



Amy Bassano  
Acting Deputy Administrator and Director  
Center for Medicare & Medicaid Innovation  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Director Bassano:

I am writing on behalf of Kidney Care Partners (KCP) to ask for additional guidance regarding the implementation of the ESRD Treatment Choices (ETC) Model. We also ask that the Center for Medicare & Medicaid Innovation (CMMI) prioritize rulemaking during 2021 to address some of the policies that can only be resolved through the rulemaking process. KCP and our members appreciate CMMI's engagement with KCP and willingness to work through the technical issues. We are supportive of the goals of expanding the adoption of home dialysis and increasing transplants for patients with kidney failure.

KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

KCP continues to engage with Discern Health to help us work through the methodology questions and to craft solutions to address barriers and unintended consequences. While this work is ongoing, we have some immediate requests from the community for guidance. In addition, we ask that CMMI engage in rulemaking to address those concerns that would require rulemaking to address. We also ask that CMS revise other Medicare policies that create barriers to achieving the goals of the ETC model.

#### **I. Request for Guidance in Early 2021**

Through a consensus-based work group process, the KCP members have identified several questions about the implementation of the ETC model. We ask that CMS provide guidance in the following areas of:

- **Aggregation**  
Provide an opportunity to review the aggregation groups in the participating HRRs and the comparator areas. Review of aggregation groups should happen as soon as possible to ensure the accuracy of the benchmarks, which relied upon these aggregation groups. It is important

to include the TIN level of review for physicians. CMS consistently allows providers and suppliers to review data before it is publicly released, so this request is consistent with that practice. We recognize that CMS has not released benchmark setting aggregation data, as we are asking CMMI to do in this case, but that is because the benchmarks in other programs, such as the ESRD QIP and Dialysis Facility Compare Five Star do not require the aggregation of providers to establish them.

- Benchmarks
  - Ensure the benchmarks are determined in an equitable manner and not unintendedly skewed in a manner that disadvantages a particular group of participants.
  - Address the impact of COVID-19 on the benchmarks, particularly the transplant waitlist benchmark, and modify the benchmarks as needed.
  - Provide physicians and facilities in participating HRRs with their benchmark data to allow the participants to understand their baseline performance.
  
- Transplant Data
  - Provide data related to the transplant waitlist by coordinating with HRSA, UNOS, and relevant contractors to share the data that was used in the establishment of benchmarks with the kidney community.
  
- Self-Dialysis
  - Provide a definition of the patients who are eligible for self-care dialysis (see Appendix A for suggested language).
  - Provide the specific requirements for staffing and training.
  - Establish clear billing documentation requirements.
  - Share example about in-center self-care dialysis patients attribution that address self-dialysis patients.
  
- Care Coordination and Education
  - Provide explicit safe harbors for providers who furnish telehealth equipment needed for home dialysis.
  - Allow licensed health care professionals to provide education on all modalities to a hospitalized patient with kidney failure at the request of the patient's care team, including discussion of in-center and home dialysis modalities, management of kidney failure without dialysis, and kidney transplantation. The decision regarding modality choice should be the result of a shared decision making process between the patient and the nephrologist.

## **II. Request to Engage in Rulemaking during 2021**

In addition to the immediate need for additional guidance on the topics in Section I, KCP asks that CMMI begin the process of developing a rule to address issues that cannot be resolved through guidance. We continue to work with Discern Health to develop targeted recommendations with regard to the following issues that the community has identified as needing to be modified. These include, but are not limited to:

- Maintaining the improvement component of scoring through the entire period of the model and allowing improvement to be a scoring option for the 90<sup>th</sup> percentile.
- Addressing the need for appropriate risk adjusters to avoid the inadvertent exacerbation of longstanding disparities in kidney care.
- Providing relief to small chains that have more than 30 percent of their dialysis centers included in the mandatory model, as the national participation goal is only 30 percent.
- Considering the use of absolute benchmarks, rather than relative benchmarks.
- Making sure that the penalties are right-sized to incentivize home dialysis and transplant, but not so large as to place patient care at risk.
- Refining the home dialysis and transplant measures to ensure validity, reliability, and actionability of the metrics, as well as to avoid their design leading to unintended consequences.
- Setting reasonable targets that promote home dialysis and transplant while not sacrificing individualized, patient-centered care.
- Establishing a transparent process that allows for stakeholder input for modifying aspects of the model as may be needed.

## **III. Remove Barriers Created by Other Policies**

We also ask your assistance with removing barriers created by other policies outside of the ETC model.

- Coverage of PD
  - Recognizing that the modality a patient relies upon initially often becomes the patient's permanent modality. To achieve the goals of the ETC model, it would help for CMS to recognize and reimburse for urgent start PD home dialysis. As shown during the pandemic, AKI patients can benefit from starting on home dialysis as well. CMS should also recognize and reimburse for AKI patients who start on home dialysis, especially in light of the fact that many AKI patients will progress to kidney failure.
- Survey and Certification
  - Expediting the approval of home dialysis programs.
  - Allowing dialysis facilities to repurpose in-center dialysis space to train

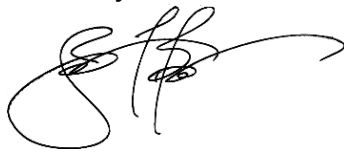
home dialysis patients.

- Education
  - Expanding the Medicare Kidney Disease Education program to:  
(1) allow dialysis facilities to provide kidney disease education services under certain circumstances and (2) provide access to these services to Medicare beneficiaries with Stage 5 Chronic Kidney Disease (CKD) not yet on dialysis.

#### **IV. Conclusion**

Again, I want to thank you on behalf of KCP and its members for your ongoing efforts to work with us. We share the goals of removing barriers that may make selecting home dialysis more difficult for patients and increasing transplants. We look forward to continued engagement with CMMI.

Sincerely,

A handwritten signature in black ink, appearing to be 'John Butler', with a long horizontal flourish extending to the right.

John Butler  
Chairman

cc: Kathleen M. Blackwell, CMMI  
Tom Duvall, CMMI

## Appendix A

- For example, the KCP suggests that a patient dialyzing in- center should be considered to be engaged in self-care dialysis for each treatment that:
  - Dialysis machine is turned towards patient;
  - The patient is allowed to touch the machine;
  - The patient weighs self;
  - The patient washes his/her arm;
  - The patient checks his/her blood pressure, heart rate and temperature;
  - The patient enters his/her current weight, goal weight, goal for treatment today, blood pressure, heart rate, and temperature into the chart;
  - The patient sets up the machine -- every step until ready to start dialysis; and
  - The patient pulls needles at end of treatment.

Patients should be trained on self-cannulation, but it also should be acceptable for a patient to receive clinical assistance with cannulation and qualify as conducting self-care dialysis, if the other clinical criteria are met. Patients that require further assistance or that are unable to reliably perform the above clinical tasks on their own, should not be defined as self-care dialysis patients.

This suggested definition is consistent with the current regulatory definition of “self-dialysis” at 42 CFR 494.10 as “dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.” It is also consistent with the State Operations Manual that recognizes that a “self-dialysis patient as an in-center dialysis patient (or their personal care partner) who wishes to self-administer most or all of their dialysis treatment without professional help.” (SOM § 2273). Both definitions recognize that there may be a role for some clinical assistance in limited ways.

## **Appendix B: KCP Members**

Akebia Therapeutics  
American Kidney Fund  
American Nephrology Nurses' Association  
American Renal Associates, Inc.  
American Society of Pediatric Nephrology  
Amgen  
Ardelyx  
American Society of Nephrology  
AstraZeneca  
Atlantic Dialysis  
Baxter  
BBraun  
Cara Therapeutics  
Centers for Dialysis Care  
Cormedix  
DaVita  
DialyzeDirect  
Dialysis Patient Citizens  
Dialysis Vascular Access Coalition  
Fresenius Medical Care North America  
Fresenius Medical Care Renal Therapies Group  
Greenfield Health Systems  
Kidney Care Council  
Nephrology Nursing Certification Commission  
Otsuka  
Renal Physicians Association  
Renal Healthcare Association  
Renal Support Network  
Rockwell Medical  
Rogosin Institute  
Satellite Healthcare  
U.S. Renal Care  
Vertex  
Vifor Pharma