ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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September 6, 2016

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

RE: CMS-1654-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the July 2016 "Proposed Rule: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017." 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 are the preservation of equitable patient access to optimal quality chronic kidney disease (CKD) and end-stage renal disease (ESRD) care (including kidney transplantation and dialysis) and the integrity of the patient-physician relationship.

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

- Finalize the proposal to expand telehealth services for patients with kidney diseases; ASN appreciates that CMS continues to expand telehealth services for this patient population
- Consider adding additional services to the list of telehealth eligible services, including care of patients with acute kidney injury (AKI) who receive dialysis in ESRD facilities as well as kidney transplant patients and prior live kidney donors
- Continue to identify opportunities to remove barriers to home dialysis, including by exploring ways to address misalignment regarding the Monthly Capitation Payment for home dialysis patients
- Permit patients to voluntarily align themselves with their "main doctor" for purposes of attribution in shared savings models—including specialists such as nephrologists
- Strengthen access to the chronic care management (CCM) codes by eliminating the patient copayment requirement and permitting people with ESRD to access this benefit
- Revise the proposals to revalue certain dialysis vascular access-related codes

Medicare Telehealth Services: ESRD care

ASN commends CMS for its continued efforts to broaden the types of services available via telehealth, particularly its attention to how telehealth services may uniquely benefit patients with ESRD. The society thanks CMS for its shared recognition that adding services for these patients—such as home dialysis monthly codes—to the Medicare telehealth list will facilitate dialysis patients' access, choice, and improved health outcomes.

This year, CMS proposes to continue this trend by adding codes related to services for dialysis less than a full month of service (90967 and 90969) to the list of approved telehealth services. While this change may benefit only a limited number of patients, ASN supports the proposal and believes it would be of utility in certain circumstances. For example, for a patient who resides in a rural area who is hospitalized at the times of the month when his or her MCP nephrologist typically travels to the dialysis unit, the ability to interface with the nephrologist via telehealth at a different time may facilitate better access to care and a more continuous patient-physician relationship.

CMS also proposes adding certain advance care planning services to the list of eligible telehealth services. ASN has historically been strongly supportive of CMS' efforts to increase access to advance care planning services and commends the Agency for this proposal. Advance care planning services are increasingly and appropriately recognized as important components of care to offer patients and their families and this proposal may help more patients access them. For example, patients who live far from their healthcare professional and may not have the ability to travel for this conversation in-person, or patients who run out of time in a visit with their healthcare team to have or complete this important discussion, may benefit from being able to do so via telehealth. Additionally the more flexible nature of telehealth interactions may allow more patients' families to participate in these discussions with the healthcare team. ASN thanks CMS for adding 99497 and 99498 to the list of telehealth eligible services and encourages the agency to finalize this proposal.

While the number of patients who can benefit from telehealth services at this time remains constrained by the limitations on the definition of an Originating Site, ASN recognizes that this issue is not within CMS' control and appreciates that the Agency is taking the initiative to expand access within the bounds of its authority.

Medicare Telehealth Services: Acute Kidney Injury care in ESRD facilities

Beginning January 1, 2017, patients diagnosed with acute kidney injury (AKI-D) who are discharged from the hospital will have the option to transition from acute care facilities to outpatient ESRD facilities for ongoing dialysis treatments. As CMS has recognized (including in the CY2017 ESRD Prospective Payment System Proposed Rule), patients with AKI-D have the potential to recover kidney function and come off dialysis, making them distinct from patients with ESRD. Active measures to enable and identify recovery include frequent face-to-face evaluations of the patient by a physician and/or an appropriately trained advanced practitioner.

In-person patient-nephrologist interactions are ideal for this vulnerable AKI-D patient population, and in a perfect world this would be the case for every visit for every AKI-D patient. However, because the new law permits AKI-D patients to receive dialysis in *any* ESRD unit, it is conceivable that some AKI-D patients will receive their care in rural areas, or in areas where it is not feasible for the nephrologist to visit them in-person as often as would be ideal for AKI recovery supervision. The upside for patients is more convenient, patient-centered care closer to home—but the potential downside is lack of proximity to a nephrologist. So particularly for patients with AKI-D who reside in rural areas, having *some* interactions via telemedicine could

help these patients receive optimal care close to home—even if home is not located near the nephrologist's practice. ASN urges CMS to consider the advantages that adding nephrologist care and evaluation of patients with AKI-D to the list of telehealth eligible services would provide from patient experience and patient quality of life perspectives—recognizing that in-person face-to-face contact still plays an important role and cannot be totally substituted by telehealth.

CMS has recognized the benefits of permitting telehealth interactions between nephrologists and patients with ESRD receiving dialysis, and suggests that the Agency similarly permit nephrologists and patients with AKI-D receiving dialysis to interact via telehealth for their AKI-D care.

Medicare Telehealth Services: Transplantation evaluation and care

In the future, ASN also encourages CMS to explore the possibility of adding codes related to transplant recipient evaluation, living donor evaluation, and transplant recipient and living donor follow-up care to the list of telehealth eligible services. Many aspects of this care would lend themselves ideally to telehealth services, as they generally entail assessment of lab values and dialogue with patients. Significant disparities in access to transplantation exist for patients who live in rural and underserved areas, and telehealth services may help reduce the gap by facilitating evaluation and follow-up where it may otherwise be difficult to provide.

End Stage Renal Disease Home Dialysis Services (CPT codes 90963 – 90970) (p. 102)

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.

As the Agency describes in the proposed rule, the Government Accountability Office (GAO) recently issued a report regarding home dialysis access that found, among other things, that home dialysis utilization is significantly lower than experts and stakeholders believe it could and should be. As CMS reviews, under the current MCP methodology, a physician would have to provide at least four ESRD-related visits per month to receive the highest payment. However, payment for home dialysis MCP services only varies by the age of beneficiary and is less than that for four-ESRD-related visits per month. CMS understandably and appropriately expects physicians to provide clinically appropriate care to manage home dialysis patients.

ASN concurs with the GAO's conclusion that "that future increases in the use of home dialysis are possible," and observes that a number of barriers exist to achieving this important goal. These barriers include a lack of consistent exposure to home dialysis patients during physician training, a lack of patient education concerning home dialysis options (as the GAO reported, the Medicare Kidney Disease Education Benefit is severely underutilized), and, as GAO also observed, a lack of reliable cost report data to ascertain whether dialysis facilities are appropriately reimbursed for maintaining a home dialysis program. In addition, GAO identified that the discrepancy between payment to physicians for in-center dialysis care and home dialysis care may be a contributing factor in the underutilization of home dialysis—an observation ASN believes is valid. In addition to the GAO's findings, a recent survey of ASN's membership on this issue indicated that physicians viewed the discrepancy as one of the elements influencing home dialysis use. The society appreciates that Congress and CMS have maintained a longstanding policy goal of encouraging the use of home dialysis among patients for whom it is appropriate.

Reflecting the GAO's finding and CMS' policy goals concerning home dialysis—which ASN strongly supports—the society encourages CMS to use its authority to establish parity between payment for four ESRD-related visits per month for in-center dialysis patients and payment for the care of home dialysis patients for an entire month.

Chronic Care Management Codes

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.

ASN appreciates that the agency is assessing ways to reduce the burden of providing CCM services and supports these steps. However, in the proposed rule, CMS continues to place the responsibility for remembering which physician is allowed to bill using the CCM code on patients; this is not appropriate. ASN is also concerned that the required copayment may deter some patients from having a clinician provide these important services. ASN recommends that CMS eliminate the copayment requirement on the CCM codes, as well as stop placing the beneficiary in the role of having to consent to the codes being used.

While applauding CMS for maintaining and striving to improve access to CCM codes, ASN continues to have concerns that these codes cannot be billed during the same service period as certain ESRD services (CPT codes 90951–90970), meaning patients with ESRD may be missing out on benefits covered by CCM that are not covered by ESRD services.

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 multiple specialists. Given the number of comorbidities, patients with ESRD often have a number of different providers and specialists. Their care needs go beyond just dialysis—while requiring coordination with and expert input from the nephrologist. More than 50% of patients with CKD have 5 or more other co-morbid conditions, and CKD 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).

Reflecting the complexity of their care, people with ESRD 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. ASN observes that *none* of the CCM services listed below are included under the scope of the ESRD care codes that, under current CMS policy, exclude patients from eligibility for CCM services.

- *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 as part of the services clinicians provide in CCM would protect patient safety and ensure patients' individual care wishes are enacted.
- *Managing non-ESRD related care conditions*: 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.
- *Access to care (24/7 coverage), and enhanced communication capabilities between patients and providers*: 24/7 access 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, for timely attention to urgent chronic care needs, and to reduce hospitalizations.

ASN believes that patients with ESRD would benefit from access to CCM services from any qualified provider. The society also believes that nephrologists, who are specifically trained to manage patients with multiple co-morbidities, are particularly well-positioned for the role of CCM provider and offer significant patient benefit in that capacity.

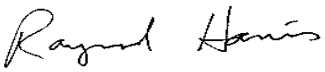
Looking ahead, ASN anticipates that Alternative Payment Models (APMs) and Advanced Alternative Payment (AAPMs) models will encourage innovation and the development of more sophisticated care delivery systems that provide effective comprehensive and coordinated care. But until APMs and AAPMs are more widespread and our health care system has made further 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.

Interventional Nephrology Codes

Recently, the Relative Value Update Committee (RUC) recommended payment reductions to nine new dialysis circuit code bundles. ASN understands that the RUC has proposed revaluing these codes and is concerned that, in this proposed rule, CMS recommends further payment reductions. ASN is alarmed that these proposals may have unintended consequences on patient care and outcomes, including jeopardizing the gains made on achieving the Fistula First/Catheter Last goals and potentially increasing risk of vascular access infections. Vascular access is the 'lifeline' of the hemodialysis patient. Ensuring reliable, consistent access to high-quality vascular access placement services in imperative to giving patients alternatives to catheters and, therefore, to keeping patients healthy and infection-free. ASN urges CMS to consider the serious patient safety implications of this proposal and reevaluate its proposed approach to payment for these nine codes.

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

Sincerely,



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