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Nonprofit Kidney Care Alliance

September 16, 2019

VIA ELECTRONIC SUBMISSION THROUGH WWW.REGULATIONS.GOV

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-5527-P: **Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures; The End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model)**

Dear Administrator Verma:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), we are writing to comment on the proposed ESRD Treatment Choices (ETC) model, part of the Advancing American Kidney Health (AAKH) Initiative. NKCA represents six nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Centers of Lincoln; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 21,000 patients at more than 300 facilities in 30 states. In an effort to keep patients off dialysis, we also serve more than 5,700 patients with chronic kidney disease (CKD) with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). Four of our members are also participating in the Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model.

NKCA has long advocated for a more comprehensive Medicare policy toward kidney care which recognizes the need to address CKD before an individual requires dialysis. Success in this endeavor will result in fewer patients requiring dialysis, more kidney transplants, and delayed start of dialysis for other CKD patients. Those who do require dialysis will be better prepared and more aware of their options, including the option of home dialysis. Many NKCA members have already made this a focus and have transplant and home dialysis rates much higher than the national averages.

We are very pleased by the Department of Health and Human Services' (HHS) commitment to improving kidney health. This attention will change the way care is delivered to those with kidney disease and ensure that individuals have greater access to more modality options. We are excited to be a partner as HHS and CMS pursue these goals and look forward to working with you to ensure that these changes are attainable and meaningful for providers and the patients they serve.

The proposed ETC model seeks to incent the use of kidney transplant and home dialysis, two modalities we believe to be excellent choices for many patients with kidney disease, and is the first of many efforts by CMMI to improve care for patients with kidney disease under the AAKH. The ETC will be joined in the near future by multiple voluntary kidney care models that are more comprehensive. We are optimistic about the voluntary models, which include management of individuals with stage 4 and 5 CKD as well as the coordination of care amongst nephrologists, transplant providers, and dialysis providers and look forward to gaining more insight and working with the agency as those models move forward. In particular, we believe it is critical that the ETC model be designed and implemented in a manner that complements and does not inhibit or discourage participation in these other models.

Summary of Views

Our views are summarized here before being described in greater detail below. Our comments focus on ensuring that the ETC model promotes appropriate care for beneficiaries without burdening providers, particularly smaller providers who may face disproportionately large risks and burdens from a mandatory model. We believe the ETC, as proposed, is too broad, and its penalties too severe to reasonably achieve the goals of the program without significant provider burden and risk, which can negatively impact patients overall.

In order to achieve a fair and appropriate start to this model, and to ensure its ultimate success, we believe, first and foremost, that three critical issues need to be addressed:

1. Right-sizing the model. We feel strongly that in order to thoughtfully proceed with the ETC in combination with 4 other voluntary kidney models beginning in 2020, the ETC model should only be mandated for 25% of the Hospital Referral Regions (HRRs) and that the selected HRRs should contain approximately one-fourth of the total Medicare dialysis population.

2. Protections for small providers. Due to the increased financial risk faced especially by smaller providers operating in a single HRR relative to large providers who will have facilities in many non-selected HRRs, we strongly urge CMS to limit the mandatory nature of this demonstration to providers with more than 35 clinics, while still allowing providers with 35 or less clinics the choice to opt into the program.

3. Appropriate down-side risk. Any provider mandated into the program should not be subject to risk greater than 2 percent.

Summary of other provisions:

4. Start Date. We believe that the start date for the ETC model should be July 1, 2020 at the earliest, and that selected HRRs be announced at least six months prior to the launch of the model. This is critical to allow providers adequate time to prepare.

5. Home Dialysis and Transplant. We urge CMS to finalize and launch the home-dialysis arm of the model and, in a step-by step process, phase-in implementation of the transplant arm. During this phase-in, we encourage CMS to proceed with the proposed Learning Collaborative, working over the next two years to develop a strategy to achieve both a closer working

relationship of dialysis and transplant centers/surgeons and to develop a new and more meaningful set of transplant milestones, including metrics appropriate and applicable to each accountable stakeholder.

6. Home Dialysis Payment Adjustment (HPDA). To help providers achieve the objectives of the ETC models and grow their home programs, we recommend that a participating dialysis provider receive payment incentives that increase over time to reward facilities that successfully maintain patients on home dialysis.

7. Performance Payment Adjustment (PPA). Because of the concern that large, sustained penalties may result in facility closure and/or further industry consolidation, we propose that the penalties be limited to 2%. We recognize that this may result in a limit to the maximum rate for bonus payments, but believe that would be acceptable.

8. Social Determinants of Health We believe that inclusion of at least some of the social determinants of health deemed to be most important is critical to assisting patients to make choices about their care. We believe the use of the Accountable Health Communities (AHC) Screening Tool, along with further stakeholder input, can begin to make this a reality.

9. Reliability Adjustment. A lack of detail in the proposed rule regarding the calculations that will be used to determine the reliability adjustment creates substantial uncertainty for providers. We urge CMS to provide greater clarity and an opportunity for comment before implementation.

10. Protections for Patients in Certain Facilities. We are concerned about the potential adverse impact of payment reductions proposed in the ETC model on patients in certain types of facilities. To mitigate this risk, we propose that isolated facilities (i.e., those more than 20 miles from another facility), facilities meeting the criteria for low volume, and facilities servicing a disproportionate share of high-need patients be protected from the downside risk inherent in the model.

11. Exclusion of Certain Facilities. We recommend that providers that provide only home dialysis in one HRR be excluded from participation in the ETC. If a provider only cares for home patients in a selected HRR, that provider will automatically be placed in the top tier for payment and will artificially decrease the home-dialysis rate for other providers in the HRR.

12. Overlap with Voluntary Models. We believe that the overlap of the ETC model and the forthcoming voluntary kidney models may be overly problematic. To ensure that the ETC model does not discourage providers from opting into the Comprehensive Kidney Care Contracting (CKCC) models, we believe nephrologist-owners and facilities participating in the CKCC model should either be exempt from the ETC model or deemed to be meeting the requirements of the ETC by virtue of their participation in one of the voluntary CKCC models.

13. Inclusion of In-Center Self-Dialysis. We want to ensure that the ETC model does not artificially push some patients into a modality that is not their true choice or not actually

sustainable for them. We therefore recommend future notice and rulemaking to allow for the inclusion of in-center self-care dialysis in the future.

14. Annual Rulemaking. We believe that it is imperative that CMS provide stakeholders with adequate opportunity to comment throughout the duration of the model so that necessary refinements and adjustments can be made. We ask that CMS publish a proposed rule in 2020 and each year of the model so that providers will have the opportunity to offer additional input on the ETC before payment reductions begin.

15. Timely Certification of Home Programs. To accommodate the growth and establishment of new home-dialysis programs through this model, CMS must consider and put into place ways to ensure timely certification of the home-dialysis programs of these facilities.

The balance of this letter provides greater detail on the points above.

Detailed Comments

Limiting the Scope of the Model

For a number of reasons, we believe it to be critically important that the ETC model be limited to 25 percent of the HRRs across the country and believe that CMMI should strive to ensure that the number of Medicare dialysis patients in the selected HRRs is also approximately one-fourth of the total Medicare dialysis population. First, the ETC model will be one of five CMMI kidney models in operation beginning in 2020, and we believe it is critical that a sufficient number of facilities be unencumbered by this model now so that they can join one of the more comprehensive models in the future. It is important that these models achieve adequate participation as well. Second, as described below, we believe that modifications to the transplantation arm of the ETC will permit this model to be more accurately tested with fewer participants. And finally, the ETC offers great promise for patients, but also poses significant downside financial risk for providers and especially those that are smaller. Limiting the scope of the model will reduce that risk for all providers.

Selecting ETC Model Participants

We agree with CMS that HRRs are adequate for the unit of selection. However, we note that for smaller, regional dialysis providers, like most of our members, a single HRR could capture all or a large proportion of their clinics, thus imposing disproportionally greater risk on them relative to large providers, who will be naturally diversified across included and excluded HRRs. For this reason, we strongly urge CMS to limit the mandatory nature of this demonstration to providers with more than 35 facilities. Because the model imposes greater relative risk on smaller providers, there is a possible unintended consequence that the ETC may encourage further market consolidation. Such a modification will have little impact on the total number of patients in the ETC model and will have no impact on the comparison-group of providers located in the non-selected HRRs.

We also recognize that many smaller providers may, after evaluating the final rule, be interested in participating in the ETC. For example, all NKCA members share the objective of increasing home dialysis and transplant rates and have advocated for advancing these modalities. We would encourage CMS to allow smaller providers the option of participating in the ETC if they choose which is similar

to the flexibility provided in the current Comprehensive ESRD Care (CEC) model allowing dialysis providers the option to participate as a one-sided or two-sided risk arrangement based on their resources and experience in the program. We appreciate the continued collaboration with CMMI on behalf of small and non-profit providers in the CEC model and look forward to a similar collaboration for the ETC.

Additionally, as Maryland is treated separately in the proposed rule, we believe that Maryland-specific policies also must recognize the risks faced by small providers in the state, and CMS should limit the mandatory demonstration to providers with more than 35 facilities. We believe that small providers can offer the quality and innovative care that is essential for this model to succeed. However, certain flexibilities must be included in the final rule to ensure that small providers are not disproportionally exposed to greater financial risk.

Start Date

The ETC model will be a huge undertaking for providers of any size, and, because the participating HRRs have not been announced, providers are not yet able to prepare for participation in the model. The proposed timing of the ETC – that is, a January 1 or April 1 start date – would require scores of providers, including many small providers, to very quickly design, implement, and execute new policies, forcing some providers to incur burdensome new costs that are likely to divert clinical resources away from patient care. We believe the start date should be July 1, 2020 at the earliest, and that the list of included HRRs must be released at least six months before the start date.

Balancing ETC Goals: Increased Home Dialysis and Transplant

We agree that kidney transplantation is the optimal renal replacement therapy, and we support CMS's goal of increasing transplant under the ETC model. We believe that an effective approach to transplant is the implementation of a step-by-step process that brings all stakeholders to the table. However, as currently proposed, the dual objectives of the ETC model to promote both home dialysis and kidney transplant requires the demonstration to be much larger than necessary for the determination of the effectiveness of the proposed home-dialysis incentives. At the same time, it may well not achieve the desired outcome of increased kidney transplantation.

In the proposed rule, CMS recognizes that the home-dialysis component of the demonstration is needlessly large, acknowledging that a major reason for the size of the demonstration is to achieve sufficient statistical power based on the relatively small number of transplants. Moreover, CMS acknowledges that those who are required to participate in the model lack the tools necessary to reach higher transplant numbers. Specifically, for example, transplant centers and Organ Procurement Organizations (OPOs) are not part of the current model. CMS also acknowledges that the supply of organs is limited. Accordingly, we propose the following step-by step approach as an alternative to the transplant component of the ETC as currently proposed.

First, as outlined in the proposed rule, CMS, along with other agencies, such as the Health Resources and Services Administration (HRSA), should promptly launch the proposed Learning Collaborative (LC), working over the next two years to develop a strategy to achieve the collaboration and communication of the critical stakeholders and a practical and meaningful set of transplant milestones and metrics, applicable to each accountable stakeholder. The LC must bring all transplant stakeholders

to the table—patients, transplant centers, transplant surgeons, OPOs, dialysis organizations, and nephrologists – if this is to be achieved.
In the interim, we recommend that CMS proceed with the home-dialysis arm in a final rule, while deferring finalization of the transplant provisions at this time. During the two-year LC period, CMS could still move forward with additional work with kidney education and transplant wait-listing objectives.

At the close of year two and upon completion of the LC's work, CMS should, through notice and comment rulemaking, propose a revised set of transplant model parameters that incorporates all the transplant stakeholders, either directly through the model or other regulatory frameworks, such as the ESRD PPS/QIP, transplant center Conditions of Participation, OPO Conditions for Coverage, and other regulatory means.

We believe that this phased-in approach to transplant will better capture all the elements that are needed in order to truly achieve a meaningfully increase in U.S. kidney transplant rates.

Home Dialysis Payment Adjustment (HPDA)

To help providers achieve the objectives of the ETC model with respect to the growth of home-dialysis programs, we recommend that a dialysis provider receive payment incentives to reward facilities that successfully maintain patients on home dialysis and that these incentives increase over time. It would also be beneficial to count the first six months of the program (or remainder of the program in 2020) as "Year 0", in order to allow providers to put in place the elements necessary for increasing their ability to provide home dialysis. After this period, the HDPA payment adjustments can be phased in over time as follows:

- 1 percent payment adjustment beginning in 2021,
- 2 percent payment adjustment beginning in 2022, and
- 3 percent payment adjustment for 2023.

We also would like to ensure that these incentives are applied to all payments related to home care, including training payments. It is critically important that these payments incent all home-dialysis-related services, if the goal of significantly increasing the number of patients receiving home dialysis is to be achieved. Finally, if the savings attained through the increase in home, as opposed to in-center, dialysis are found to exceed the amount paid with the home-dialysis adjustment, we encourage CMMI to continue this bonus payment beyond the first three years of the ETC model.

Performance Payment Adjustment (PPA)

We want to make sure that the ETC does not limit access to care or facilitate provider consolidation. We are concerned that the large penalties currently proposed will threaten the financial viability of some dialysis clinics, perhaps forcing closures that could lead to in-center patients traveling longer distances three days a week to receive their dialysis care, and lead to further consolidation in an already highly concentrated provider market.

Accordingly, we propose that the potential penalties for failure to achieve the specified benchmarks be limited to 2 percent for the entire program. We believe that 2 percent risk (similar to the incentives of

the ESRD Quality Improvement Program (QIP)) has been shown to successfully drive behavior and encourage better care.

Evidence of the importance of lowering the penalties in the ETC model, we note that average Medicare margins in dialysis clinics are smaller today than when CMS decreased reimbursement in 2015. In CY 2015, MedPAC reported the average Medicare margin to be a positive 0.4 percent for ESRD facilities. The same for 2019 is projected to be a negative 0.4 percent.

Social Determinants of Health

CMS asked for feedback on ways to account for the effects of age and housing insecurity on home dialysis rates in the ETC model. Although these effects are difficult to measure quantitatively, we believe it is important that these parameters be addressed in the model, particularly given the limitations that housing characteristics place on the practicality of home dialysis. CMMI's Accountable Health Communities (AHC) program uses a screening tool that addresses many of the social determinants of health that are important to this beneficiary demographic and their needs. We believe that use of all or the applicable parts of this screening tool is the best way to include these considerations in the ETC. Any such modifications should include stakeholder input.

Reliability Adjustment

The lack of detail in the proposed rule regarding the calculations that will determine the reliability adjustments creates substantial uncertainty for providers and may result in final payment adjustments that seem arbitrary, unpredictable, and potentially error-prone. We are concerned that such uncertainty may, at the least, undermine provider trust in the model and therefore be a distraction that will reduce their focus on its critical elements and goals. We believe it is vitally important that the basis for the reliability adjustment factor be determined in a transparent and reproduceable manner. We encourage CMS to provide greater clarity and an opportunity for comment before implementation of this section of the rule.

Protections for Patients in Certain Facilities

We are concerned about the potential adverse impact on patients in certain types of facilities if those facilities are forced to sustain significant payment cuts as a result of the ETC. To mitigate this risk, we propose that certain types of facilities that are participating in the ETC be protected from downside risk. Specifically:

- *Isolated Facilities.* An ESRD facility greater than 20 miles from the nearest alternative ESRD facility should not be at risk of payment reduction in the model. If this type of clinic is in the bottom tier of the PPA for two years, for example, it may not be able to sustain the losses and will most likely cut service or close. If this were to happen, patients receiving in-center dialysis care in this clinic may need to travel a much longer distance three times a week to receive their dialysis care. This would not lead to better care.
- *Facilities Serving High-Need Patients:* ESRD facilities and managing clinicians that take care of a higher proportion of patients with Medicaid, including dual-eligibles, should not be at risk of payment reduction in the ETC model. In most cases, if an ESRD facility and/or managing clinician has a high proportion of Medicaid patients, they are a "safety net" provider for the HRR.

- *Low-Volume Facilities:* We believe CMS should use the PPS definition of low-volume and should not apply negative adjustments to offset the positive adjustments being received through the PPS.

Exclusion of Certain Facilities

We strongly believe that patients deserve the right to choose between in-center dialysis and home dialysis. To incentivize increased choice, we recommend that organizations/companies that only provide home dialysis in an HRR not be allowed to have their clinics in that HRR participate in the ETC. If a provider only cares for home patients in an HRR, that provider would automatically be placed in the top tier for payment and would artificially decrease the home-dialysis rate for other providers in the HRR.

We believe that the purpose of the ETC is to encourage all providers to make it more likely for their patients to dialyze at home. If home-only providers were allowed to participate in the ETC, the model would not accurately reflect the change in home dialysis for each provider.

Overlap with Voluntary Models

We believe the overlap of the ETC model with the voluntary kidney models may create problems for both patients and providers. Standing up just one model can be difficult and costly. Especially because we believe the CKCC model to be a more comprehensive model, we want to ensure that we are not deterring providers from participating in a CKCC model if they are also selected for mandatory participation in the ETC. Accordingly, we believe that nephrologist-owners and facilities participating in the CKCC model should be exempt from the ETC model. Alternatively, if CMS does not want to exempt entities outright, the Agency should deem voluntary-model participants to be meeting the requirements of the ETC by virtue of their participation in one of the voluntary CKCC models. We see this approach as similar to the way CMS treats physicians who participate in an AAPM. If the physician is an owner in an AAPM, then the physician is excluded from the administrative requirements of MIPS.

Since beneficiary attribution will change in the CKCC and be based on nephrologist-ownership instead of the first-touch rule, we ask that a dialysis facility be considered to be a CKCC participants if more than 50 percent of the Medicare beneficiaries are attributed to the CKCC. If a facility meets these criteria, we ask that it be given the opportunity to choose whether or not to also participate in the ETC.

Inclusion of In-Center Self-Dialysis

While we strongly believe that home dialysis is a better option for many patients, there are circumstances where home dialysis is not appropriate. These circumstances may include health status, available home support system, social needs, and space restrictions, among others. We want to ensure that the ETC model does not push patients into a modality that is not their choice, unsustainable, or medically unsafe. However, in the spirit of promoting better quality and engaging the patient directly in his or her care, we believe that in-center self-care dialysis should be included in the model. Using appropriate standards, in-center self-care dialysis empowers the patient to be an active care participant, with such care even leading to full home dialysis in the future. We recommend that CMS consider the inclusion of self-care in the future, requesting stakeholder input on a suitable definition and standards.

Annual Rulemaking

With the large changes in care coordination and payment rules that will be brought to bear on patient care and dialysis provider function by the ETC, we believe that CMS should provide stakeholders with adequate opportunity to provide comment throughout the duration of the model so that refinements and adjustments to the model can be made as needed We therefore ask that CMS publish a proposed rule annually to receive feedback about the model so that patients, providers and other stakeholders have the opportunity to offer additional input on the ETC over time.

Timely Certification of Home Programs

NKCA member companies have experienced long wait times and complex processes in order to obtain certification for new, or even to expand existing, home-dialysis units. Separate certifications are often needed for both home hemodialysis and peritoneal dialysis, so that even more time may be required before any patient may be treated. This reality must be taken into account if the growth and establishment of new home dialysis programs required by the ETC model is to be achieved. CMS must recognize this challenge and consider ways to ensure timely certification of facilities, if the goals of ETC with regards to home dialysis are to be achieved.

Conclusion

Thank you for the opportunity to comment on the proposed ETC rule. As nonprofit providers, we have a unique perspective on the effects of the care and reimbursement changes directed by the ETC model. We very much appreciate your consideration of our views and suggestions. Our intent is to strengthen the ETC model for both patients and providers. We would be pleased to discuss any of the above comments and/or suggestions in greater detail at any time. If you have any questions, please feel free to contact NKCA's Executive Director, Marty Corry, at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director