

September 16, 2019

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: 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 American Society of Nephrology, the National Kidney Foundation, and the Renal Physicians Association, we thank you for the opportunity to provide comments on the proposed rule for the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model developed at the direction of the July 10, 2019 Executive Order creating the Advancing American Kidney Health (AAKH) initiative.

Our respective organizations were founded to advocate for the highest quality health care possible for people with kidney disease – 37 million Americans and more than 850 million people worldwide affected by kidney disease. In keeping with our collective mission, we applaud the Trump Administration for creating an ambitious agenda for kidney health. The AAKH initiative will potentially bring sweeping changes to care for people with kidney disease, including more focus on upstream treatment to slow the progression of kidney disease, choices for dialysis modalities, greater access to transplantation, and concerted support for development of innovative therapies, including artificial kidneys.

For people who do progress to end-stage renal disease (ESRD), also known as kidney failure, a kidney transplant or dialysis is necessary for survival. New projections indicate an expected 11-18% increase in kidney failure from 2015 to 2030.<sup>1</sup> Nearly 100,000 individuals are currently waiting for a kidney transplant and last year nearly 20,000 received a kidney. Unfortunately, most people with kidney failure will die without having the opportunity to receive a kidney transplant with a hemodialysis patient mortality rate of close to 60 percent over five years.<sup>2</sup>

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<sup>1</sup> McCullough KP, et al. Projecting ESRD Incidence and Prevalence in the United States through 2030, *J Am Soc Nephrol*. 2019 Jan;30(1):127-135. doi: 10.1681/ASN.2018050531. Epub 2018 Dec 17.

<sup>2</sup> United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

The paradigm for treating kidney failure is broken. For this reason, we strongly support the objectives of this proposed model to expand patient access to a variety of dialysis modalities and to increase patient access to kidney transplantation. We have identified five key essential principles that we believe will lead to better patient outcomes that should be supported in the proposed ETC Model.

We offer the following five principles in that spirit.

- Establishing patient-centered targets, benchmarks, and risk adjustments that ensure there are guardrails in the Model for patients with contraindications or insurmountable barriers for home dialysis or transplant. In addition, correctly risk adjusting the patient population that is to be placed in the denominator for evaluating ETC Participants – clinicians and dialysis facilities – would empower them to make truly shared, patient-centered choices.
- Empowering patients and care teams when evaluating treatment choices. The model should encourage the use of shared decision-making tools by patients and their care team when educating and evaluating kidney replacement therapies (KRTs).
- Guaranteeing access to home dialysis programs. Enhancing patient access to kidney failure treatment choices and the education needed to properly evaluate those choices) is a key goal of the ETC model that we support. However, ensuring reasonable patient access to a home dialysis program does not require that every dialysis facility offer a home dialysis program.
- Incentivizing and investing wisely in the proposed model. We believe the model must balance appropriate adjustments that are not overly punitive while providing more up-front investment to make possible the desired achievements in increased home dialysis and transplantation rates. The truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis – results that will require investment in order to achieve.
- Providing ETC participants the time to properly prepare for the model and the opportunity to comment as the model progresses. We believe the success of all participants in the model would be enhanced by providing more time before commencing the ETC Model date for stakeholders to prepare starting April 1, 2020. We also believe the success of the model would be enhanced by using the rulemaking process throughout the life of the model.

We strongly support the goals and objectives of the AAKH initiative and stand ready to work with the Center for Medicare and Medicaid Innovation to support these five principles in all facets of the proposed ETC Model.

Sincerely,

American Society of Nephrology  
National Kidney Foundation  
Renal Physicians Association