October 21, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, DC 20201

RE: Requested Delay in Implementation of the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Mandatory Model Until After Conclusion of the COVID-19 Public Health Emergency (PHE)

Dear Administrator Verma:

On behalf of the National Renal Administrators Association (NRAA), I write to respectfully and urgently request delayed implementation of the ESRD Treatment Choices (ETC) Mandatory Model until after the COVID-19 Public Health Emergency concludes. Requiring ETC Model participation for selected dialysis facilities that are working diligently and tirelessly to safely care for ESRD patients in the midst of the ongoing COVID-19 PHE poses unnecessary risk and burden to these providers and the highly vulnerable patients they are caring for who are at serious risk for severe outcomes, including death, from COVID-19.

The National Renal Administrators Association (NRAA) is a voluntary organization representing dialysis providers throughout the United States. Our membership primarily includes small and independent for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in both free-standing and hospital-based facilities. We strongly support efforts by the Centers for Medicare and Medicaid Services (CMS) to improve patient quality of care and health outcomes for Medicare beneficiaries with Chronic Kidney Disease (CKD) of all stages. We appreciate the ongoing recognition by CMS of the unique challenges posed to small and medium facilities providing high quality care to these vulnerable pediatric and adult patient populations.

The NRAA welcomed release of the President's Executive Order on Advancing American Kidney Health and the corresponding Advancing American Kidney Initiative from the U.S. Department of Health and Human Services (HHS), as we strongly agree with the goals of this critically important undertaking. Indeed, we firmly believe that kidney transplant represents the goal for patients with severe renal disease who want to pursue that treatment option and for whom it is medically appropriate We also strongly support expanding patient access to home dialysis because this treatment modality can offer meaningful improvement in quality of life and health outcomes for ESRD patients for whom it is medically appropriate. The NRAA thus is eager and committed to working with the Administration to make both kidney transplant and home dialysis more widely available to patients with severe kidney disease.

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However, the NRAA is extremely concerned that making the costly and time-consuming structural changes to care practices necessary for successful participation in the ETC Model is beyond what can reasonably be expected from dialysis facilities during the COVID-19 public health crisis – particularly for small and independent providers oftentimes treating patients in rural and underserved communities. Moreover, although we are still analyzing the modifications made to the ETC Model in the final rule, the NRAA continues have a number of concerns with the Model that were finalized as proposed, including:

- **The ETC Model should exclude dialysis facilities in organizations within 35 clinics or less.** Data analysis performed by Dobson DaVanzo and Associates on behalf of the NRAA shoes that low-volume and rural ESRD facilities currently disproportionately do not offer home therapy relative to other facility types and, in many cases, are small and independent facilities with limited resources available to make the substantial up-front investment necessary to initiate and grow home therapy programs. Therefore, the NRAA continues to urge CMS to exclude dialysis facilities in organizations with 35 clinics or less from the ETC Model.

- **The Home Dialysis Payment Adjustment (HDPA) is inadequate to support the initiation and growth of home therapy programs – particularly for small and independent clinics with very limited resources further strained by the COVID-19 pandemic.** The Model's slight payment increase to support home dialysis simply is substantially outweighed by the significant upfront costs necessary to start and grow home therapy programs. Thus, the NRAA continues to urge CMS to significantly increase the HDPA amount so that providers with constrained resources and small or no home therapy programs can have at least some opportunity for successful participation in the Model.

- **A number of significant methodological issues remain unclear and should be fully explained by CMS before ETC Model implementation so that participants have a much better understanding of the performance they need to achieve to avoid the Model's potentially substantial payment reductions (up to -10 percent for dialysis facilities).** Outstanding questions remain about a number of critical methodological issues with the ETC Model, including details about the comparison groups, the benchmarking methodology, the improvement scoring methodology, and the use of Hospital Referral Regions (HRRs) for selection of Model participants that may result in patients not receiving care from providers that are most accessible to patients. The NRAA respectfully urges CMS to clarify these methodological issues with adequate time for participants to prepare before actually implementing the ETC Model.

The NRAA respectfully makes these requests to advance our mutually shared goal of promoting the safe delivery of dialysis treatment to ESRD patients during the COVID-19 pandemic while at the same time ensuring these patients have more meaningful treatment choices that lead to better health outcomes and improved quality of life.

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1. Delay ETC Model Implementation Until After the COVID-19 PHE Concludes

The COVID-19 pandemic is continuing and expanding throughout the U.S. Unfortunately, ESRD patients typically suffer from multiple underlying conditions beyond ESRD that place them at especially serious risk for contracting COVID-19 and experiencing severe adverse health outcomes, including death, from the virus. The risk of COVID-19 exposure is especially high for these patients and their healthcare providers, as the vast majority of ESRD patients receive treatment three times per week in dialysis facilities – with frequent patient entry and exit into facilities significantly increasing the risk for contracting and spreading the virus for patients and care team members.

Given the ongoing challenges with the pandemic, dialysis facilities are laser-focused on ensuring that ESRD patients can access the life-sustaining treatment they need in a manner that safely protects both patients and providers. The NRAA thus ardently believes that asking dialysis facilities to divert attention and resources away from caring for the extremely vulnerable ESRD patient population during the COVID-19 PHE to make the fundamental, costly changes to care practices to avoid significant payment reductions in the ETC Model is simply excessively burdensome and poses unnecessary risks to ESRD patients and their care providers. For example, while the NRAA strongly supports growing rates of home dialysis, training patients on home dialysis requires nurses to sit face-to-face with patients and their families in closed training rooms for long periods of time, presenting an unnecessary risk and care challenge in the midst of the pandemic when many facilities are already facing nursing shortages.

Indeed, dialysis providers are under enormous stress trying their best to safely manage daily COVID-19 routines and procedures so that patients can continue to receive life-sustaining treatment. After approximately eight months of ongoing new burden and stress from COVID-19, dialysis providers are experiencing significant physical and mental fatigue with extremely limited ability to undertake the substantial efforts necessary to successfully participate in the new ETC treatment paradigm. Safely caring for Medicare beneficiaries with ESRD should serve as the sole focus and priority for dialysis providers during the pandemic. **As such, the NRAA respectfully urges CMS to delay implementation of the ETC Model until after conclusion of the COVID-19 PHE.**

The NRAA wishes to underscore that concerns about simultaneously moving ahead with the ETC Model during the pandemic are especially problematic for small and independent with limited resources in many cases treating ESRD beneficiaries in rural and underserved areas. As we have expressed to the agency previously, the NRAA remains extremely concerned that the substantial payment reductions in the ETC Mandatory Model will lead to facility closure and further consolidation of the dialysis industry; many small and independent providers do not have sufficient existing resources to make the investments necessary for successful Model participation and just cannot absorb the magnitude of the payment cuts that result from poor Model performance. The ongoing significant challenges presented by COVID-19 make the likelihood of avoiding substantial payment reductions in the ETC Model even more daunting and overwhelming for many small and independent dialysis clinics. Hence, delaying implementation of the ETC Model until after conclusion of the COVID-19 pandemic is particularly urgent for these facilities so that they can remain open over the long-term and ensure care

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continuity. Again, therefore, we respectfully urge and request CMS to delay implementation of the ETC Model until after the public health crisis ends.

2. Exclude Dialysis Facilities in Organizations with 35 of More Clinics from the ETC Model

The NRAA continues to respectfully urge CMS to exclude small and independent dialysis clinics in organizations with 35 or less facilities from the ETC Model unless they voluntarily opt to participate. Many low-volume and rural facilities are small and independent providers with negative Medicare margins and limited resources available to make the substantial up-front investment necessary to initiate and grow home therapy programs.

Analysis by Dobson DaVanzo and Associates performed on behalf of the NRAA shows that low-volume and rural ESRD facilities currently disproportionately do not offer home therapy relative to other facility types – a substantial number of which are small and independent providers. The distributions of home dialysis and transplant rates are even more highly skewed toward zero percent for these facilities than ESRD facilities as a whole, indicating that in practice low-volume and rural facilities may not be competitive in this model (see Tables 1 and 2 below). Specifically, the Dobson DaVanzo analysis found:

- **Low-volume facilities:** 70 percent of facilities classified as "low-volume" currently have a zero percent home dialysis rate and 61 percent of facilities have a zero percent transplant rate.[1]

- **Rural facilities:** 43 percent of rural facilities register a zero percent transplant rate.
- **Low-volume and rural facilities:** Among those facilities that are both rural and low-volume, 75 percent of facilities have a zero percent home dialysis rate and 64 percent have a 0 percent transplant rate.

Table 1: Home Dialysis and Kidney Transplant Rates by Facility Type

[1] A low-volume facility meets the ESRD PPS definition of 4,000 treatments in each of the 3 years preceding the payment year.

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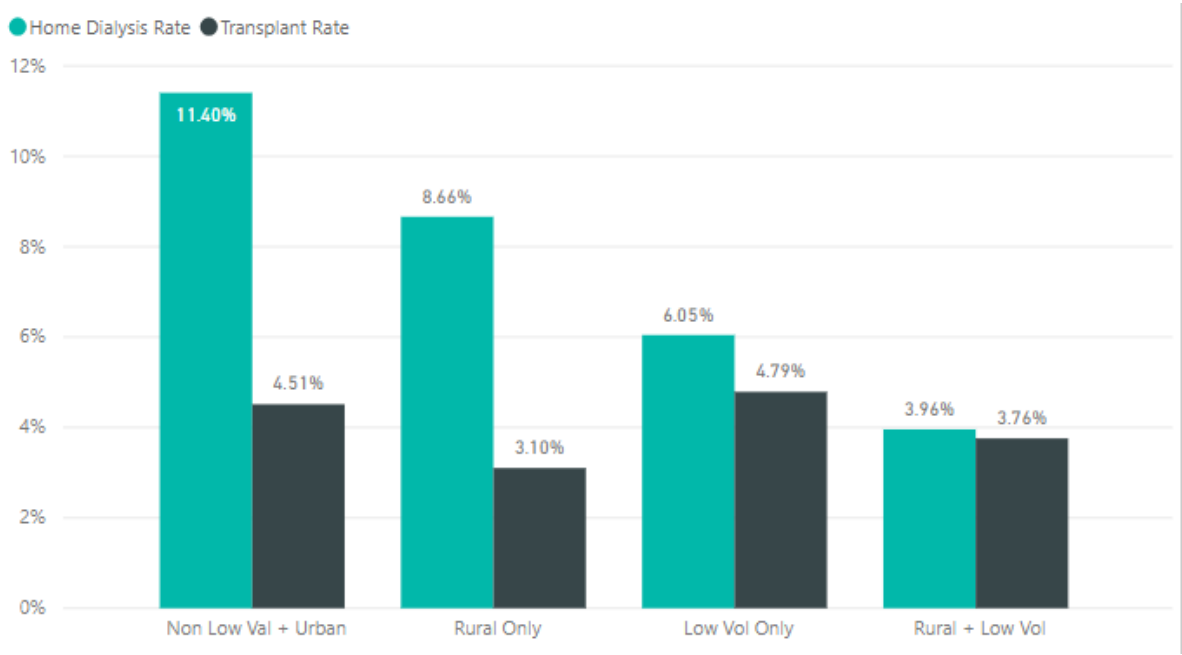

Source: Dobson | DaVanzo analysis of 2018 LDS quarterly data, DUA 22335

Table 2: Home Dialysis and Kidney Transplant Rates by Facility Type

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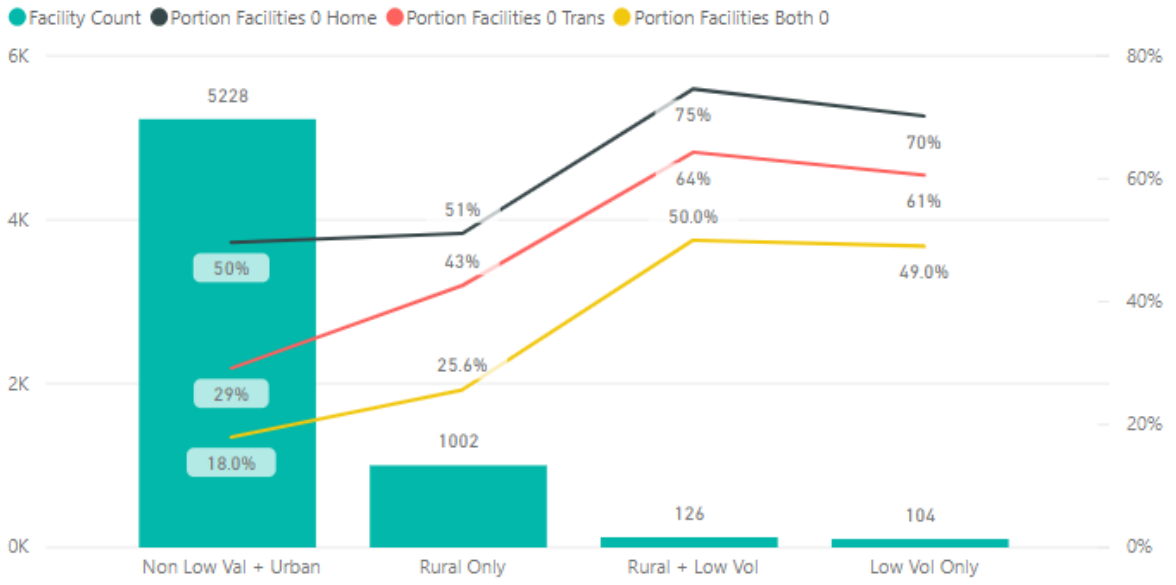

Source: Dobson | DaVanzo analysis of 2018 LDS quarterly data, DUA 22335

Notably, the Medicare Payment Advisory Commission (MedPAC) March 2020 Report to Congress indicates that rural facilities and facilities in the three lowest quantiles based on treatment volume have negative Medicare margins (-21.3 percent in the lowest quintile by volume).[2] This means that rural and low-volume facilities have minimal existing resources available and little opportunity to make the required substantial financial investment to start and expand home dialysis programs. Further, we note that CMS finalized its proposal to exclude facilities with 11 beneficiary treatment years from the Model. However, as explained above, Dobson DaVanzo's analysis demonstrates that low-volume and rural facilities with even slightly more treatment volume have numerator distributions already highly skewed toward zero percent rates of home dialysis, again demonstrating that it will be difficult for those facilities to initiate and grow home therapy programs and avoid the significant payment reductions in the Model.

Thus, the NRAA continues to respectfully urge CMS to exclude facilities in organizations with 35 or less clinics from the Model unless the voluntarily opt to participate. Without giving these small and independent facilities the option to opt-out of the Model, these facilities could be forced to close due the enormity of the payment reductions. Such an outcome would severely jeopardize ESRD beneficiary access to life-sustaining dialysis treatment particularly in rural and underserved areas – an outcome clearly not intended by the Model.

[2] MedPAC. March 2020 Report to Congress: Medicare Payment Policy, page 192.

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3. Increase the Home Dialysis Payment Adjustment (HDPA) to Support Facilities Initiating and Growing Home Dialysis Programs

The Home Dialysis Payment Adjustment will increase payments to dialysis facilities for the first three years of the ETC Model by +3 percent, +2 percent, and +1 percent, respectively. ESRD facilities need significantly more financial resources than the finalized HDPA amounts to start and grow home dialysis programs – especially small and independent facilities operating on low to negative Medicare margins with limited resources.

Indeed, the Model's slight payment increase to support home dialysis is substantially outweighed by the significant upfront costs necessary to commence and expand home therapy programs. Of particularly vexing concern is the fact that costs of home dialysis equipment and supplies have grown in the range of 20 percent to 30 percent recently due to extremely limited supplier competition (only 2 vendors) and are only expected to grow with Model implementation. Moreover, a shortage in supply of registered nurses trained in home dialysis coupled with lack of adequate reimbursement in ESRD payment system for home dialysis training make the costs of home dialysis even more burdensome and unaffordable for providers. **Therefore, the NRAA respectfully urges CMS to modify the HDPA and make significantly higher payments to dialysis clinics to support the establishment and expansion of home dialysis programs. Higher HDPAs will meaningfully improve the opportunity for small and independent dialysis providers to start and grow home dialysis programs, which will benefit the patients cared for by these facilities often in rural and underserved areas for whom home dialysis is medically appropriate.**

4. Provide Clarity on Outstanding Methodological Issues

A number of critical methodological issues remain outstanding and uncertain for ETC Model participants, which the NRAA respectfully urges CMS to address prior to Model implementation, including:

- **Comparison groups:** For the integrity of the Model to be maintained, having a clear and transparent understanding of the methodology for measuring and calculating performance in the comparison group is critical. The NRAA therefore respectfully urges CMS to provide additional detail about the comparison group(s) and related methodology about how the group(s) is determined.

- **Benchmarks:** CMS finalized the benchmarks only for Measurement Years (MYs) 1 and 2 of the ETC Model and stated in the final rule that it expected to go through formal rulemaking to implement a new benchmark methodology for later years of the Model. Lack of certainty about the benchmark methodology is not appropriate for Model participants that need to have a clear understanding of the actions necessary to perform successfully in the ETC Model and avoid payment reductions of such substantial magnitude (as much as -10 percent) that could lead to

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facility closure. The NRAA thus respectfully urges CMS to provide a clear and transparent understanding of how the benchmark will be determined and updated over time.

- **Improvement scoring:** The improvement score scale for MY1 and MY2 indicates the improvement necessary to obtain 0.5, 1.0 or 1.5 points. The NRAA respectfully requests that CMS provide clear and specific examples detailing the calculations for each of the improvement percentages.

- **Patients potentially receiving care from previously unknown providers particularly in rural areas due to use of Hospital Referral Regions as the unit of geographic selection:** CMS randomly selected Model participants from the 306 Hospital Referral Regions (HRRs) across the U.S. While the HRRs may generally reflect tertiary patterns of care, use of HRRs in many rural areas does not align with the local hospitals where dialysis patients receive a majority of their inpatient care. This may lead to patients having to travel much farther distances to HRR hospitals and providers with whom they have no previous relationship. This is particularly problematic for the ESRD patient population, which is comprised of high touch, high complexity patients who have established relationships through frequent, ongoing interactions with their providers. This challenge should be addressed so that patients do not have adverse care experiences.

The NRAA respectfully requests that CMS clarify each of these methodological issues in a highly transparent and clear manner with adequate time for participants to prepare before actual implementation of the ETC Model. These issues are critical to ensuring that Model participants understand the performance necessary for success and avoidance of the Model's substantial payment reductions.

Conclusion

In conclusion, the NRAA wishes to thank CMS for its clear recognition that immunosuppressed ESRD beneficiaries and their healthcare providers are at especially high risk for COVID-19 exposure, as demonstrated by important the regulatory flexibilities the agency has extended to dialysis providers on the front lines of the PHE caring for patients. The risk for virus exposure and transmission unfortunately remains high for ESRD patients and their providers as the pandemic continues to spread throughout the country. The NRAA therefore wishes to thank you for your consideration of our urgent request to delay implementation of the ETC Model until after the COVID-19 pandemic ceases. Delaying implementation of the ETC Model critically will enable dialysis facilities to stay focused on safely delivering treatment to patients and also give the agency additional time to address the aforementioned methodological issues that are unclear to Model participants. If you have any questions concerning our comments, please do not hesitate to call NRAA Executive Director Marc Chow at (831) 234-1299.

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Sincerely,

Maria Regnier, RN, MSN, CNN

NRAA President

cc: Brad Smith
Deputy Administrator and Director
Center for Medicare and Medicaid Innovation

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