American Nephrology Nurses Association (ANNA) Medicare Specialty Care Models To Improve Quality of Care and Reduce Expenditures End-Stage Renal Disease Treatment Choices (ETC) Model	
ANNA Comments	**ETC Final Rule**
Implementation Date Extend the implementation period beyond the proposed April 2020 date to allow patients, nurses, and others impacted by these reforms to properly prepare and address barriers to home therapies and transplants.	We appreciate the feedback from the commenters about alternative start dates for the Model that would allow ETC Participants sufficient time to prepare for the Model. We had intended to delay the ETC Model implementation date until July 1, 2020, as had been recommended by some of the commenters, but as we were completing this final rule, the U.S. began responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as ''coronavirus disease 2019'' (COVID–19), which created a serious public health threat greatly impacting the U.S. health care system…. We are delaying implementation until January 1, 2021 to ensure that participation in the ETC Model does not further strain the ETC Participants' capacity, potentially hindering the delivery of safe and efficient dialysis care. We believe this delayed implementation will provide ETC Participants with sufficient time to prepare for participation in the Model and adhere to Model requirements.
Nurse Staffing Shortages [I]t is critical that the Agency recognize that the lack of adequate nurse staffing and the shortage of nephrology nurses available to assist may thwart any move towards a new model of care. The need to recruit new registered nurses and retain the nurses currently working in nephrology is an important issue, one we believe the Agency and the industry needs to address directly. Additionally, the United States is facing a shortage of nephrologists entering practice compounded by an increasing number of retiring nephrologists. To address this issue, nephrology nurse practitioners have been hired to fill this void and additional nephrology nurse practitioners will need to be recruited and educated to meet patient demands.	Many commenters noted that establishing a home dialysis program or building upon an existing program requires hiring and training staff, particularly dialysis nurses, who several commenters noted are in short supply; securing additional space and equipment; establishing training protocols for patients; undergoing a survey and certification process (depending on the State); obtaining zoning and building permits; and obtaining federal and State regulatory approval. CMS believes that providing positive payment adjustments via the HDPA [Home Dialysis Payment Adjustment] over the first three years of the Model will provide sufficient time for ETC Participants to build out infrastructure to establish or build upon home dialysis programs.

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The need to recruit new registered nurses and retain the nurses currently working in nephrology is an important issue, one we believe the Agency and the industry needs to address directly.	While CMS cannot easily affect the supply of dialysis nurses or the number of vendors in the home dialysis market, it can provide ETC Participants with positive payment adjustments through the HDPA to help overcome these market obstacles.
Staffing and Hotline ANNA is concerned that these demands and burnout will increase with home dialysis patients requiring a 24-hour, seven-day-a-week resource, via a nurse-staffed hotline or phone system, to address clinical concerns or assist with technical problems with the patient's home dialysis equipment. We agree this would be a role nephrology nurses are qualified and suited to provide; however, without adequate nurse staffing this added responsibility can lead to overload and burnout. ANNA encourages the Agency and the industry to account for the need of registered nurses to manage these types of services when calculating the demand for nursing staff.	We received one comment asking CMS to change payment for Kidney Disease Benefit (KDE) to ''per treatment-hour reimbursement'' to incentivize ESRD facilities to educate patients as early as possible for transition to home dialysis. The commenter also suggested that ''highly skilled, 24/7 centralized real-time equipment and clinical telephone support'' must be in place after patients begin dialyzing at home. We thank the commenter for this feedback. We did not propose to change payment for the KDE benefit in the proposed rule, nor did we propose to require that ''highly skilled, 24/7 centralized real-time equipment and clinical telephone support'' be in place after patients begin dialyzing at home, and we therefore are not finalizing these policies in this final rule.
Kidney Disease Education Benefit The revised model would provide tools for coordinating care by providing Stark Law/anti-kickback waivers to allow facility health care professionals (such as dieticians and social workers) to assist clinicians in educational efforts, as well as expanding the proposed Kidney Disease Education (KDE) waivers to allow facilities to also bill Medicare for these educational services.	After considering the public comments, we are finalizing the proposed waivers of select requirements of the KDE Benefit for purposes of testing the ETC Model, with changes, in our regulation at § 512.397(b). Specifically, we will waive the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. Our regulation at § 512.397(b) will now list the Supplier and Non-Physician Practitioner types that will be able to furnish and bill for the KDE benefit under this waiver.

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Appropriateness of Home Dialysis ANNA fears that the proposed payment model and incentive for home dialysis therapy may stimulate the encouragement of both incident and prevalent ESRD patients to choose home dialysis when they may not be clinically appropriate or ready for this modality leading to a high failure rate.	In terms of the commenters' concerns that the Model does not address some or all of the key barriers to home dialysis and transplantation and does not sufficiently incentivize supporting patient choice, this Model is one piece of the larger HHS effort to improve care for beneficiaries with kidney disease, which also includes the Kidney Care Choice (KCC) Model. While the ETC Model focuses primarily on modality selection, other parts of the HHS effort focus more directly on other ways to improve care for beneficiaries with kidney disease, including education and prevention, care coordination, organ supply, and technological innovation. We agree that supporting patient choice in modality selection is vital, and we believe the ETC Model will support providers and suppliers in their ability to assist beneficiaries choosing renal replacement modalities other than in-center dialysis. We address the commenters' specific comments about the interaction with the KCC Model in section IV.C.6 of this final rule, and in other sections of this final rule where particular policies are discussed.

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Scope of Model The Agency needs to reduce the scope of the program, which is proposed to encompass 50 percent of the United States using the Hospital Referral Regions (HRRs).	Several commenters asserted that requiring participation by approximately half of the country does not constitute a model test, but rather a substantive change to Medicare payment policy. Some commenters stated that this exceeds the scope of the Innovation Center's authority. Some commenters stated that, the scope and mandatory nature of the Model, coupled with the downward payment adjustments, constitute an overall payment reduction for ESRD facilities and Managing Clinicians, which will cause unintended consequences, including market consolidation, decrease in availability of services, and disruption of patient care. We do not believe that the size, scope, and duration of the Model constitute a substantive change to Medicare payment policy, as the model test is limited in duration and is not a permanent change to the Medicare program. We also believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize the ETC Model as we have proposed and are finalizing it.