

November 20, 2017

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: Request for Information by the Centers for Medicare and Medicaid Services Innovation Center

Dear Administrator Verma:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the Request for Information (RFI) by the Centers for Medicare and Medicaid Services (CMS) Innovation Center. ASN represents over 17,000 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) care, end-stage renal disease (ESRD) care including transplantation, and the integrity of the patient-physician relationship.

The burden of kidney diseases in the United States is not acceptable. Currently, 40 million Americans are living with kidney diseases, and for nearly 700,000 of those individuals, access to dialysis or kidney transplantation is their only chance to live. Unfortunately, dialysis patients face a daunting life expectancy of only 5 to 10 years. Transplant can prolong survival for those fortunate enough to receive a donated organ, but our patients with kidney failure are also faced with a national organ shortage crisis: every 14 minutes, a patient is added to the kidney wait list, and every day, 13 patients die awaiting a kidney transplant.

As a nation, we need to directly address the burden of kidney diseases; the devastating toll on patients, their families, and caregivers in the US and across the globe; and the challenges we face confronting this epidemic. The opportunity exists to improve care for patients across the kidney care spectrum: kidney diseases, acute kidney injury, kidney failure, transplantation, and end-of-life care.

Physician-Led Payment Models and Nephrology Leadership

CMS and its Innovation Center are seeking feedback on a new direction to promote patient-centered care, and test market-driven reforms, as well as physician-focused payment models. ASN strongly supports the focus on physician-led models. Physician-led models reinforce the patient-physician relationship at the heart of sound, individualized care for patients. The focus of physician-led models is, by its very nature, is on the patient's needs and not the overly burdensome processes and requirements that often come with care delivery systems envisioned by administrators, not clinicians. Particularly at a time when many of the existing Advanced Alternative Payment Model (AAPM) options are structured financially such that large entities with significant reserves are the only participants who can sign up—and these entities are rarely physician-led—the piloting and establishment of models that squarely place physicians in the driver's seat will be critical. Additionally, the society sees a potential role in using Consumer-Directed Care and Market-Based Innovation Models to develop payment pathways for new innovative products that do not fit clearly or neatly into existing payment structures.

Nephrologists are specifically trained to manage patients with multiple co-morbid conditions, and, in a comprehensive kidney care (CKC) delivery model, the nephrologist and nephrology practice would assume principle responsibility for patients with advanced kidney diseases across the spectrum of their condition. Importantly, this does not mean that primary care providers are not involved in this model, but rather that they are not the care team leader for this complex patient population. Effective management of co-morbid conditions is especially important for patients with advanced CKD, when proper care coordination by a nephrologist can help slow the progression of kidney disease, reduce the incidence of acute kidney injury in those undergoing surgery or other interventions, reduce use of unsafe medications by patients for whom many medications either require dose reduction or should be avoided, and help prevent the worsening of co-morbidities that are caused or exacerbated by kidney diseases, such as hypertension and heart disease.

Comprehensive Kidney Care Delivery Model

ASN strongly encourages CMS and the Innovation Center to test a comprehensive kidney care (CKC) delivery model that would be broader in scope than the current End-Stage Renal Disease (ESRD) Seamless Care Organization (ESCO)—encompassing patients with advanced CKD and including kidney transplant recipients, coordinating their transitions across kidney disease stages, and managing and slowing progression of kidney diseases and other complex chronic conditions that are common in the kidney patient population.

Led by the nephrologist as the care leader for a population of patients from the time of their diagnosis of advanced CKD, this model would assume responsibility for their care—in coordination or partnership with other caregivers, including other physicians such as cardiologists, endocrinologists, and palliative care specialists—through the

transition periods of dialysis initiation, transplantation, or to end-of-life care. These transitions are among the most costly and dangerous times in a patient's life, in large part due to the lack of continuity among health professionals across the silos of care the patient is transitioning between.

Indeed, silos divide kidney care in almost every conceivable manner. Payments for CKD, ESRD, and transplant care are all handled differently both in payment mechanisms and in the metrics by which the nephrologists, dialysis facilities, transplant centers, transplant nephrologists, and surgeons are evaluated. These siloed payment structures and metrics make it difficult to achieve seamless care for patients with kidney diseases consequently leading to less efficient and more expensive care.

A CKC delivery model would present a unique opportunity to provide better, more cost-effective, and more patient-centered care than is possible under the current delivery system *or* in the context of the current ESCO program. This is possible through care integration across medical settings and disease phases, led by nephrologists serving as principal care providers, to improve care quality and patient outcomes in all stages of advanced kidney disease including as patients progress to kidney failure, kidney replacement therapy and/or end-of-life care, as well as achieve savings.

Reflecting the fact that kidney transplantation is the optimal therapy kidney replacement therapy for many patients with ESRD, this model would include transplant recipients for the duration of their lives. This approach would, appropriately, create inherent incentives to promote transplantation and pre-emptive transplantation for the greatest number of patients possible who are candidates while introducing efficiencies in the transplant evaluation process, post-transplant care, and in the transition back from transplant to dialysis if and when kidney transplants fail. Post-transplant patients require very similar care to patients with advanced CKD, and in the current care delivery system, transplant patients often find it challenging to see the many clinicians responsible for their care; this model would improve that experience by coordinating their post-transplant care.

Besides a focus on promoting access to transplantation, ASN envisions that a CKC model would emphasize patient education regarding, and access to, home dialysis modalities and assisted dialysis options and palliative and/or conservative care options that delay or eliminate the need for dialysis, as those become appropriate considerations.

Aligning financial and quality incentives across all sites of care included in the model would contribute to more patient-centered, cost-efficient care for those with the complexity of illness associated with advanced CKD than current care delivery systems. A CKC delivery model would emphasize individualized, patient-centered care while incentivizing care coordination that improves outcomes and reduce costs, including:

- Focusing on slowing kidney disease progression, including patient education and incorporation of various innovative methods of disease-monitoring to enhance

self-care. Eliminating the fragmentation that often characterizes the transitions of care from CKD to dialysis to transplantation.

- Facilitating timely, optimal preparation and education for the preferred forms of kidney replacement therapy, including all aspects of and options for kidney transplantation, exposure to home therapy modalities, and vascular access planning and procedures.
- Allowing for thorough discussions of goals of care with patients and their families and allowing transitions to comprehensive conservative care and/or palliative care for those individuals who do not desire kidney replacement therapy.

Here, ASN offers two potential model concepts to achieve the goals of a CKC delivery model outlined above.

1. Expanded ESRD Seamless Care Organization: Building upon the early successes of the ESRD care demonstration, this model further incorporates transplant care stakeholders and encompasses advanced CKD care.

2. Per-Patient Per-Month Model: Building upon the Comprehensive Primary Care Plus (CPC+) demonstration, this physician-only model would also span advanced CKD care, dialysis, transplantation, and end-of-life.

Comprehensive Kidney Care Model Concept

1. Expanded ESRD Seamless Care Organization Model

In its first performance year, the ESCO Model has been among the most successful of all models the Innovation Center has operated. ASN believes that this both points to the benefits of care coordination for the ESRD patient population as well as suggests that even greater gains in terms of improved outcomes and reduced costs can be made through future, physician-led payment models that encompass more of the kidney patient population.

An expanded ESCO model that brings together nephrology practices (ideally, with a greater role in governance structures than the current ESCO program) and dialysis providers – with the addition of transplant centers and potentially transplant surgeons – would span the artificial silos among advanced CKD care, kidney replacement therapy care including dialysis and transplantation, and end of life care.

The expanded ESCO Model would include a nephrologist/nephrology care team (including transplant nephrology), transplant surgeons, dialysis organizations, transplant centers, hospice and palliative care organizations, and other specialists/physicians. Including transplant patients and transplantation expands the risk pool and allows the achievement of greater savings than without them, particularly when longer term outcomes beyond the year following transplantation are accounted for.

Ideally, patients both over and under 65 years of age who are already have advanced CKD would be included into the model—creating incentives for participants to slow the progression of kidney disease and prevent or delay the onset of kidney replacement therapy (and the enrollment of patients under 65 in Medicare due to that ESRD status). Thus, making this approach an “all-payer” model, potentially including Medicaid as well as private payers would be desirable. The model would follow the patient across all stages of care and accomplish cost savings when progression is slowed, “crashing into dialysis” is avoided, and transplantation rates are increased. Savings are accomplished, and care improved by providing continuity of care across transitions, and reducing hospital admissions/readmissions and emergency department visits.

ASN envisions the expanded ESCO having an active role for transplant centers and transplant surgeons. The transplant centers should become the active lead in evaluating ESRD patients for transplantation and working with nephrologists to identify advanced CKD patients for pre-emptive transplantation.

Within the geographic region that the model is being tested, ASN would also recommend that waivers be developed permitting transplant centers and Organ Procurement Organizations (OPOs) to—within safe and medically appropriate bounds—have somewhat relaxed standards for metrics by which they are judged. Additionally, the transplant centers that participate in the program should also have greater flexibility – possibly COIIN-like waivers from UNOS/OPTN and CMS would be established. This would enable receipt of a kidney transplant by patients who may not be ‘top-grade’ candidates but who nonetheless would be likely to experience better quality of life at lower cost compared to dialysis (and enable the procurement and use of organs that may not be ‘top-grade’ to enable more patients to have transplant as an option). By providing a bit more flexibility to transplant centers and OPOs, the waivers would better align their incentives to achieve performance standards with the goal of providing more patients on or near dialysis with the optimal therapy from quality and cost perspectives.

2. Per-Patient per Month (PPPM) Model

A second physician-led approach that could be considered is the establishment of a per-patient per month (PPPM) model. Sharing the same goals (preventing progression, managing care across the spectrum of kidney disease, and aligning incentives) and encompassing the same patient population as the Expanded ESCO Model described above (patients eligible at an eGFR of 30 and do not have a mandated leave-point), a PPPM comprehensive kidney care model would include *only* physicians as its participants. The Comprehensive Primary Care Plus (CPC+) model serves as the basis for this Chronic Kidney Care Plus (CKC+) PPPM comprehensive kidney care model concept. The advantages of this approach as compared to the Expanded ESCO Model include is that it would be more implementable across geographies and practice sizes and, because the physicians themselves would be the sole participants, ensure true physician-led care delivery (as well as help nephrologists transition to assuming more risk).

Similar to the CPC+ model, a PPPM comprehensive kidney care model would be tested in a large geographic region in which all nephrologists would be eligible to participate. Participants would receive a risk-adjusted, prospective, monthly care management fee (CMF) for attributed patients, in addition to the standard fee for service payments that would otherwise be provided. Participants would either keep or return the CMF based on performance—ideally on a small number of meaningful quality metrics, as opposed to a plethora of process-related or tangentially meaningful metrics. ASN recommends a two-track option offering either less risk or more risk for participants given that some nephrologists who would participate may be in small clinical practices.

To place greater emphasis on care people with advanced kidney disease and to build capacity to better coordinate and slow the progression of disease, ASN envisions that the PPPM CMF would be higher for advanced CKD care than for ESRD care. For patients who have received a successful kidney transplant, the PPPM CMF would more closely resemble the PPPM CMF for advanced CKD (reflecting the fact that post-transplant patients are more similar to non-dialysis CKD from a clinical perspective). As the PPPM CMFs functionally provide more parity across the various stages of disease progression, this model would create an incentive for nephrologists to take on advanced CKD patients earlier than they may have otherwise and intervene with greater resources to organize and integrate care for these individuals with multiple often severe chronic conditions.

Because the nephrologists would still assume responsibility for patients post-transplant (and because we envision adjusted transplantation rate would be among the quality measures), it also creates incentives for more pre-emptive transplantation. Pre-emptive transplantation is the best and most cost-effective therapy for many patients, but, in the current siloed care delivery system, is vastly underutilized with just 2.6% of patients receiving this option. This model would be “care environment agnostic,” permitting nephrologists the flexibility to see their patients when and where they see fit. Additionally, it would permit use of telehealth and telephonic communications with patients via waivers.

Payment Pathways for CKC+:

- Track 1:
 - CMF average \$X in addition to FFS payment for CKD E&M
 - CMF average \$X-Y in addition to FFS payment for ESRD services
 - CMF average \$X in addition to FFS payment for post-tpx E&M
 - CMF average \$X in addition to FFS payment (for pre/peri/post-transplant for transplant nephrologists)

- Track 2 (\$Z > \$X):
 - CMF average \$Z in addition to reduced FFS payment for CKD E&M
 - CMF average \$Z-Y in addition to reduced FFS payment for ESRD services
 - CMF average \$Z in addition to reduced FFS payment for post-tpx E&M

- CMF average \$Z in addition to reduced FFS payment (for pre/peri/post-transplant for transplant nephrologists)

A third risk track could also be considered that involves greater risk and the opportunity for shared savings based on risk/shared savings as a percentage of FFS payments to a physician. In this third track, participants would receive similar CMF payments as described above, but their performance would be assessed on a percentage of total FFS revenues (Medicare Part A and B) and quality metric performance. Nephrologists who deliver savings compared to the benchmark group (and perform well on quality metrics) would be eligible to share in those savings, above the CMF provided on the per-month basis.

For example, if a nephrologist's patients place him or her in the top quintile of adjusted expenditures, he or she would receive a 10% reduction in the FFS+CMF reimbursement. If the patients place the nephrologist in the lowest quintile of adjusted expenditures, the nephrologist would receive a 10% bonus in the FFS+CMF reimbursement. Adjusted performance among physicians would be benchmarked against regional variation in resource use and quality metric achievement among Medicare patients with similarly advanced stages of kidney disease.

Within the geographic region that the model is being tested, ASN would also recommend that waivers be developed permitting transplant centers to—within safe and medically appropriate bounds—have somewhat relaxed standards for probation or shutdown possibly COIIN-like waivers from UNOS/OPTN and CMS would be established. Similar flexibility should be provided to the Organ Procurement Organization (OPO) operating in the geographic area so that more kidneys can be procured that are under the current incentive structure.

As was stated above, this would enable patients with kidney disease to receive a transplant who may not be 'top-grade' candidates but who nonetheless would be likely to experience better quality of life at lower cost compared to dialysis (and enable the use and procurement of organs that may not be 'top-grade' to enable more patients transplant as an option). By providing a bit more flexibility to transplant centers and OPOs, the waivers would better align their incentives to achieve performance standards with the goal of providing more patients on or near dialysis with the optimal therapy from quality and cost perspectives.

Ultimately, as we work to integrate these concepts with existing practices in kidney care, key elements from each concept may potentially form a template for coordinated kidney care in US healthcare.

Consumer-Directed Care and Market-Based Innovation Models

ASN recommends that the CMS Innovation Center consider developing pilot payment models for innovative devices that do not currently fit neatly or clearly into existing payment structures. As innovators look to develop—and investors consider supporting

the commercialization of—cutting-edge new drugs, therapies and devices, having a clear payment pathway forward to support adoption of these products will be critical. Developing and piloting payment models for innovative devices could potentially take place under CMS Innovation Center’s Consumer-Directed Care & Market-Based Innovation Models.

As an example, the Kidney Health Initiative (KHI), a private-public partnership between ASN and the U.S. Food and Drug Administration (FDA), has initiated a project titled [Development of a Roadmap for Innovations in Renal Replacement Therapy](#). This project aims to clarify and address the scientific, technical, regulatory and reimbursement challenges towards bioartificial or bioengineered alternatives to dialysis to enter the market, thus allowing for a robust pipeline of future therapies for patients with kidney diseases.

Given the lack of innovation in the kidney space (and particularly in the dialysis space), ASN hopes that this roadmap will help address the lack of options for patients by bringing more clarity for innovators and investors. Yet a crucial component for success is, of course, a clearly defined payment pathway—one that is lacking in light of the current expanded ESRD bundle. The society would welcome the opportunity to discuss the concept of a role for the Innovation Center in meeting this need in more detail through pilot Consumer-Directed Care & Market-Based Innovation Models.

Conclusion

CMS’ RFI and its design of the Quality Payment Program (QPP) make this an opportune time to align the kidney care delivery system with the patients’ needs – moving across silos to improve outcomes and deliver savings. ASN stands ready to work with CMS and the Innovation Center to create a kidney care model that is physician-focused, and patient aligned and ready for testing. 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,

A handwritten signature in cursive script, appearing to read "Eleanor D. Lederer".

Eleanor D. Lederer, MD, FASN
President

Sincerely,