



February 10, 2017

Patrick Conway, M.D.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Ave., SW, Room 445-G  
Washington, DC 20201

**Re: PACE Innovation Act Request for Information**

Dear Administrator Conway:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer comments on the Request for Information regarding the PACE Innovation Act. NKCA represents five nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve over 20,000 patients at more than 280 clinics in 30 states. Consistent with our belief that we can do more to keep patients *off dialysis*, we also serve more than 4,500 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, onset of end stage renal disease (ESRD). Approximately 85 percent of our patients are covered by Medicare, including Medicare Advantage plans.

Approximately 26 million Americans suffer from kidney disease, at an estimated cost to the Medicare program of \$99 billion<sup>1</sup>. Our goal is to improve patients' quality of life by providing the best care not just for dialysis patients but also for those with chronic kidney disease to reduce the risk and slow the progression of kidney disease to avoid, or at least delay, the onset of ESRD, and increase the number of patients who can benefit from kidney transplants. Kidney disease (both CKD and ESRD) is a chronic illness that doesn't exist alone. It is often accompanied by multiple co-morbidities, including diabetes, congestive heart failure, and high blood pressure. Kidney disease also exists over many years, making it a particularly appropriate candidate for coordinated care models like the PACE program, which includes coordination of the necessary social services that are critical to patients trying to navigate a difficult and often all-consuming diagnosis and treatment. Many of these social services can be seen in the example in the appendix of this comment including nutrition counseling, social work, and transportation.

The NKCA believes the single most important change that can occur for patients with kidney disease is to better align the incentives of the current reimbursement system and metrics to encompass care for patients with kidney disease, at whatever stage of their journey, rather than focus predominately on

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<sup>1</sup> USRDS. 2014 Annual Report

patients on dialysis. To provide optimal care, interventions should focus on the patient where that person currently sits, instead of seeing the patient as someone who may need dialysis in the future. We believe that by focusing on CKD “upstream” we can reduce the number of patients who need dialysis, and increase those who can benefit from transplant. Based on these beliefs, we strongly believe that CMS should look not only at ESRD in a PACE model, but also chronic kidney disease. We believe there is a great deal of value in integrating care as well as social services across the spectrum of kidney disease to assist patients in preventing or delaying dialysis so that if they do transition in their care, they have been educated about their care options and are better prepared to ease the transition.

For earlier stages of CKD, prior to dialysis, some of the social services that can assist in care coordination include nutrition counseling, exercise, and smoking cessation. For those on dialysis, transportation, mental health services, and social work are critical for patients. In particular, for patients choosing in-center dialysis, who must be in the clinic three times a week for four hours per visit, in both rural and urban areas access can be a challenge and transportation assistance can be critical.

For those individuals who need dialysis as a therapy, it is critical to work with the patient early enough that the patient can make the best decision for his or her care. Unfortunately, too many patients start dialysis in the emergency room unaware until then that they had kidney disease, or at least are ill-prepared. By preparing patients early, and following them closely there are many positive results for patients dealing with this disease. Several of our members have programs specific to CKD in which we see the following:

- **More patients receive a pre-emptive kidney transplant and avoid dialysis.** Nationwide the pre-emptive transplant rate is 2.6%. In the Rogosin CKD program, patients have a 14% pre-emptive transplant rate.
- **Patients are educated on medical management without dialysis and when appropriate patients choose this option.** In the DCI CKD program in Spartanburg, SC, more than 15% of patients are choosing medical management without dialysis.
- **More patients receive education on and then choose home dialysis.** In the Northwest Kidney Centers’ Choices CKD program in Seattle, WA, 31% of patients start dialysis at home.
- **More patients start hemodialysis with a permanent access.** In the Northwest Kidney Centers’ Choices CKD program, more than 76% of patients start hemodialysis or peritoneal dialysis with a permanent access and never have a catheter.
- **More patients receive their first dialysis treatment as an outpatient and avoid an initial hospitalization.** In the DCI program in Spartanburg, SC, 58%, and in the Northwest Kidney Centers’ Choices CKD Program 64% of patients starting dialysis in 2015 from the CKD program avoided a hospitalization for their first treatment.
- In the DCI REACH program 500 (out of 4500 patients in 29 sites) are now being cared for at CKD Stage 5 and are being kept off dialysis.

Based on the RFI we appreciate the opportunity to provide additional information and look forward to future dialogue to outline an appropriate PACE model for this population.

### ***Appropriate Criteria for Identifying Population***

We recommend that a PACE program identify the eligible population based on their Glomerular Filtration Rate (GFR). We believe the most appropriate GFR level for the model should be a GFR less than 45, or CKD Stage 3b, in order to provide the opportunity to slow progression of CKD and, ideally, avoid dialysis.

We estimate that a program managing this population would have the following distribution of patients based on the National Health and Nutrition Examination Survey (NHANES) data<sup>2</sup>:

- Stage 3b (GFR 30 – 45): 69.2% (14,750 patients per 1 million patients)
- Stage 4a (GFR 20-30): 15.0% (3,200 patients per 1 million patients)
- Stage 4b (GFR 15-20): 7.5% (1,600 patients per 1 million patients)
- Stage 5, not on dialysis (GFR < 15): 6.6% (1,450 patients per 1 million patients)
- Transitioning to renal replacement therapy each year: 1.7% (359 patients per 1 million patients)

The cost of care for these patients is significant and as the patient’s kidney disease progresses, the cost of care increases. The following is an estimate of cost of care by stage, based on an analysis of 2013 Medicare 5% claims data:

- Stage 3: \$23,680 per year (2.2 times the cost of care for typical patient with Medicare coverage)
- Stage 4: \$33,374 per year (3.1 times the cost of care for typical patient with Medicare coverage)
- Stage 5 *not on dialysis*: \$36,147 per year (3.3 times the cost of care for typical patient with Medicare coverage)
- Stage 5, *on dialysis*: \$84,645 per year (7.8 times the cost of care for typical patient with Medicare coverage)

We note the difference in cost of care for a patient with stage 5 CKD not on dialysis and a patient on dialysis. For every month that the start of dialysis is delayed, there is not only a decrease in the cost of care for Medicare by more than \$4,000 per patient but also for some a better quality of life. These costs can also be compounded since many CKD patients also have diabetes and hypertension.

Currently, there is a huge missed opportunity to improve care for these patients, since most of these patients are not receiving care related to their kidney disease. According to the USRDS, only 7.7% of patients with stage 3 CKD even know that they have kidney disease and for patients with stage 4 CKD, only 53% of the patients are aware. Data suggests that earlier referral to nephrologists can slow the rate of progression of kidney disease and better prepare a patient for transition to the next step in care. Equally important is that patients’ primary care physicians diagnose CKD earlier. Unfortunately in the United States, the majority of patients still “crash” into dialysis without having the opportunity to be educated and explore the full set of options available to them.

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<sup>2</sup> 2015 USRDS

### ***Improved Health Outcomes and Quality Measurement***

As there are already measures associated with the ESRD population through the Comprehensive ESRD Care (CEC) Model, we recommend any new model in this area, including PACE, pull from these existing measures for consistency and to offer providers an efficient transition between models. While we believe using consistent measures and outcomes is important, we do think some of the measures must be updated to promote better outcomes. For example, we would recommend CMS consider revision of the Standardized Mortality Ratio (SMR) measure to include transplant survival time for having more patients on the transplant waiting list. This has many benefits for patients by incentivizing facilities to promote transplant referral. In addition, while the number of metrics should not be large, some additional measures may be warranted, such as delay in the onset of ESRD and start of dialysis, the “mortality benefit” associated with transplant, and transition to end of life when appropriate.

### ***Payment and Costs***

We understand that the typical mechanism for the PACE model is based on capitation but encourage CMS, as the RFI indicated, to look into other mechanisms that could promote broader participation and provide appropriate payment. As smaller, non-profit providers, it can be difficult, if not impossible to accept the risk of a capitated model. In order to have broad participation of a PACE model, we recommend CMS look into alternative payment mechanisms that both small and large providers would be able to utilize. The Centers for Medicare and Medicaid Innovation (CMMI) has done this successfully with the CEC model which includes both small and large dialysis providers.

### ***Incorporating PACE with Existing Alternative Payment Models (APMs)***

NKCA members have been very active in the development of the CMMI CEC model. Collectively, four of our members operate nine ESRD Seamless Care Organizations (ESCOs) across the country. We see ESCOs as the primary model of integrated care for patients with ESRD, and have been interested in further steps to expand this or other models in order to better serve patients with CKD and patients who have received a kidney transplant. With this in mind, we would encourage CMS to find ways to complement the current CEC model, and even explore the possibility of a PACE model for CKD which could transition into the ESRD model if a patient’s disease progresses. It should be possible to design a model in such a way that would not preclude providers from participating in both models.

### **Conclusion**

Thank you for the opportunity to comment on the PACE Innovation Act Request for Information. We stand ready to assist in crafting a PACE model for patients with kidney disease and would appreciate the opportunity for further dialogue. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or [info@nonprofitkidneycare.org](mailto:info@nonprofitkidneycare.org).

Sincerely,



Martin Corry  
Executive Director

## **APPENDIX**

Below we describe examples of needed interventions for each stage of kidney disease based on the experience of one of our member's program, REACH Kidney Care, currently serving 4,500 patients across 27 sites.

### **Stage 3b (GFR 30-45)**

We start our formal interventions at stage 3b. The fact that a patient has lost more than 50% of kidney function is often an indicator that this patient has some condition that has not been adequately controlled, and therefore has damaged their kidney function. We strongly believe that in person, one-on-one care coordination is essential to provide optimal care, with significant time spent for a first visit. This first meeting does not focus specifically on kidney disease, but instead on the patient's life goals.

For patients with a GFR 30 – 45, our intervention is primarily focused on population health:

- Improved blood pressure control
- Improved blood sugar control
- Increased exercise
- Smoking cessation
- Weight loss
- Cardiovascular Disease (CVD) Screening & Referral/Management as needed

In addition, we also work with patients to protect their kidney health and educate them on kidney disease, with topics including:

- Avoidance of nonsteroidal anti-inflammatory drugs (NSAIDS)
- Protecting their potential access arm
- Diet
- Sodium
- Anemia
- Phosphorous

It is important that CKD programs partner with the patient's primary care physician and other physicians in order to coordinate care. Progress notes should be shared between the program and the primary care physician to provide clinical updates. It is critical to ensure that adequate kidney screening has been performed for these patients. If the patient has not been checked for urine proteinuria, we recommend that this be checked. If a patient has rapidly progressing kidney disease and/or significant proteinuria, a referral to a nephrologist is recommended.

### **Stage 4a (GFR 20 – 30)**

If a patient's kidney disease does progress to stage 4a, care is intensified and we recommend a patient be seen by a nephrologist. In addition, we review the patient's medication list to ensure that the patient is on the correct medication, at the correct dose for their current renal function. We also continue to provide population health management for these patients and intensify the efforts started for a patient with stage 3b CKD.

### **Stage 4b (GFR 15 – 20)**

At stage 4b, in addition to the interventions and education in previous stages, it is important to carefully manage those patients who will progress to renal replacement therapy so that they can begin as late as possible in the progression of their CKD. In addition, it is important to start preparing the patient for their next step in care, educating the patient on the following four options:

- Transplant
- Home Dialysis
- In Center Dialysis, preferably with a fistula
- Medical Management Without Dialysis

NKCA believes it is necessary to not only provide education on the various treatment options available, but also provide navigation services to help patients prepare for transition.

### **Stage 5, not on dialysis (GFR < 15)**

We believe patients can still be effectively managed at stage 5 CKD, without dialysis. One of our members, DCI is currently following more than 600 patients with stage 5 CKD and effectively keeping them off dialysis. These patients should be seen more often to manage their symptoms and push back the start of dialysis as far as possible while maintaining patient safety, ability for self-determination and patient-expressed expectation of acceptable quality of life. Each patient is different and should be treated as such. By individualizing the care for each patient, a patient can safely start on dialysis later in the progression of their CKD. In the Spartanburg, SC program operated by DCI, more than half of our patients are starting dialysis with a GFR of 5-10.

### ***Transition in Care***

As we've discussed, patients should be educated and afforded all their options for care as their disease progresses. Below we've provided recommendations on the appropriate care transitions that should be made available to patients and the coordinating question based on CMS' request for information.

These transitions include

- Transplant
- Medical management without dialysis
- Home dialysis
- In center dialysis

### **Medical Management without Dialysis**

For most patients starting dialysis, they are making a commitment to start a therapy that will require them to receive three, four hour treatments per week. After including the time for travel to and from dialysis, and the recovery from dialysis care, many patients essentially "lose" three out of seven days a week because of the obligations of dialysis care. Based on recent published literature, we know that patients who are older than 80 with multiple comorbidities have similar survival outcomes if they choose medical management without dialysis instead of dialysis. For those who live longer on dialysis, most of those extra days were spent in a dialysis clinic or in a hospital.

We strongly believe that a patient with CKD should have the right to choose that dialysis is not the right choice for him or her. If the patient makes this decision, we recommend that the care coordinator meet with the patient's family and help them understand the patient's decision. In addition, it is critical for the patient to know that they will not be abandoned if s/he makes the decision to select medical

management without dialysis and will continue to intensively manage the patient, if requested. The only difference would be that the patient would not start dialysis. Finally, it is critical for the patient to know that s/he can change her decision at any time. Following this process in Spartanburg, SC, DCI is seeing that less than 5% of patients who select medical management without dialysis change their mind and start dialysis.

### **In Center Dialysis**

For patients choosing in center dialysis, we recommend they start dialysis with a permanent access and never have a hemodialysis catheter. These patients are less likely to have an infection, less likely to be in the hospital, and more likely to live and their care is less expensive. Although a fistula is the ideal access for many patients, other patients (especially elderly patients) will receive most effective care with a graft. By educating patients early about the importance of a permanent access, more patients can start dialysis with a permanent access and never have a catheter. Currently nationwide, only 24% of patients start dialysis with a permanent access.<sup>3</sup> In the DCI program in Spartanburg, SC, 65% of patients starting dialysis in 2015 from the CKD program started dialysis with a fistula and never had a catheter.

NKCA also believes that this early education and intervention will decrease the likelihood that a patient will receive his or her first dialysis treatment in a hospital. We see this as an important improvement in care since patients avoiding a hospitalization will also be able to avoid the complications from a hospitalization. In addition, we have seen that patients can have a smoother transition to dialysis if their first treatment is in the outpatient setting instead of the hospital. We recognize, however, that certain patients should receive their first treatment in the hospital to ensure that they receive safe care and therefore err towards starting a patient in the hospital if there is a clinical indication to do this. In addition, we expect that Medicare will see significant savings if we can increase the number of patients avoiding the first hospitalization before a dialysis treatment. We estimate that the cost of hospitalization and follow-up care is \$25,000 for a patient on dialysis. Clinical experience indicate that the vast majority of patients receive their first dialysis in the hospital; in contrast, in the DCI CKD program 58% and in the Northwest Kidney Center CKD program 64% of patients started dialysis as an outpatient and avoided a hospitalization for their first treatment.

Patients who receive a kidney transplant are more likely to live longer, have a better quality of life and require fewer hospitalizations. Additionally, a transplant can “pay” for itself in about 2.5 years and allow for savings in a healthier patient. Currently, there are no incentives or benchmarks that promote referral of patients for consideration of their transplant options. Additionally, many transplant programs exist without any real integration into the local dialysis or CKD community. By coordinating education and outreach with dialysis providers, CKD education programs and transplant programs, there is the potential to increase the early and overall referral rates.

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<sup>3</sup> Dialysis Facility Report (DFR) for FY 2017