patient access to optimal quality kidney care and related services regardless of socioeconomic status, geographic location, complexity of comorbid illness, or demographic characteristics.

Kidney Disease Education Telehealth Services

ASN commends CMS for its recommendation to maintain individual and group Kidney Disease Education (KDE) services on the list of approved telehealth services. The society strongly 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. Because many ESRD patients live in rural areas where convenient access to essential health-related resources is limited, telehealth services are central to ensuring the availability of high-quality, patient-centered kidney care. To reiterate, ASN appreciates CMS's continued recognition that preserving KDE services on the list of approved telehealth services is beneficial for Americans with kidney disease.

Pediatric End-Stage Renal Disease Measures

ASN endorses the recommendations made by the American Society of Pediatric Nephrology (ASPN) to support the proposed new pediatric ESRD quality measures (Pediatric Kidney Disease: Adequacy of Volume Management and the National Quality Forum (NQF) #1667 -

Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL) in the 2013 Physician Quality Reporting System (PQRS). ASN is also pleased that the pediatric ESRD measures previously included in PQRS will remain in place in the future.

NQF #0323/ PQRS #81 Adequacy: Solute (ESRD receiving hemodialysis three times a week that have a $spKt/V \geq 1.2$ Adult Kidney Disease: Hemodialysis and Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL)

ASN supports both NQF measure #0321, the Hemodialysis Adequacy: Solute and PQRS #81 Adequacy: Solute. ASN believes that the measures are appropriate and adequately evidence-based. ASN also believes it is reasonable to assess data over the full calendar year rather than on a month-to-month basis or other timetable. However, ASN notes that certain patients are chronically non-adherent to their dialysis regimen and—despite nephrologists' and dialysis units' best efforts—have suboptimal Kt/V levels.

PQRS121 - Adult Kidney: Disease Laboratory Testing Lipid Profile Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period)

ASN recommends that CMS not finalize PQRS #121/NQF#1668 at this time. Although a growing body of evidence indicates that lipid level control and outcomes in patients with CKD may be important, there is insufficient data to substantiate a measure promoting specific target levels. Currently available evidence does not contraindicate a quality measure examining whether lipid level screening is performed. However, ASN is generally not supportive of “process” measures that do not assess clinical care provided and patient outcomes. Given the absence of evidence that assessment of lipid levels contributes to improved CKD patient outcomes, the society recommends against finalizing the measure at this time.

PQRS # 122 Adult Kidney Disease: Blood Pressure Management (Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR $\geq 130/80$ mmHg with a documented plan of care)

ASN concurs with CMS that blood pressure management is a crucial component of care for patients with kidney disease. However, 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. That was the finding in Action to Control Cardiovascular Risk in Diabetes (ACCORD), African American Study of Kidney Disease and Hypertension (AASK), and other studies. 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.

PQRS #123 Adult Kidney Disease: Patients On Erythropoiesis - Stimulating Agent (ESA) (Hemoglobin Level > 12.0 g/dL Percentage of calendar months within a 12- month period during which a Hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy

[RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy AND have a Hemoglobin level > 12.0 g/dL)

ASN recognizes the potential value of a quality measure that identifies consistently and appropriately, high hemoglobin levels in many CKD 4-5 and hemodialysis patients. However, the society has several concerns with measure 1666 and does not support this measure as proposed.

Hemoglobin and ESA dosing information is already reported to CMS for dialysis patients, but the vast majority of nephrology practices possess no infrastructure to report this data for patients with CKD, rendering actual implementation of the measure unfeasible. Consequently, ASN is concerned that this measure would impose a significant data collection and reporting burden for many nephrology practices.

Furthermore, while there may be risk associated with targeting and maintaining hemoglobin levels above 12 g/dL in many CKD patients, ASN is concerned that maintenance of hemoglobin levels at or near 12 g/dL may be appropriate in some circumstances. Moreover, some patients have intermittent hemoglobin level fluctuations that are clinically insignificant. ASN believes it is of utmost importance to preserve nephrologists' flexibility to individualize ESA therapy, balancing anticipated risks and benefits with each patient individually. The society also maintains that it is unfair to penalize physicians or other healthcare professionals for hemoglobin fluctuations that occur despite their best efforts to provide high quality care.

In summary, ASN does not support measure 1666, primarily due to the undue administrative burden reporting hemoglobin values for patients with CKD stages 4 and 5 imposes on nephrologists' offices.

Complex Chronic Care Management Services

ASN applauds CMS for recognizing that coordinated care management is a critical component contributing to better health for individuals and reduced expenditures to the Medicare program. The care management component included in many E/M codes does not adequately 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 CKD and ESRD. ASN strongly recommends that CMS permit nephrologists to utilize the proposed complex chronic care management services billing codes, and that the agency does everything possible to facilitate their use in the care of patients with CKD and ESRD. When administered by nephrologists, the improved access to comprehensive, coordinated care management that the proposed codes would make possible would likely significantly improve outcomes and quality of life for patients with kidney disease.

Patients with kidney disease typically have multiple other serious chronic co-morbidities, including hypertension, diabetes, and various 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. For example, current data show that 43% of patients starting ESRD therapy have not seen a nephrologist prior to initiation. Of these patients, 89% initiated dialysis with a catheter and only 3% with a mature fistula—the optimal form of vascular access. In contrast, patients with more than one year of pre-ESRD nephrologist care were far more likely to initiate dialysis with a mature fistula, with more than 26% starting with a fistula. Permitting nephrologists to coordinate care management for patients with CKD would help ensure that more patients receive timely referral to an interventional nephrologist or vascular surgeon who could place a fistula—as well as refer patients to dietitians, cardiologists, endocrinologists, and other healthcare professionals who would help achieve the appropriate care plan.

Currently, specialists caring for patients who have a serious condition, such as CKD or ESRD, often become the patients' principal care provider. Frequently, it is in the best interest of the patient that nephrologists coordinate aspects of care that are not specific to kidney care but that are important for patients' overall health and quality of life. Within the context of the current payment system—which emphasizes an overall orientation towards episodic care—nephrologists more commonly assume the principal care provider and coordinator role for patients on dialysis. Implementing complex chronic care management services billing codes would enable and incentivize more nephrologists to take the lead in providing comprehensive care to patients with CKD. Although primary care physicians, such as general internists and family physicians, currently provide care to many patients with CKD, their medical training and expertise is limited compared to that of nephrologists in managing CKD related issues. The proposed codes would help increase patient access to the optimal quality of kidney care and overall care management from a nephrologist.

Beyond this general support for the concept of codes for complex chronic care management services, ASN offers several observations and suggestions for improvement that would facilitate beneficiaries' access to the potential benefits of the codes. First and foremost, ASN recommends that CMS *not* finalize the proposal that the complex chronic care management may not be billed separately if ESRD services are billed during the same 90 days. The scope and requirements of the proposed new codes vastly exceed the scope and requirements that either dialysis units (under the Conditions for Coverage) or nephrologists (as per Monthly Capitated Payments) are required to provide.

ASN questions the logic of making one life-sustaining benefit—ESRD services to treat kidney failure (mutually exclusive of another service)—a coordinated, comprehensive plan of care for and management of all health issues. This proposal is especially worrisome considering, as described above, that patients with kidney disease are among the most complex with multiple chronic co-morbidities and therefore are among the most likely patient populations to see substantial benefits as a result of access to such coordinated care. ASN urges CMS to permit billing for both ESRD services and complex chronic care coordination services during the same 90 days.

ASN also observes that the requirements for billing for complex chronic care coordination—including 24 hour, 7 day per week availability—are substantial. While fully supporting the concept of the proposed codes, ASN recommends that CMS consider how to temper the scope of the requirements such that nephrologists and other providers will actually be able to adopt the new codes and make the benefits accessible to patients. One potential solution could be gradually phasing in the scope of services required.

Modifications in Payment Codes

In the proposed rule, CMS proposes several changes that could potentially compromise current and prospective dialysis patient access to timely care. As described above, patient access to vascular access services is a crucial aspect of ensuring the highest quality dialysis care and optimal patient outcomes. “Non-facility settings” (such as vascular access centers) are often more feasible and accommodating places for patients to receive this care than “facility settings” (such as hospital outpatient departments or ambulatory surgical centers). Additionally, the non-facility setting has been demonstrated to be a site of high-quality, excellent patient satisfaction, and low cost. Much of the improvement seen in the CMS Fistula First Breakthrough Initiative can be attributed to improvement in processes and teamwork facilitated in part by these office-based access centers. ASN is concerned that the proposal to cap practice expense relative value units (PE RVUs) assigned to services provided in the non-facility setting to ensure that payments would not exceed the total combined payment that Medicare would pay for the same service in the facility setting could compromise patient access to vascular care. ASN respectfully requests that CMS not implement this proposal in the 2014 final rule for two primary reasons.

1. ASN believes that the premise of capping non-facility practice expense based upon the facility practice expense may be flawed. CMS gave two reasons for capping the non-facility PE RVUs at or below the facility level. First, CMS believes that there are greater indirect costs when a service is provided in the facility compared to the non-facility setting due to factors such as maintenance of 24/7 staffing and providing emergency care. Second, CMS assumes that the cost data is more reliable in the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgery Centers (ASC), compared to the cost data collected under the resource-based relative value scale (RBRVS).

While ASN agrees with the first premise related to increased indirect cost in the hospital setting, this assertion is not necessarily true for ambulatory surgery centers that neither provide emergency care nor remain open 24 hours per day. Additionally, it is not clear which cost data are more accurate—the OPPS or RBRVS. The RBRVS PE data are based upon actual line itemized costs for every CPT code, which should be more accurate than the OPPS estimates. However, the RBRVS is updated less frequently through the Relative Value Scale Update Committee (RUC) process than the OPPS cost estimates, which are updated annually. These differences make it impossible to determine which is more accurate for determining actual practice expense. ASN believes it is clear that capping non-facility (office site of service) PE RVU at the ASC PE RVU is not appropriate and that further study is required before a cap at the OPPS level can be determined to be correct.

2. ASN believes that the cumulative impact on total RVU's of the proposed rule disproportionately impacts kidney patient care. If the 2014 proposed values are implemented, the total RVUs for services critically important to vascular access and central in the care of patients with ESRD would be significantly reduced - over the course of two rulemaking cycles - by approximately 33% (CPT code 36147 - diagnostic fistulagram), 37% (CPT code 35475 - Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), and 24% (CPT code 35476 - Transluminal balloon angioplasty, percutaneous; venous). ASN is concerned that if these reductions were implemented, vascular access care is very likely to be shifted to hospital outpatient departments, compromising timely patient access to an important access of their care. The result of such a shift will compromise overall quality of care and increase costs to CMS.

ASN notes that more research is needed to fully verify the effect of these procedures on patient morbidity, mortality, and quality of life. While this concern is addressed, ASN recommends that CMS preserve patient access to these services in both facility and non-facility settings.

Therefore, ASN requests that CMS not adopt the proposal to apply a facility cap to non-facility practice expense RVU's. If a cap is applied, the society requests that an ASC cap not be utilized.

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 Shaffer at (202) 640-4659 or at rshaffer@asn-online.org.

Sincerely,

A handwritten signature in cursive script that reads "Bruce A. Molitoris".

Bruce A. Molitoris, MD, FASN
President