1. **Integrated nephrology care delivery model pilot programs (pilots) or demonstration projects (demos) should include patients with later-stage CKD in addition to those with ESRD to provide full potential for meaningful benefit to patients and realize more optimal cost savings.**

Kidney disease care encompasses much more than just dialysis. An integrated nephrology care delivery model would ideally encompass a significant spectrum of kidney disease including late-stage CKD (late stage 4 and stage 5), dialysis, transplantation or palliative care, addressing the fragmentation that typically characterizes transitions of care through these stages. As nephrologists play a central role in the care of kidney patients throughout these stages, their leadership in a demo or pilot will be vital.

Improved care coordination could facilitate myriad functions to improve outcomes and reduce costs: slowing the progression of kidney disease, educating patients about their choices, planning for pre-emptive transplant or selecting the most appropriate modality type and environment, planning and initiating the most suitable vascular access type, and formulating palliative care plans where appropriate. Including late-stage CKD also mitigates the potential for preferential patient selection (“cherry-picking” the most financially rewarding patients). Late-stage CKD care could also be an appropriate stage at which to promote development of individualized care plans to help determine the best option for ESRD care, including electing to not receive kidney replacement therapy.

In addition, significant population benefits may be achieved by including the upstream spectrum of kidney disease into primary care-focused ACO’s. These should encompass an aim to prevent or slow the progression of incipient CKD, and better manage early-mid stages of CKD (stages 1-3). Alternatively, in many healthcare systems, CKD clinics have proven to be effective tools in enhancing pre-ESRD care and reducing costs for this patient population. In either case, many challenges exist to these aims. First, many people with early stage kidney disease are unaware that they have it. Second, primary care providers do not always consult nephrologists regarding CKD patients at the appropriate time. Nonetheless, there is tremendous potential to improve pre-ESRD patient outcomes and reduce long-term costs through enhanced interactions and communications between the nephrology and primary care communities.

2. **Integrated nephrology care delivery model pilots or demos should enable the participation of a diversity of dialysis provider sizes and types.**

Maintaining the heterogeneity of dialysis provider sizes and types creates more opportunities for unique approaches to CKD and ESRD care innovation, increasing the likelihood that the project will lead to long-term improvements in the delivery of kidney care. Furthermore, in an environment in which two providers care for nearly 70% of dialysis patients, maintaining a diversity of providers is important to ensure patient choice and care innovation.
To maintain the variety of dialysis organizations, the threshold for the number of patients in an integrated nephrology care delivery model should be set as low as possible.

Promoting diversity in dialysis organizations would be especially important if CMS implements a pilot model (which has a built-in sunset date) rather than a demonstration project (which, barring significant safety signals, would continue in perpetuity). If the demos are successful from both patient care and financial perspectives, the early participants in the projects would likely have substantially more ability to negotiate contracts with ACOs or hospital systems in the future. Accordingly, from a long-term patient choice and access perspective, it becomes even more important to ensure a diversity of dialysis providers permitted to participate in a demo from the outset—especially since, as a whole, independent and small dialysis organizations provide a significant portion of dialysis care.

3. Integrated nephrology care delivery model pilots or demos must include opportunities/incentives for pre-emptive transplant, or promoting transplant as a treatment option for prevalent ESRD patients.

Kidney transplantation is the optimal treatment for ESRD for most patients who are healthy enough to undergo the procedure. Despite the quality of life and financial benefits, transplant rates—especially pre-emptive transplant rates—could be improved. While the organ donor list limits the number of deceased donor transplants, helping CKD patients consider pre-emptive living donor transplantation, and helping patients on dialysis consider their suitability for living donor transplantation or wait list candidacy must be encouraged.

An integrated nephrology care delivery model should ask participating providers to undertake efforts to ensure appropriate referral and evaluation for transplantation. Furthermore, to account for the needs of patients preparing for a transplant and in the peri-transplant period, an integrated nephrology care delivery model must offer and facilitate patient access to services beyond dialysis.

4. The nephrologist should maintain a leadership role, with considerable input into the design and execution of any integrated nephrology care delivery model pilots or demos.

Nephrologist leadership is important for the long-term success of an integrated nephrology care delivery model, as their clinical expertise is necessary to ensure that the program design will improve care for patients and reduce costs. The nephrologist is the only clinician who orchestrates and follows the dialysis patient throughout the continuum of care, from CKD through progression to ESRD and transplant as well as in the outpatient dialysis clinic and hospital setting. Nephrologists possess a comprehensive understanding of kidney patient care, which neither dialysis providers nor hospitals can provide.

Furthermore, a strong presence of nephrologists (who are not employed by for-profit dialysis organizations) in the care delivery model governance structure is crucial to preserving the physician as the patient's advocate. Physician flexibility to individualize care becomes especially important in a shared-risk environment in which less utilization may contribute to greater profit margins. Physician leadership and patient advocacy is critical to ensure that the care delivery model remains committed first to improving the quality of patient care, and second to reducing costs. We believe strongly that dialysis organizations, whether for-profit or not-for-profit, acting independently of physicians or physician organizations, should not be major, active participants in ACOs for patients with CKD who have not progressed to ESRD and that their role in ESRD
patient care models should likewise be secondary to that of the nephrologists and other physicians caring for these patients.

5. **Integrated nephrology care delivery model pilots or demos must be established in a way that facilitates research and innovation in both pre-ESRD and dialysis care.**

The kidney research and care community should have access to the data that are generated through these pilot programs. The dialysis industry invests very little on research and development compared to the medical and pharmaceutical industries. At the very least, an integrated nephrology care delivery model should generate databases (with greater granularity and timelines than USRDS offers) that the nephrology research community can access.

6. **Safeguards to monitor and address preferential patient selection or changes in outcomes must be in place within integrated nephrology care delivery model pilots or demos.**

In any new care delivery model or payment system, it is imperative to monitor changes in patient outcomes and access in as close to real time as possible. Even under the current dialysis care system, it is widely acknowledged that cherry-picking occurs. It is critically important that CMS or CMMI put in place safeguards to prevent and identify preferential patient selection—especially if the model includes incentives to dialysis providers to 'go upstream' and become involved in care for patients who are not yet attributed to their care delivery model to obtain beneficial downstream effects (e.g. fistulas instead of catheters).