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 10, 2018

Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program [CMS-1693-P]

Dear Administrator Verma:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the July 12, 2018, combined proposed rule for the Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) for performance year 2019. ASN represents more than 19,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. 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.

ASN appreciates CMS's continued commitment to a transition to value-based care and away from a volume-based reimbursement system. In service of this transition, the merger of the components of the QPP and the PFS seems to be a logical and timely step. ASN recognizes that there are significant challenges to creating a system to accurately and reliably assess and promote value in the context of complex medical decision making. These challenges are particularly difficult when considering both the heterogeneity and medical complexity of patients with kidney disease.

ASN is discouraged by the proposed devaluation of complex outpatient non-procedure medical care, care that is imperative for individuals with advanced severe chronic conditions, including chronic kidney disease, to improve their quality of life. This care is also imperative to prevent complications, costly adverse outcomes, and hospitalizations that are harmful to patients and to the overall healthcare system.

ASN was pleased to see CMS take steps forward on several fronts of importance across medicine, such as:

- Paying physicians for their time when they reach out to beneficiaries via telephone or other telecommunications devices to decide whether an office visit or other service is needed
- Paying for the time it takes physicians to review a video or image sent by patient seeking care or diagnosis for an ailment

- Allowing practitioners to designate the level of a patient's care needs using their medical decision making or time they spent with the patient instead of applying the old Evaluation and Management (E/M) documentation guidelines
- Eliminating the requirement to justify the medical necessity of a home visit in lieu of an office visit
- Allowing practitioners to simply review and verify certain information in the medical record that is entered by ancillary staff or the beneficiary, rather than re-entering it
- Starting in Year 3, permitting clinicians or groups to opt-in to Merit-Based Incentive Payment System (MIPS) if they meet or exceed one or two, but not all, of the low-volume threshold criteria
- Liberalizing and expanding the rules for reporting methods and types in QPP
- Expanding MIPS-eligible clinicians to include physical therapist, occupational therapist, clinical social worker, and clinical psychologist
- Weighting costs at 15%, per Congressional direction, instead of the original 30% weighting called for in the original Medicare Access and CHIP and Reauthorization Act (MACRA) legislation

However, ASN is discouraged that the proposal to consolidate E/M codes threatens ASN's leading goal—promoting the highest quality of kidney care, including transplant care—by potentially undermining the time and resources needed for effective care delivery. High-quality advanced CKD care delivery has been shown to reduce the need for more individually and societally burdensome dialysis care. Unintended by CMS, the consequence of the proposed changes in E/M coding will be a marked negative effect on the lives of patients with advanced kidney disease. At present, it is generally easier to receive reimbursement for supervising the care of a patient on dialysis than by working to forestall the progression of kidney disease, which in some cases can even prevent the need for dialysis altogether. ASN is deeply concerned that CMS' proposals de-value the complicated, time-intensive cognitive care required to slow the progression of kidney disease and adequately prepare patients for smooth transitions to dialysis, transplant or non-dialysis conservative care.

ASN welcomes the opportunity to comment on these proposals and pledges to work with CMS and the broader medical community to find solutions to the areas of great concern to the society that are highlighted in this letter.

Evaluation and Management Coding

ASN thanks CMS for undertaking the enormous task of trying to simplify E/M coding documentation requirements and provide relief from regulatory burden for clinicians. ASN realizes that this effort is part of the Department of Health and Human Services' (HHS) high priority *Patients Over Paperwork* program. ASN congratulates the Administration on its commitment to *Patients Over Paperwork* and supports efforts to reduce regulatory burden while maintaining the needs of patients as the central focus.

The proposed changes to E/M coding and valuation begin with a laudable goal of allowing physicians to justify the level of complexity of a visit based on medical decision making and time involved; unfortunately, the result is a valuation system devoid of nuance for the gradation of care involved. Either there exist gradations of care that grow with the increasing complexity of the patient and their healthcare needs and that require corresponding increases in expertise or these gradations do not exist. ASN maintains that there **are** gradations of care and that physicians should be reimbursed accordingly and with regard to those gradations.

These proposed changes to E/M valuation will have enormous consequences. ASN does not believe the current comment period is sufficient to evaluate the impact of these proposed changes and would welcome the opportunity to work with CMS to refine these proposals over the next year. As CMS wrote, "*In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services*." "*Stakeholders have long maintained that all of the E/M documentation guidelines are administratively burdensome and outdated with respect to the practice of medicine. Stakeholders have provided CMS with examples of such outdated material (on history, exam and MDM) that can be found within all versions of the E/M guidelines (the American Medical Association's CPT codebook, the 1995 guidelines and the 1997 guidelines).* [i]"

The proposed documentation burden reduction efforts are welcome and may provide some burden relief, helping to alleviate the concerns of widespread burnout among physicians. The proposed change would benefit patients by allowing physicians to devote a greater share of their time and effort towards directly caring for patients. As CMS indicated in the proposed rule, there is room to simplify E/M reporting.

However, ASN is concerned about the concomitant proposed revision of reimbursement that effectively compresses reimbursement rates for E/M coding for levels 2-5 into one singular reimbursement payment set between the current levels 3 and 4 for all established outpatient visits and into a second singular code for new patients (CPT codes 99201-99505 and 99211-99215). This proposal reduces the reimbursement for the most complex patient encounters by $76 per visit for new patients and by $55 per visit for established patients, while reducing reimbursement for current level 4 visits by $32 and $16, respectively. These proposed changes have many potential adverse consequences for patients and clinicians – particularly in nephrology.

ASN has identified at least five areas of concern regarding the proposed E/M changes that would have negative implications for patients with kidney disease.

1. Undervalues the Management of Complex Patients
2. Reinforces the Gap Between Cognitive and Procedural Care
3. Disincentivizes Chronic Kidney Disease and Preventative Care
4. Fails to Account for Critical Patient Care Documentation Needs
5. Understates the Impacts on Nephrology Practices, with Reductions Far Higher than Suggested by CMS

In the "recommendations" section of this letter, the society summarizes its recommendations that CMS: 1) Finalize several of its proposals related to documentation; and 2) Collaborate with the physician community develop a refined approach to payment-related changes that help achieve the goal of burden reduction while ensuring patient access to care. **The society believes that a collaborative process over the coming year will alleviate many of the concerns raised about the proposed E/M changes and urges CMS not to finalize any of its proposals related to outpatient/office visit reimbursement.**

1. Undervalues the Management of Complex Patients

Patients with kidney diseases, most of whom are covered by Medicare and cared for by nephrologists, are highly complex patients and have multiple comorbid conditions. The medication management of patients with kidney diseases epitomize the complexity of their care.

Polypharmacy, dose adjustments for changing renal function and drug interactions are common in the CKD population, which is often elderly and vulnerable. In one recent study of patients with CKD not receiving dialysis, the average number of unique medications following an acute care hospitalization was 13.[ii] Critically, the expense associated with adequate reimbursement for ambulatory care likely is more than offset by avoiding costs associated with hospital readmissions, adverse patient safety events, or delayed recovery. These latter costs are particularly common in individuals with advanced CKD, including those with functioning kidney transplants. Medication management is just one of the many time-intensive, knowledge-intensive aspects of care for these patients.

This level of care is not adequately reflected in CMS' proposed single payment amount for all visits 30 minutes or less that would have formerly been billed as anything from a level 2 visit to a level 5 visit. ASN recognizes that CMS has proposed a potential add-on code for time, but, as currently envisioned, this is inadequate. The knowledge and time needed by nephrologists to provide complex care management for a kidney patient is not properly valued in this proposal even when factoring in the add-on code for extra time. As described in more detail elsewhere in this letter, ASN is open to the future development of time-based reimbursement, but the current proposal to make payment the same for a 10-minute visit as a 30-minute visit makes no sense.

CMS' own Actuary has long recognized that reduced reimbursement leads to "behavioral offsets" wherein physicians see more patients in order to compensate for the lowered payment—thereby reducing their time with each individual patient. This well-documented effect does not serve patients well and seems counter-intuitive to the goals of *Patients Over Paperwork*, which aims to allow the patient-physician relationship to thrive with more relaxed face-to-face interaction. The society is concerned that an unintended consequence of lumping all visits under 30 minutes into the same payment category—with no accounting for gradations in the complexity of the patient treated in that window—could result in shortened patient-physician interactions. ASN suggests that CMS work with the physician community, including nephrology, to explore the possibility of developing a more nuanced time-based approach to E/M reimbursement—among other possible approaches—in the coming year.

ASN is providing case examples, with minor changes to preserve patient privacy, from members of its Quality Committee who helped evaluate the effects of proposed regulations on patient outcomes within the clinical practice of nephrology.

ASN Real Case Example

50 year-old man with CKD stage 5 due to chronic glomerulonephritis *(estimated GFR of 8 mL/min per 1.73m^2), not currently receiving dialysis but with an embedded (buried) PD catheter in place, seen in clinic for follow-up. He has mild fatigue but otherwise feels well. Detailed history and review of systems reveal no significant symptoms of uremia. On examination, he has no evidence of volume overload. Laboratory results are notable for hyperparathyroidism and metabolic acidosis with bicarbonate of 19 mEq/L. His hemoglobin is 10.2 g/dL. He is on multiple medications including calcitriol, lisinopril, amlodipine, and sodium bicarbonate. The visit consisted of a very detailed history, review of systems and physical examination to evaluate for symptoms and signs that would suggest that he have the peritoneal dialysis (PD) catheter externalized and begin training for home peritoneal dialysis. There was an extensive review of laboratory results and discussion of warning signs that would indicate a need to return to clinic urgently. We discussed diet at length, reviewing protein intake as a low to moderate protein diet is indicated at this stage. We reviewed his home situation, most notable as he was moving between an apartment and a family member's home, as this is critical for being able to succeed*

at peritoneal dialysis. Given the details needed here and the complexity of management and decision making (is it safe to not start dialysis), this is a level 5 visit. One critical point with this case was that with this level of detail and decision making, currently reimbursed at ~$200, we were able to continue to not begin dialysis (which, for the first month would cost approximately $3000). We will continue to see him every 4 weeks to manage comorbid conditions and to try to optimally time dialysis initiation to avoid hospitalization.

The case study represents an intensive balancing act between patient's healthcare needs and the reality of the patient's life. To delay the start of dialysis required intense review of patient's health and an investment of the clinician's time in other ways. While time could be used as a determinant of reimbursement in a more refined future payment approach, the proposal to lump payment for very complex patients such as the man described above into the same 30-minute or less category of less complex patients does not capture the value of the specialized care provided. While ASN would welcome the opportunity to work with CMS on a more nuanced approach to time and medical decision-making, this proposal does not capture the nuance of time and complexity for patients with kidney diseases.

2. Reinforces the Gap between Cognitive and Procedural Care

The long-running discussion of cognitive versus procedural care has direct relevance to the proposed revisions to E&M coding. As Christine A. Sinsky, MD, and David C. Dugdale, MD, wrote in a *JAMA Internal Medicine titled* Medicare Payment for Cognitive vs Procedural Care: Minding the Gap, "Historically, US physicians have been paid more for performing costly procedures that drive up spending and less for cognitive services that may conserve costs and promote population health*."*[iii]

Their analytical study compared cognitive services versus procedural reimbursement generated by physicians performing screening colonoscopy or cataract extraction, codes that are among the top 40 services ranked by charges submitted to Medicare.[iv] The conclusions, stated below, quantify the broad gap between cognitive and procedural care, specifically stressing that cognitive care historically is devalued.
Medicare reimburses physicians for procedural care at 368% (screening colonoscopy) and 486% (cataract extraction) of the rate of cognitive care. This relative overvaluing of physician time spent on procedures has multiple effects on the health care system. This value discrepancy is a major contributor to the decline in the number of physicians choosing primary care careers. Such a discrepancy may also contribute to an excess of expensive procedural care. We believe the strong financial incentives described compromise access to primary care and ultimately contribute to the lower quality and higher costs experienced in the United States compared with other developed countries[v]

The society shares the concerns characterized above, noting that the current PFS proposal further devalues cognitive care. An unintended consequence of the proposed revisions would be a further entrenchment in this divide, leading to more costly care at the expense of more preventative care and its associated improvement in patients' quality of life and healthcare savings.

Again, ASN suggests that CMS work with the physician community to explore the possibility of developing a refined approach to E/M reimbursement—which includes appropriate valuation of the services provided by clinicians who treat the most complex patients through cognitive care—in the coming year.

3. Disincentivizes Chronic Kidney Disease (CKD)/Preventative Care

Kidney diseases affect more than 40 million people in the United States, with Medicare alone spending more than $33[vi] billion annually on its ESRD program and over $103[vii] billion annually for all kidney diseases. This outlay does not include Medicaid, the Veterans Department, the Department of Defense, and private insurers. These numbers are growing. **To improve the public health, ASN believes firmly that efforts to slow the progression of kidney diseases, manage the complications of advanced kidney diseases, and optimally prepare patients for kidney failure, including preparations for dialysis, transplant, and conservative non-dialysis care, are essential – and have historically been undervalued**. These efforts can be time intensive and should be supported financially to facilitate optimal care. The proposed PFS further disincentivizes clinicians from focusing on the complex, cognitive care that is required to slow the progression of CKD to dialysis and to optimally care for people who have received a kidney transplant.

CMS should find this prospect particularly concerning in light of the broader context of nephrology reimbursement. Clinicians providing care for in-center patients on dialysis receive a monthly capitation rate (MCP) (which is not affected by the E/M coding payment proposal) to manage those patients' kidney care needs, which is an appropriate reimbursement for the detailed care needed by dialysis patients. Critically, under this proposal, nephrologists managing complex CKD patients who are not yet on dialysis will receive significantly less reimbursement than those same nephrologists will receive when making rounds in a dialysis facility. This change, if finalized, will have the effect of promoting more dialysis, a fact that runs counter to the goal of keeping patients off of dialysis through slowing the progression of CKD and pre-emptive transplant.

ASN notes that when individuals with kidney diseases develop advanced CKD, the nephrologist often becomes the principal provider of medical care. Similarly, the nephrologist also often serves as the principal care provider for people who have received a kidney transplant, particularly in the first year following transplant. Given this reality, the society was very discouraged that nephrology was not included in the list of specialties that frequently utilize level 4 and level 5 visits, and that, in the proposed rule, it appears the GPC1X code for primary care may be off-limits to nephrologists. As part of working with the broader medical community to refine changes to physician payment, including a focus on appropriately valuing the complex care that specialists provide, ASN urges CMS to consider clarifying that clinicians serving as principal care providers can also be recognized for their efforts in this regard.

ASN Quality Committee Member Real Case Example

35 year-old patient, new visit, with a fifteen year history of hypertension*, never worked up for secondary causes, is referred for blood pressure evaluation and management and electrolyte abnormalities. He had been taking chlorthalidone 25 mg daily and lisinopril 40 mg daily, and, on laboratory evaluation, had a serum sodium level of 125 mEq/L, a value that is dangerously low, and a potassium level on 5.2 mEq/L, a level that is elevated. In this visit, we reviewed his personal history, which included an episode of syncope while performing a work procedure requiring precision that was attributed to a beta blocker he was taking at the time. We extensively reviewed his family history, which was notable for early onset hypertension and cardiovascular disease. We rigorously ascertained blood pressure, as recommended in the current American College of Cardiology/American Heart Association guideline. We evaluated him for end-organ damage, including evidence of chronic kidney disease. We obtained and interpreted an evaluation for secondary causes of hypertension, and we evaluated the etiology*

of hyponatremia, which, in this case was polydipsia. This resulted in an extensive discussion about appropriate water intake to maintain optimal health in an active individual. This constitutes a level 5 visit, and represents considerable patient-physician interaction, significant cognitive effort and detailed decision making.

This patient visit required extensive time and, more importantly, medical decision making on behalf of the nephrologist that another physician would have been unable to provide. This visit likely reduced the patient's likelihood of developing chronic kidney disease, developing cardiovascular disease and developing cerebrovascular disease, a valuable investment benefitting him as well as the healthcare system. Unfortunately, if finalized, the proposed collapsing of E/M levels 2 – 5 will make it even more difficult for nephrologists to dedicate the time and expertise required to provide this preventative care to patients as part of their routine practice.

Again, ASN urges CMS to work with the physician community to develop a more nuanced payment system that reflects and rewards the unique and important contributions to kidney patient health like the one described here, which the current proposal to collapse E/M levels 2 – 5 fails to do.

4. **Fails to account for critical patient care documentation needs**

ASN understands that CMS anticipates that one of the benefits of reducing the documentation requirements will be to give clinicians more time. CMS also anticipates that clinicians will use some of the extra time not dedicated to documentation to see more patients than before, helping to offset the reduced reimbursement cause by the proposed collapsing of levels 2 – 5. For several reasons, this assumption is not correct for nephrologists. Because the patients that nephrologists treat are so complex and so vulnerable, there is a substantial amount of vital documentation that will still be necessary regarding the plan of care recommendations. Nephrologists spend (and want to spend) most of their time developing the plan of care recommendations, and these must be documented so that other clinicians can appropriately care for the patient. So even if CMS finalizes its proposal to eliminate some aspects of the documentation requirements, nephrologists—and other providers who treat very complex patients—will still have to dedicate a substantial amount of time to documentation.

ASN members report that, if finalized, the net amount of documentation would likely remain virtually unchanged, as nephrologists will shift the time previously dedicated to checkboxes and documenting redundant medical history to documenting a more thorough and useful plan of care. ASN also notes that a considerable amount of documentation takes place after business hours and on weekends, rendering it infeasible for many nephrologists to "swap" paperwork for face time with patients. Importantly, the documentation that is done will be considerably more useful because it will not be buried amidst "note bloat." But, the fact that "note bloat," may be reduced is a separate consideration from the flawed assumption that nephrologists will be able to make up the reduced reimbursement by seeing more patients.

ASN Quality Committee Member Real Case Example

A 12-year-old boy is seen for follow-up of his Chronic Kidney Disease Stage 4 *from obstructive uropathy. His kidney function has been steadily declining and, on today's laboratories, and he now has a serum creatinine corresponding to an eGFR of 20 ml/min/1.73m^2. He has begun to have more systemic manifestations associated with kidney failure, and he is currently being treated through his pediatric nephrologist for kidney-failure*

related anemia, metabolic acidosis, growth impairment, hyperphosphatemia, and secondary hyperparathyroidism. His family reports during today's visit that he is manifesting increasing anxiety about his kidney disease and how it makes him "different" than his peers.

During this visit, the nephrologist:

- *Adjusts the erythropoietin dose and oral iron supplementation based on recent labs work*
- *Reviews growth curve and interval growth velocity and adjustment to growth hormone dose to optimize ongoing growth*
- *Reinforces ongoing provision of sodium bicarbonate, calcitriol, and sevelamer therapy and confirmation of patient and family's understanding of rationale for these therapies*
- *Communicates with the kidney dietitian so she could follow up with the child and his family about questions they had about aspects of his diet*
- *Discusses with the child and his family about seeking consultation with psychology through the Coping Clinic to deal with issues of chronic disease and anxiety*
- *Discusses with the child and his family the need to initiate transplant evaluation and potential identification of a living donor*

This case, as with the others, demonstrates the many ways in which patients with kidney diseases are complex and demand significant investments of time and effort. In addition to the unique expertise required during the visit, it was necessary for this clinician to spend significant time documenting aspects of care needs relevant for subsequent visits with psychology and the transplant team. Thus, in addition to the nephrologist's time and skills for this patient whose complexity is not supported by the proposed collapsed E/M payment, it also highlights the extensive documentation necessary to enable other care providers to understand his needs and ensure his safety.

While ASN appreciates that CMS proposes to reduce other elements of documentation requirements, it is important to recognize that documentation needs for complex patients such as the one described here remain substantial and payment for their care should reflect this critical investment of physician time. The society looks forward to working with CMS to develop a more appropriately aligned approach to documentation requirements for reimbursement in the coming months.

5. Understates the Impacts on Nephrology Practices, with Reductions Far Higher Than Suggested by CMS

CMS has provided estimates of the effect of the proposed E/M coding on various specialties' reimbursement, including an estimated 1% decrease in nephrology revenue. However, an E/M Impact Analysis conducted by the American Medical Association[viii] indicates that nephrology will be the 6th most negatively affected specialty, with a **reimbursement decrease of 13%**. ASN is disappointed that the methodology used to determine the effect of these changes on nephrology and other specialties was not made transparent. Especially in light of the lack of transparency concerning the methodology used to determine these estimates and a significant reduction in reimbursement, a short 60-day window to comment and conduct analysis is insufficient. ASN requests that CMS work with nephrologists during the coming year to develop a more nuanced approach to valuing medical decision-making and patient contact time.

The G-code proposal is a clear example of how these changes need to be refined and nuanced. CMS proposes to create a HCPCS G-code to be used by specialists and primary care physicians who currently bill primarily levels 4 and 5 visits and for whom E/M services make up a large percentage of their allowed charges. The proposed code provides additional reimbursement to go with the E/M services to compensate for complex patients. CMS writes:

> *We are proposing to create HCPCS code CGG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management centered care [Add-on code, list separately in addition to an evaluation and management visit.])*[ix]

It remains unclear if other specialists may use this code. CMS does not identify nephrology in the list of specialties that CMS believes have "complexity inherent to evaluation and management." In light of the complexity of patients whom nephrologists treat, described extensively in this comment letter, ASN is surprised and perturbed that nephrologists were not included in the list.

The exclusion of non-dialysis, non-hospital nephrology from use of the proposed G code further would magnify the proposed E/M reimbursement cut. In concept, ASN is not opposed to the notion of developing a complexity add-on code as part of CMS' physician reimbursement. However, ASN urges the agency to consider this possibility working in partnership with specialty societies over the course of the next year and further urges CMS not to finalize the proposal as written. This effort in partnership would clarify whether and how specialists other than those listed in proposed rule could utilize it and make transparent the methodology used in its development.

ASN Quality Committee Member Real Case Example

A case of post-transplant lymphoproliferative disorder (PTLD), the most serious and potentially fatal complication of immunosuppression. *A 22-year-old man with ESRD due to congenital nephropathy who received a living donor kidney transplant 5 years ago reports vague abdominal discomfort at a follow-up appointment. Further questioning elicited weight loss and night sweats.*

- *The patient had received thymoglobulin for induction immunosuppression; maintenance immunosuppression included tacrolimus/mycophenolate mofetil and prednisone. Review of pre-transplant serologies showed donor EBV+/recipient EBV – status*
- *Physical examination was unremarkable*
- *Labs demonstrated stable allograft function and mild increase in white blood cell count*
- *CT of the abdomen showed thickening of the cecum and terminal ileum, and mesenteric and retroperitoneal lymphadenopathy. These lesions were found to be hypermetabolic on PET/CT. The ultimate diagnosis was post-transplant lymphoproliferative disorder*

The patient required reduction in immunosuppression and chemotherapy to prevent life-threatening progression of PTLD.

The presentation of PTLD can be subtle, and easily missed without careful evaluation. The case demonstrates the need for nephrologists and transplant nephrologists to receive complexity adjustments should the rule be finalized.

In addition to the impact the proposed changes would have on nephrology in general, the impact on transplant nephrologists is even higher. Transplant nephrologists serve a life-preserving role for patients with transplant – a role that no other clinician can fill. Their billing codes are almost all level 4 and 5 and based on very complex and time consuming medical judgment. The proposed changes to E/M codes would be detrimental to kidney transplant recipients if they lead to impairing – in any way – transplant patient access to the best transplant nephrology care possible. ASN stands ready to work with CMS and the broader medical community to align complexity of care with appropriate reimbursement in order to support optimal care for kidney disease patients, including those with kidney transplants.

Recommendations

ASN believes that, although CMS has made strides in approaching the need to simplify E/M coding and in moving in a direction that allows physicians more latitude to rely on medical decision making, the proposed reimbursement side of the equation is out of balance and will motivate clinicians to move away from dedicating their time to cognitive medicine.

ASN strongly urges CMS to work with clinicians over the next year to develop guidelines that account for the gradation and nuances in medical care. The society stands ready and willing to contribute to this effort, drawing upon the relevant expertise of its more than 19,000 members to this important endeavor. For now, ASN strongly recommends that CMS finalize the following changes to **documentation requirement proposals** while retaining the existing five-level coding structure:

1. Allow physicians to **document** visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current guidelines.

2. If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients).

3. Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient.

4. Remove the need to justify providing a home visit instead of an office visit.

5. Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty.

ASN also strongly urges CMS not to finalize any of the **payment-related proposals** contained in this proposal rule. Instead, ASN and peer societies hope to work with CMS to develop revised reimbursement policies, which we believe would better avoid unintended consequences and create more transparency in the methodology. These are steps that we believe would give CMS and the medical community an opportunity to ensure accurate reimbursement that reflects patients' needs and protects their access to care, while appropriately reimbursing nephrologists for the complex care delivered.

Telehealth

ASN is pleased to see CMS building upon the progress that has been made in moving toward greater latitude for clinicians to choose telehealth options and to be reimbursed for doing so. The society welcomes the ability of nephrologists to provide care for home dialysis patients via telehealth for two out of three monthly exams beginning January 2019. ASN also supports expanding telehealth coverage to in-center dialysis rounds in all communities is currently covered with GT modifier in rural communities.

The recommendations in the proposed PFS/QPP to pay physicians for their time when they reach out to beneficiaries via telephone or other telecommunications devices to decide whether an office visit or other service is needed is welcomed, and ASN encourages CMS to finalize this proposal. ASN also supports CMS finalizing the proposal to pay for the time it takes physicians to review a video or image sent by patient seeking care or diagnosis for an ailment.

CMS requested comment on the necessity of the physician to obtain approval from the patient to bill the E/M services involved in these cases. ASN believes that it should be sufficient to inform the patient during the exchange for verbal approval.

ASN looks forward to working with CMS to safely advance telehealth options providing better quality of life for patients.

Facility-Based Measurement

In the CY 2018 QPP final rule, CMS requested comment on the propriety of assigning a clinician or a group a score under facility-based measurement. CMS specifically requested comment on the possibility of using dialysis facility-based quality scores (the ESRD Quality Incentive Program) to evaluate nephrologists' quality performance in the MIPS program. ASN appreciates CMS requesting input on this matter; many nephrologists do spend a considerable amount of time treating patient in dialysis units and the society understands why the agency is exploring this possibility. However, many nephrologists spend very little time treating patients in dialysis units. ASN notes that the typical nephrology practice involves work at multiple facilities, often seeing patients at several hospitals, multiple dialysis units, and at least one outpatient clinic.

Commonly, nephrologists who do focus on dialysis care treat patients in several different dialysis facilities. These nephrologists may have just a handful of patients, a small percent of the patient population, in any given facility. Other nephrologists, often from other practices, care for the other patients receiving dialysis in that unit. As such, it would be very difficult to: a) identify which among the many units a nephrologist provides care in should be attributed, and b) distinguish between the outcomes of the patients for whom they are serving as the MCP nephrologist and those they are not, in determining performance.

Dialysis facilities are typically not owned by nephrologists and are instead owned by dialysis organizations, which credential nephrologists to treat patients in a given dialysis facility (though there are exceptions in which nephrologists do have an ownership role, such as joint ventures). Ensuring the quality and individualization of patient care is very much part of the role of the nephrologist. However, in an environment that is almost always operated, and in which many aspects of patient care are provided by, another entity, it can be problematic to attribute facility-level performance—good or bad—to an individual nephrologist (or even a group of nephrologists). For all these reasons, ASN recommends that CMS generally not use dialysis

facility-based quality scores (the ESRD Quality Incentive Program) to evaluate nephrologists' quality performance in the MIPS program.

However, there is one specific scenario in which ASN believes it would be reasonable to permit ESRD Quality Incentive Program scores to be used for this purpose: the MIPS scores of nephrologists who serve as medical directors. Medical directors have a well-defined role in the dialysis facility, with oversight of the overall quality of care and patient safety. Because medical directors assume responsibility for all patients in a facility, not just those for whom they are serving as the MCP nephrologist, and because it is clear which unit(s) they are responsible for as medical directors, not every unit in which they might provide care, ASN believes it would be reasonable to permit nephrologists who serve as medical directors to elect to have the ESRD Quality Incentive Program scores for the units in which they serve as medical directors to be used for purposes of the quality performance score in the MIPS program. Importantly, ASN believes that if CMS moves in this direction it should be optional, not mandatory, for ESRD Quality Incentive Program scores to be used in the MIPS program. It is unclear to the society how this could be achieved for a group of nephrologists but would be open to dialogue with CMS if the agency has a specific vision.

ASN urges CMS to move cautiously and measure the reaction to this proposal carefully as this move could harbor several unintended consequences that would place the non-facility-based clinicians at a disadvantage. ASN also urges CMS not to finalize any proposal along these lines without thorough vetting by both the physician community as well as the kidney and dialysis communities.

Quality Payment Program (QPP)

As the QPP moves into its third year, the bulk of CMS' proposals seem to be ones of refinement and alignment, which is to be expected. However, ASN feels that as we approach rulemaking for CY 2020, there will need to be more group data available to determine if nephrologists and the QPP are, indeed, on track. Data ASN would like to request are as follows:

- How many nephrologists are participating in the elements of the QPP: MIPS and APMs/AAPMs?
- How many do not meet the low-volume threshold?
- How do nephrologists compare to other clinicians and specialties in the four MIPS categories?
- What quality metrics are they reporting?
- How many nephrologists appealed their 2017 data?

Several issues that ASN would like to see CMS address in the 2019 final rule and in work throughout the next few years are further described below.

<u>Reporting Periods</u>

- Limit the Quality data reporting for 2018 to 90 days to reflect the lateness in which data became available for examination by clinicians.
- Establish uniform 90-day reporting periods across all four performance categories in MIPS.

Nephrology-Specific Measures

With the Quality Performance at 45 percent of the total MIPS score in 2019, ASN is requesting that CMS create an internal Reporting Metrics Task Force to determine how to align reporting requirements for specialties like nephrology that have virtually no nephrologist-specific quality measures.

Costs Episodes

As with quality metrics, ASN is concerned that the rate of increase of the weight of the costs score is going to rapidly outpace the development of costs episodes. ASN requests that CMS provide more transparency into how CMS will account for this imbalance.

Promoting Interoperability

Promoting interoperability is paramount. ASN remains concerned that interoperability remains an objective that physicians must strive to support when it is in reality a responsibility of system developers. If CMS can require groups that submit quality metrics that are approved as MIPS metrics to allow other QCDRs to use them for free, it can certainly begin to require interoperability between systems and that those systems perform medication reconciliation. To do so, CMS may need to address issues of consent and HIPPA.

ASN is also concerned about the complexity and lack of transparency in the scoring of the Promoting Interoperability performance category and urges CMS to provide more details regarding how it calculates participants' scores.

Conclusion

ASN appreciates the enormous time and effort CMS has invested in the transition to value-based care and to the reduction of regulatory burden. These efforts were clearly well-intended and designed to assist patients and physicians. However, the proposed changes to the reimbursement structure supporting E/M visits have many potential unintended consequences. The society stands ready to work with CMS to further refine the E/M proposals and continue the progression to a system that restores balance to the patient-physician relationship.

Sincerely,

Mark D. Okusa, MD, FASN
President

---

[i] Federal Register / Vol. 83, No. 145 / Friday, July 27, 2018 / Proposed Rules
[ii] http://cjasn.asnjournals.org/content/13/2/231.full.pdf+html
[iii] JAMA Internal Medicine, October 14, 2013, Volume 173, Number 18
[iv] *Ibid*
[v] *Ibid*
[vi] USRDS 2016
[vii] Government Accountability Office, January 18, 2017, "Kidney Disease Research Funding and Priority Setting."
[viii] Insert url
[ix] Federal Register/Vol. 83, No. 145/Friday, July 27, 2018/Proposed Rules – 35774.