KIDNEY CARE PARTNERS

August 26, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1749-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease [ESRD] Prospective Payment System [PPS], Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury [AKI], End-Stage Renal Disease Quality Incentive Program [QIP], and End-Stage Renal Disease Treatment Choices [ETC] Model Proposed Rule" (Proposed Rule). This letter focuses on the ESRD ETC Model and the request for information related to that rule. Our comments on the ESRD PPS, AKI, and QIP programs will be provided in separate letters. We appreciate CMMI's decision to issue a proposed rule with refinements to the ESRD ETC Model and support many of the proposals. We are pleased that CMMI has sought to address many of the concerns KCP has raised and included proposals to try to avoid the Model's methodology from unintentionally discretizing home dialysis and transplant, especially for Black and Hispanic individuals living with kidney disease. We offer a few modifications that we think CMMI could adopt to achieve this goal as well.

In brief, our comments including the following recommendations, and we urge CMS to adopt the proposed recommendations related to the nocturnal dialysis proposal, benchmarks, and KDE waivers in the final rule.

- KCP supports the clarification of the scope of the ETC Model applying to the ESRD PPS claims, the living kidney donor transplant adjustment proposal, the PPA transplant rate proposal, and the process for sharing data with ETC participants at both the individual and aggregate levels.

- While KCP supports the proposal to expand modality options under the ETC Model to include nocturnal dialysis, we do not support adopting incentives that

apply only to facilities whose ownership structure falls below a certain number of facilities.

- KCP also supports using a known 10 percent increase over a two MY period to increase the benchmarks, stratifying the benchmarks by dual-eligibility and LIS status, as well as an HEI adjustment for improvement. However, we offer suggested modifications to these policies to ensure that they incentivize the adoption of home dialysis and improve access to transplant for beneficiaries. The suggestions include using a set benchmark (using a population-weight methodology) rather than a moving benchmark that changes annual based upon performance in the Comparative Geographic Areas (CGAs), reducing the HEI qualifying performance percentage to 1 percentage increase every two MYs, and allowing improvement scoring options for all patient improvement, not only those with dual eligibility or LIS status.

- KCP supports extending existing telehealth and Kidney Disease Education waivers and requests additional waivers to expand access to these education services.

- Finally, KCP provides recommendations to incentivize the placement of PD catheters, recommends that CMMI support existing work on a home dialysis patient satisfaction measure, and offers recommendations on how to publish ETC participant quality outcomes.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

KCP wants to thank CMS for working with KCP members during the pandemic. As the Centers for Disease Control and Prevention (CDC) has recognized, patients with Chronic Kidney Disease (CKD), especially those with Stage 5 kidney failure, are at a heighten risk of contracting COVID-19. Thus, finding ways to promote care in the home through expanding telehealth services and access to laboratory testing in the home are important steps to reduce the risk of infection. In addition, allowing facilities to have the flexibility to implement programs to help patients who require in-center hemodialysis, even after diagnosed with COVID-19, has helped to ensure that all patients receive the care they need during these difficult times. Most importantly, we appreciate the Biden-Harris Administration's decision to allocate vaccines directly to dialysis facilities to allow them to leverage their thrice weekly contact with patients and encourage them to be vaccinated.

In addition, we strongly support the Administration's efforts to address inequities in health care. As we described in detail in our July letter to the Office of Management and

Budget (OMB) request for information "Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government," patients with kidney disease are disproportionately from communities of color and experience inequities in the delivery of health care. Throughout this letter, KCP makes recommendations that we believe will help address this systemic problem.

As CMS and others have recognized, the modifications to the ESRD programs alone are not enough. The systemic barriers to accessing basic health care likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure. The leading causes of CKD and ERSD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.[1] We know from several years of research that people of color have greater difficulties accessing preventive care and chronic disease management services.[2] It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in chronic diseases, such as diabetes, obesity, and heart disease, not being fully managed, which led to the development of kidney disease. We specially encourage CMS to remove existing regulatory barriers that make it difficult to identify, educate, and treat patients with earlier stages of CKD. KCP renews its commitment to work with CMS and other federal agencies to find ways to address these challenges that exist prior to an individual's kidneys failing.

Improving quality outcomes remains a top priority for KCP as well. KCP since 2005 has led the kidney community in its efforts to shift to a patient-centered, quality-based approach to providing kidney care in America. Through the Kidney Care Quality Alliance (KCQA), our members have developed measures, navigated them through the National Quality Forum's (NQF) endorsement and maintenance processes, and advocated for their inclusion in the Medicare ESRD QIP and other quality programs. In the Spring of 2021, KCQA renewed its measure development agenda. Led by Drs. George Arnoff and Keith Bellovich as the co-chairs of the KCQA Steering Committee, KCQA is developing measures in the domains of home dialysis, transplant, anemia management, bloodstream infection, and bone mineral metabolism. Each of these domains constitutes care priorities for patients. Current measures in these domains lack validity, reliability, and/or actionability. They do not provide accurate information to people living with kidney disease or the information providers need to improve outcomes. We look forward to working closely with CMS to bring these measures forward and integrate them into the ESRD QIP, Dialysis Facility Compare/Five Star, and the ETC Models. Our comments in this letter offer recommendations about our work to develop home dialysis and transplant measures that

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[1] Richard V. Reeves & Faith Smith. "Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System." *Brookings.* https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/ Aug. 7, 2020). accessed June 28, 2021.

[2] Kenneth E. Thorpe, Kathy Ko Chin, Yarira Cruz, *et al.* "The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases." *Health Affairs* (Aug. 17, 2017) https://www.healthaffairs.org/do/10.1377/hblog20170817.061561/full/. accessed June 20, 2021.

will drive the outcomes sought by the Administration through the ETC model. We look forward to working with CMMI to incorporate these measures into the ESRD ETC Model.

KCP appreciates the ongoing collaborative partnership with CMS to promote transparency, accountability, and high-quality patient-centered care for the people living with kidney disease whom we serve. We look forward to working with you on this year's rulemaking.

I. KCP supports the clarification of the scope of the ETC Model.

KCP supports the clarifies that the Home Dialysis Payment Adjustment (HDPA) and Performance Payment Adjustment (PPA) do not apply to claims from ESRD facilities that are not paid under ESRD PPS, but are instead paid through other Medicare payment systems.

We also agree that the ideal is for the EQRS to be the data source go forward. However, as the Proposed Rule recognizes, there have been serious implementation issues that have delayed data entry and created data integrity problems. These have been so severe that CMS has suspended data collection and modified the implementation of the ESRD QIP in light of these problems. We encourage CMMI to work closely with the dialysis facilities and nephrologists to make sure that the data being used from EQRS is accurate and reliable and to identify work-arounds through guidance if the problems with the system persist.

II. KCP supports the adjustment PPA beneficiary attribution for living kidney donor transplants.

KCP supports the proposal to make sure that a patient's managing physician receives credit for the patients they manage who receive a living donor transplant. We appreciate CMMI considering the implications of the current policy and suggesting modifications to avoid the unintended consequence of a different physician who might step in to manage the transplant having the patient attributed to him/her.

However, the impact of this change is minimal, and KCP encourages CMS to do more with the benchmark calculations as recommended below to incentivize and reward Managing Clinicians and dialysis facilities for achieving the goals of the Model. As the chart prepared by CDRG below shows, the impact of changes in attribution logic is limited, due to the small number of qualifying events, as displayed below. (Note that each column is a subset of the class at its left.)

Table 1: Number of Preemptive Kidney Transplants by Year (2010-2019)

	Number of preemptive kidney transplants, by year		
	Preemptive	Living-donor	Medicare
2010	2,935	1,832	400
2011	2,944	1,774	343
2012	2,867	1,658	324
2013	2,955	1,691	325
2014	3,030	1,718	316
2015	2,948	1,723	325
2016	3,231	1,814	393
2017	3,407	1,839	363
2018	3,631	1,964	406
2019	4,022	2,127	483

Despite recent growth, calendar year 2019 included only 483 transplants that were likely to be attributed to managing clinicians; only approximately 30 percent of these were attributed to clinicians participating in ETC. The straightforward conclusion is that attribution logic has very little impact on transplant rate calculations, given the far greater number of wait-listed patient-months that are included in those calculations.

III. While KCP supports expanding modality options for individuals with kidney failure who require dialysis, we do not support adopting incentives that apply only to facilities whose ownership structure falls below a certain number. Instead, we believe that CMMI should promote and incentivize expanded modality options for all patients, not only patients selecting organizations not defined by CMMI as large-dialysis organizations (LDOs).

CMMI outlined the goal of the ETC Model as incentivizing home dialysis and transplant. While patient selection of nocturnal dialysis is neither, KCP supports efforts to incentivize patient selection of all types of modalities. Federal policies should also support all modality options and be structured so as to allow patients to select the modality that is the right choice for them. Thus, we support expanding the home dialysis rate calculation to include nocturnal in-center dialysis in the numerator beginning in MY3. We also support counting patients receiving nocturnal dialysis as one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received nocturnal in-center dialysis in the numerator of this calculation.

However, we ask CMMI to remove the limitation of this expansion that restricts it only to patients who receive services in what CMMI has defined as "non-LDOs." While ownership size has been used to establish risk models in the ESCO program, it is not used, and should not be used, by CMS in other Medicare programs for payment bonuses or cuts

directly. This policy would be unprecedented and inappropriate. It would also inappropriately eliminate a large number of Managing Clinicians.

The preamble states that the rationale for adding nocturnal dialysis to the home dialysis calculation is to increase the scoring options for facilities that are part of organizations that own fewer than 500 ESRD facilities. "[W]e do not believe that ESRD facilities owned in whole or in part by LDOs face the same resource constraints in establishing a home dialysis program as independent ESRD facilities or ESRD facilities owned by small dialysis organizations."[3] However, this policy will do little to improve scoring for any facility, as the data analysis by CDRG demonstrates.

Adding nocturnal dialysis patients to the number will have little impact on the performance calculation. Very few patients select nocturnal dialysis as their modality of choice. There are many legitimate reasons for this fact. However, as with home dialysis, it is another alternative to in-center dialysis that patients should be encouraged to consider. As such, CMMI should incentivize its consideration for all individuals with kidney failure, not only those individuals who select a facility in a non-LDOs.

The table below shows the percentiles of home dialysis rates for all aggregation units formed by dialysis facilities, regardless of ETC participation. It indicates that nocturnal hemodialysis, whether accounted in all facilities or only non-LDO facilities (as proposed), currently has very small influence on critical benchmarks of home dialysis rates.

Table 2: Home dialysis rate quantiles in all aggregation units, before and after proposed policy regarding nocturnal hemodialysis

Percentile	Home dialysis rate (%)		
	Without half-credit for nocturnal HD	With half-credit for nocturnal HD in all facilities	With half-credit for nocturnal HD in non-LDO facilities
5	0.00	0.00	0.00
10	0.00	0.00	0.00
15	1.57	1.67	1.57
20	4.18	4.19	4.18
25	6.02	6.02	6.02
30	7.24	7.32	7.24
35	8.56	8.61	8.56
40	9.54	9.66	9.54
45	10.61	10.70	10.61
50	11.53	11.57	11.53
55	12.23	12.30	12.27
60	13.01	13.20	13.04
65	13.92	14.18	14.04
70	15.28	15.36	15.28
75	16.54	16.73	16.54
80	18.66	18.84	18.72
85	21.88	21.97	21.88
90	26.36	26.50	26.36
95	38.26	38.26	38.26

[3] 86 *Fed. Reg.* 36322, 36378 (July 9, 2021).

Table 3 below provides the percentiles of home dialysis rates for aggregation units formed by dialysis facilities, stratified by ETC participation (of the HRR). Observe again that accounting of nocturnal hemodialysis has little influence on critical benchmarks of home dialysis rates in non-ETC facilities.

Table 3: Home dialysis rate quantiles in aggregation units, stratified by ETC participation, before and after proposed policy regarding nocturnal hemodialysis

Percentile	Home dialysis rate (%)					
	Without half-credit for nocturnal HD		With half-credit for nocturnal HD in all facilities		With half-credit for nocturnal HD in non-LDO facilities	
	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC
5	0.00	0.00	0.00	0.00	0.00	0.00
10	0.00	0.00	0.00	0.00	0.00	0.00
15	1.32	1.99	1.39	1.99	1.32	1.99
20	3.89	4.37	3.89	4.37	3.89	4.37
25	5.94	6.29	5.96	6.29	5.94	6.29
30	7.22	7.39	7.32	7.39	7.22	7.39
35	8.69	8.26	8.83	8.28	8.69	8.26
40	9.69	9.14	9.77	9.20	9.69	9.14
45	10.74	10.27	10.87	10.40	10.74	10.27
50	11.76	11.12	11.88	11.20	11.78	11.12
55	12.38	11.85	12.49	12.00	12.40	11.85
60	13.37	12.61	13.50	12.66	13.42	12.61
65	14.48	13.12	14.61	13.43	14.48	13.12
70	15.74	14.32	15.99	14.42	15.74	14.32
75	17.35	15.59	17.54	15.61	17.35	15.61
80	19.47	16.78	19.73	16.86	19.69	16.78
85	22.50	18.90	22.79	19.05	22.79	18.94
90	27.27	24.69	27.27	24.69	27.27	24.69
95	39.33	34.24	39.33	34.24	39.33	34.24

Given the current adoption rates of nocturnal and the proposed scoring methodology, as well as the socio-economic status barriers experienced by patients, this proposal will not address the underlying concerns expressed by dialysis facilities because the adoption rates would have to increase exponentially to have any meaningful impact, and that seems very unlikely.

Second, the assumption that adding nocturnal dialysis will address resource barriers non-LDO facilities face is not correct. In speaking with several of KCP members whose facilities fall outside of the definition of non-LDO, they indicate that while they support the inclusion of nocturnal dialysis, it is not easier to provide nocturnal dialysis than home dialysis, nor are the resources associated with providing nocturnal dialysis less. Many facilities in urban areas have little to no extra space that will allow for nocturnal dialysis to be an option. Many patients cannot be away from their families at night. Other socio-economic status barriers that make home dialysis difficult to select also impact a patient's ability to select nocturnal dialysis. Because the ETC Model does not address these barriers, the non-LDO KCP members do not believe that the incentivizes in the Model will result in a significant increase in patients selecting nocturnal dialysis. Yet, they do supports

it inclusions for all dialysis facilities, regardless of the size of their organization, to support patient choice.

Data analysis by CDRG supports this position as well. In the current analysis, there are 1093 qualifying aggregation groups (AGs) across the United States; specifically, each AG includes ≥ 132 patient-months. There are 349 AGs participating in ETC. There are 162 AGs operated by the two largest dialysis provider organizations, and 187 AGs operated by all other dialysis provider organizations. The table below shows the home dialysis rate "credit" due to nocturnal in-facility hemodialysis. Note that the credit values in the table are exactly equal to one-half of the utilization (on a percentage basis) of nocturnal in-facility hemodialysis.

Table 4: Contribution of nocturnal in-facility hemodialysis

	Mean credit	AGs with credit		
		AGs (N)	Mean credit	Credit range
LDO	0.138	39	0.571	0.020-1.322
All others	0.014	3	0.875	0.010-2.221

As this chart shows, this proposal would not create a substantial increase for either LDOs or other dialysis facilities. If LDOs were included, the impact would be very similar to what other facilities would receive as well. Again, we believe this shows that there is no empirical data to support the distinction between LDOs and nonLDOs.

Based on the data and the experience of our members, KCP asks that CMMI expand the ETC Model as proposed to incentivize the selection of nocturnal dialysis, but apply it to all patients, regardless of the ownership size of their facility.

IV. KCP supports the PPA transplant rate proposal.

KCP supports the proposal to excluded ESRD beneficiaries and, when applicable, pre-emptive LDT beneficiaries who have been diagnosed with vital solid organ cancers (heart, lung, liver and kidney) and who are receiving treatment, in the form of radiation or chemotherapy, for such cancers from both components of the denominator of the transplant rate for both ESRD facilities and Managing Clinicians for the duration of the MY. We ask that CMS clarify that cancers not be limited to the list outlined in the proposed rule and that the final rule exclude all cancers from the transplant calculation. This policy should be consistent with the KDIGO transplant guidelines.[4] This alignment is important because transplant referrals that will not result in listing are time consuming for patients

[4]KIDGO. "KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation." 104 *Transplantation* S1 (2020) *available at:* https://kdigo.org/wp-content/uploads/2018/08/KDIGO-Txp-Candidate-GL-FINAL.pdf

(and, therefore, not patient-centered) and time-consuming for transplant centers (dividing their time from providing care for people listed for and with transplants). We also support the six-month lookback period for identifying these individuals.

V. KCP continues to support adopting a population-weight benchmark and allowing for improvement in the top tier of scoring (regardless of a patient's status), and, with modifications, the proposed changes to benchmarking and scoring.

A. KCP supports the certainty created by increasing achievement benchmarks a set amount, but asks CMMI to use a lower percentage increases and to adopt an absolute benchmark rather than a benchmark relative to the Comparison Geographic Areas (CGA) to avoid disincentivizing efforts to increase home dialysis and transplant for patients not participating in the ETC Model.

KCP agrees that it is important to provide participating facilities and nephrologists with the change in the benchmarks in advance so that they understand the goals they are trying to meet. CMS proposes increasing the achievement benchmarks above previous year's benchmark by 10 percent every two MYs, beginning for MY3, is an appropriate way to provide this certainty. Based on data from CDRG, it appears that 10 percent seems reasonable given 2019-20 and 2020-21 increases in home dialysis selection.

However, we disagree with the proposal to use CGA rates as the basis for this change. Doing so will inappropriately place patients in CGAs and participating HRRs at risk by disincentivizing home dialysis and transplant in the CGAs unnecessarily. Given that CGAs are 70 percent of the United States, we ask that CMS adopt population-weighted benchmark based on the current benchmarks instead. This static benchmark would be inflated to incentivize improvement and achievement above current levels. As described in section V.B., we believe benchmarks based on the population-weighted recommendations should serve as these benchmarks.

In addition, having both the percentage increased benchmark and the use of the CGAs creates a double increase factor that is not necessary or practical. The use of the CGAs also takes away the certainty that CMS seeks to establish with the percentage increase.

Adopting this modified benchmark approach will promote health equity within the CGAs as well. Disparity in the incidence of ESRD between Blacks and Whites is striking, and progress in closing this gap has been slow. According to the USRDS 2020 Annual Data

Report,[5] the adjusted prevalence of ESRD was 3.4 times higher in Blacks than Whites in 2018. (USRDS Figure 1.8 by race) Ten years earlier, that ratio was 3.8, highlighting the slow progress in addressing the disparity in ESRD prevalence.

Likewise, ESRD prevalence in Hispanic populations was found to be more than 1.5 times higher than in non-Hispanics in 2018. (USRDS Figure 1.8 by ethnicity) Additionally, Black, Asian, Native Hawaiian or Pacific Islander, and multiracial populations were more likely to be diagnosed later in the disease process. For example, compared to 58 percent of White patients, 74 percent of Blacks were diagnosed with ESRD at an eGFR of less than 10 mL/min/1.73 m^2. (USRDS Figure 1.20 by race and by ethnicity)

Black and Hispanic patients also frequently experience barriers to receiving a transplant or being able to select home modalities.[6] Black patients are less likely to initiate peritoneal dialysis (5.9 percent) or receive a preemptive kidney transplant (20.9 percent) than White patients (8.1 percent and 33.2 percent, respectively). Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years. (USRDS Figure 6.9 by race) Between 2017 and 2018, the number of Black patients on the waiting list for a kidney transplant decreased 4.7 percent, compared to only a 1.2 percent decrease in White patients. The number of White patients on the waiting list with active status increased 0.5 percent between 2017 and 2018, compared to a 1.0 percent decrease in Black patients. In 2018, the prevalence of preemptive wait-listing was 5.0 percent among White patients and 3.9 percent among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7 percent in White patients and 10.3 percent in Black patients. The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent during the past 3-4 years, whereas a large disparity in the living donor transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018. Hispanic or Latino patients were also less likely to receive a preemptive transplant (1.75 percent) than non-Hispanic patients (2.56 percent).[7]

These gaps need to be addressed on an ongoing basis. While KCP supports the ETC Model as a way to test financial incentives as a method for expanding access home dialysis and transplant, there are other models and policy changes that can, should, and will be tested during the duration of the ETC Model. Individuals living with kidney disease in CGAs will likely be the targets of many of these interventions. It is important that the ETC Model benchmarks and scoring do not disincentivize these other options. The most direct solution to allow the ETC Model to move forward testing its approach while allowing other options to be evaluated is to use absolute and not relative benchmarks.

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[5] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. Chap. 1. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.
[6] *Id.* at Chap. 6.
[7] *Id.*

Alternatively, CMMI could consider a methodology similar to that used in the ESRD Quality Incentive Program (QIP). KCP had recommended this during the initial rulemaking period as well.

KCP also wants to reiterate our support for CMMI moving away from the 80 percent goal outlined in the original ETC Model proposed rule. It is important for the overall goal of the program to be achievable, even if it includes stretch goals. Setting a target so high that it cannot be achieve creates a disincentive to try to improve performance. Based on work with the KCQA, we believe that an overarching goal should take into account he home dialysis prevalence in the majority of countries, not only the outliers, such as Hong Kong.

The most recent USRDS data indicate that home dialysis utilization stood at 12.5 percent of all dialysis patients at the end of 2018, which has been relatively stable since 2009.[8] We anticipate, however, that data from 2019 and 2020 will show an increase in home dialysis due to many factors, including the COVID-19 pandemic. Looking to performance in other countries, Hong Kong was the only country or region in which more than half of patients on dialysis received a home-based therapy in 2018 (69 percent PD, 3 percent HHD). Areas where a quarter or more of patients received a home-based therapy were the Mexican states of Jalisco (44 percent PD, no HHD) and Aguascalientes (35 percent PD, no HHD), Colombia (27 percent PD, no HHD), Finland (18 percent PD, 8 percent HHD), and Canada (20 percent PD, 5 percent HHD).[9] We ask CMS to take into account this information when setting the overarching goals.

The overarching goals should also take into account the realistic number of organ available for transplant and the willingness of transplant centers who control the waitlist to include patients of color and those with comorbidities. We continue to believe that establishing a floor for waitlist criteria that addresses historical health disparities is a critical policy step that is necessary to increase the number of kidney transplants.

B. KCP agrees that achievement benchmarking should be adjusted to account for socioeconomic factors, but stratifying benchmarks based on dual-eligibility and Low-Income Subsidy (LIS) status is not enough; we also request that CMMI take the facility's patient population into account for purposes of setting the benchmarks.

KCP appreciates that CMS has taken into account concerns our members raised earlier this year about the need to address socioeconomic factors in the ETC Model. While we continue to believe that risk adjuster would be a more appropriate way to approach this issue, we understand that dual-eligible and LIS status stratification may address many of

[8] USRDS 2020 *Annual Data Report Incidence, Prevalence, Patient Characteristic, and Treatment Modalities.*
[9] USRDS 2020 *Annual Data Report International Comparisons.*

the concerns we have identified as well. To help develop appropriate adjusters, we reiterate our recommendation that CMS more broadly collect social determinant of health data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about them. Until risk adjusters can be developed, we support stratifying the benchmarks by dual-eligible and LIS status.

KCP suggests that CMS use a threshold other than the proposed 50 percent value for the dual-eligible/LIS prevalence threshold. One option is to use a different single cut point of 40 percent. CDRG sought to identify the optimal percentage that might be appropriate if a single threshold were adopted. The table below shows the number of aggregation groups within each subgroup defined by ETC participation and DE/LIS prevalence. As the threshold value increases, the number of non-ETC AGs in the "impoverished" subgroup decreases. This will lead to less reliable benchmarks. However, as the subsequent figures show, higher threshold values also better target those aggregation groups with lower home dialysis utilization.

Table 5: Effect of threshold value for DE/LIS prevalence

	x = 30%	*x* = 40%	*x* = 50%	*x* = 60%
Non-ETC				
DE/LIS <*x*%	155	407	560	642
DE/LIS ≥*x*%	589	337	184	102
ETC				
DE/LIS <*x*%	71	178	273	317
DE/LIS ≥*x*%	278	171	76	32

Another option would be to adopt multiple thresholds that could be used to stratify the benchmarks based on dual-eligible or LIS status. CDRG analyzed the dual-eligible LIS status and identify the following curve showing in the figures below. As the figures below show, there appear to be three natural cut points. The first is between 0-35 percent; the second is between 35-70 percent; and the third is greater than 70 percent.

Figure 1: The relationship between Dual-Eligible/LIS prevalence and home dialysis utilization among all Aggregation Groups across the United States

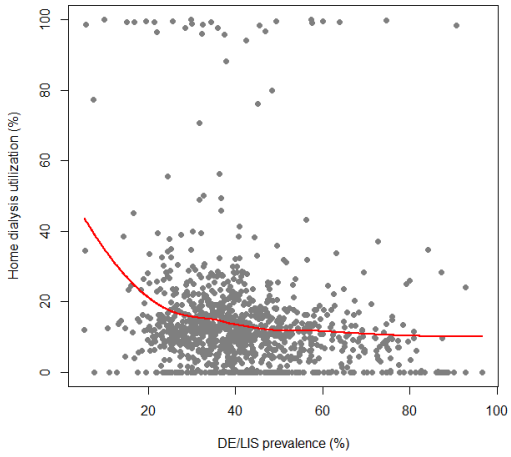
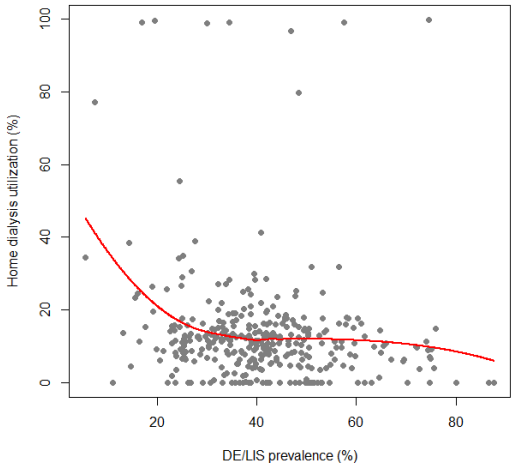


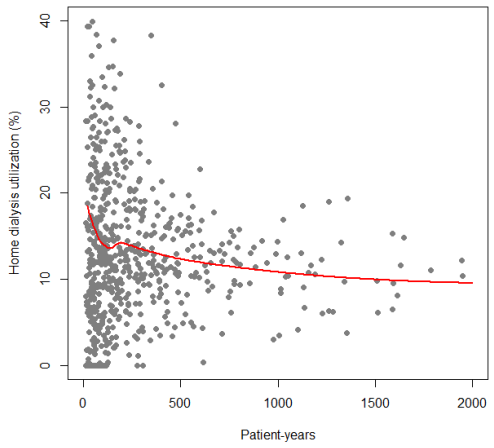
Figure 2: The relationship between Dual-Eligible/LIS prevalence and home dialysis utilization among AGs Participating in the ETC



While we support the proposal consistent with the above comments, KCP also believes it is important for CMMI to modify the calculation of the benchmarks as we discussed in meetings earlier this year. In the current ETC benchmark methodology, all aggregation groups are treated with equal importance, regardless of the number of patient-months, which different significantly by facility. An alternative methodology that KCP has recommended would weight aggregation groups by the number of patient-months. The net effect of weighting aggregation groups is to compress the home dialysis utilization benchmarks toward the median. The following set of figures shows the relationship

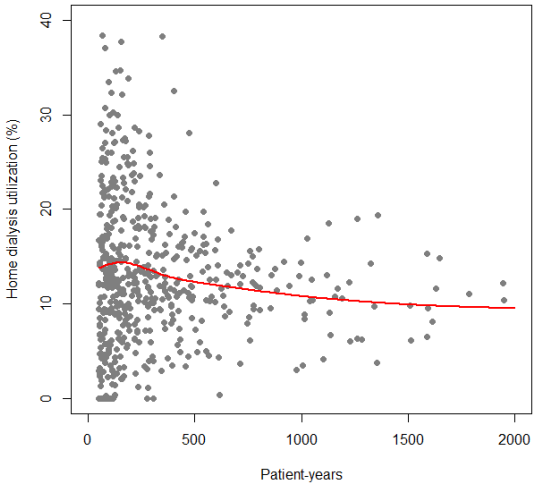
between aggregation size and home dialysis utilization among non-ETC aggregation groups.

Figure 3: Relationship between aggregation group size and home dialysis utilization among non-ETC aggregation groups



If those aggregation groups with less than 50 patient-years are excluded, the relationship between aggregation group size and home dialysis utilization is also less pronounced, as displayed below, despite the fact that excluding small aggregation groups eliminates only 2.7 percent of qualifying patient-months in non-ETC HRRs.

Figure 4: Excluding aggregation groups with less than 50 patient-years



The table below shows the distribution of patient-years in ETC aggregation group among the categories of home dialysis utilization that are implicitly created by the corresponding benchmarks. Indeed, roughly 80 percent of all patient-years reside within aggregation group between the 30th and 75th percentiles of aggregation group-wide home dialysis utilization.

Table 6: Distribution of patient-years in ETC aggregation group among the categories of home dialysis utilization

Home dialysis utilization	Patient-years (N)	Patient-years (%)
<6.83%	13,816	13.7%
6.83-12.74%	50,293	49.8%
12.75-18.32%	29,357	29.1%
18.33-28.18%	6,213	6.2%
≥28.18%	1,275	1.3%

If aggregation groups are weighted by size, then the distribution of patient-years in ETC aggregation groups shifts, resulting in a distribution of patient-years that hews more closely to the percentiles themselves. However, weighting aggregation groups ultimately increases the percentage of aggregation groups in the lowest category of home dialysis utilization. However, the practical consequence of this is less clear. For aggregation groups with home dialysis utilization <9 percent (for example), improvement scale points are already more accessible, as they are awarded on the basis of 5 percent or 10 percent relative increases in home dialysis utilization. Nevertheless, weighting does create narrower intervals between the 30th and 50th percentiles, the 50th and 75th percentiles, and the 75th and 90th percentiles, thus increasing the practical likelihood of an aggregation groups advancing from one interval to the next (and thus increasing the number of achievement points that are awarded).

Home dialysis utilization	Patient-years (N)	Patient-years (%)
<9.29%	32,931	32.6%
9.29-11.64%	21,138	20.9%
11.65-14.68%	27,463	27.2%
14.69-19.59%	14,166	14.0%
≥19.60%	5,256	5.2%

KCP continues to recommend that CMS adopt a population-weighted benchmark would avoid cherry-picking and lemon-dropping of more complex patients who are often Black or Hispanic. While the stratification based on dual-eligibility and LIS status helps to address some of the concerns, the population-weighted benchmark couple with that stratification would address the entire problem. This approach is similar to that used in Physician Compare, which use patient-weighted percentile to set benchmarks. The benefit is that facilities with a larger number of patients, which are often in larger urban areas and

often serve communities of color will be able to move among the tiers, which the current benchmark system makes extremely difficult. Knowing that movement is possible, as opposed to movement being nearly impossible, will motivate facilities and clinicians to improve.

C. KCP generally supports adding the proposed Health Equity Incentive (HEI) to the improvement scoring methodology and continues to recommend that the top tier should be accessible by improvement scoring as well as through attainment.

KCP agrees with that it is appropriate to provide an opportunity to earn an 0.5-point increase on the improvement score when the participant's aggregation group home dialysis and/or transplant raises attributed to dual-eligible or LIS beneficiaries increases. We believe that it is appropriate to award these extra points, but it should not be a 5 percentage points increase from year to year because historic data demonstrate that 5 percent is likely an unachievable goal each year. Data analysis from CDRG demonstrates the importance of this policy in terms of closing the gap created by the current methodology. Its analysis shows that the entire gap is equal to 5 percent. It is not realistic to expect that gap to be closed in a single year. Therefore, KCP recommends that CMMI apply the HEI when the participants aggregation group rates increase above previous year's benchmark by 1 percentage point every two MYs, beginning for MY3.

In an analysis of all patient-months between July 2019 and June 2020:

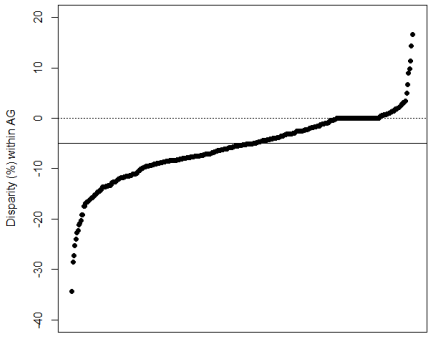
- Home dialysis utilization in dual-eligible patients was 7.8%
- Home dialysis utilization in non-dual-eligible patients was 14.8%

In the current analysis of percentile benchmarks, absolute differences in home dialysis utilization benchmarks between dual-eligible/LIS ≥50% and dual-eligible/LIS <50% among non-ETC aggregation groups were:

- At the 30th percentile, -5.9%
- At the 50th percentile, -4.3%
- At the 75th percentile, -5.2%
- At the 90th percentile, -6.3%

However, within ETC aggregation groups, there is variability in the home dialysis utilization difference between dual-eligible/LIS patient-months and non-dual-eligible/LIS patient-months. In the caterpillar plot of differences among ETC aggregation groups, the negative values indicate that home dialysis utilization among dual-eligible/LIS patient-months was lower than among non-dual-eligible/LIS patient-months.

Figure 5: Home dialysis utilization among dual-eligible/LIS patient-months compared to home dialysis utilization among non-dual-eligible/LIS patient-months



Given this analysis, we support the HEI and awarding extra points when the increase in home dialysis and/or transplant rates in the dual-eligible and/or LIS patients above previous year's benchmark is 1 percent or more every two MYs, beginning for MY3.

KCP continues to request that CMS allow all ETC Participants to earn improvement scores to reach the top tier for scoring. While the HEI with a more reasonable percentage increase would help address the underlying concern, it remains important to recognize improvement for all ETC Participants. This approach would also align the program with other value-based models and truly incentivize home dialysis and transplant options.

VI. KCP supports CMMI's proposals establishing a process for sharing beneficiary-identifiable and aggregate data with ETC participants related to their performance in the ETC Model.

It is essential for ETC participants to have access the data elements outlined in the Proposed Rule to allow for them to make informed decisions and practice pattern changes that permit improvement over time. A web-based platform that allows for easy retrieval before the start of the PPA period is essential. While CMS proposes that the data will be available no later than one month before the start of that period, we encourage CMS to provide as much time as possible. It would be helpful to participants to have the information in advance before the MY.

In addition, we ask that CMS also provide participants with the LIS patients prospectively to participants. Otherwise, these data are not available, yet they are critical to managing the patients in the Model.

We also agree that the data shared should be protected by existing federal privacy and confidentiality laws. While we do not oppose a separate data sharing agreement in principle, it is not clear from the level of detail in the Proposed Rule how it would differ

from the existing HIPAA requirements. CMMI should clearly spell out those differences in rulemaking or indicate that the current HIPAA regulations are sufficient alone. Similarly, we do not believe that there should be additional restrictions on the data being shared other than those already required by HIPAA. ETC participants should be able to use these data for the same treatment and health care operations functionals permitted under HIPAA.

KCP similarly supports the proposals to provide aggregated data to ETC participants.

VII. KCP supports the extension of the telehealth waivers and the expansion of the Kidney Disease Education (KDE) benefit waivers (including the waiver of coinsurance amounts), but requests that the KDE benefit be expanded to include dialysis facilities.

KCP supports the proposal to extend the PHE Medicare telehealth payment requirement waivers for the ETC model. Telehealth has proven to be beneficial to home dialysis and candidates for organ transplant during the pandemic. Retaining the telehealth flexibilities provides additional options for reducing barriers some patients face when considering home dialysis or accessing a transplant.

KCP also supports allowing KDE services to be furnished via telehealth with more flexibility. We strong support allowing providers to reduce or waive patient coinsurance obligations to remove financial barriers to accessing these important services. We also support Medicare reimbursing providers for 100 percent of the rate when a beneficiary does not have secondary insurance to cover the 20 percent copayment amount. CMS should clarify that the existing CMS-sponsored safe harbor will protect providers from being penalized or subject to criminal sanctions for reducing or waiving the coinsurance amounts.

KCP reiterates our recommendation that CMS extend the KDE benefit not only to allow dialysis facilities to provide qualified staff or ETC participants with financial support for supporting the KDE benefit, but also to allow facilities to provide and be reimbursed for the benefit. We respectfully disagree with the conclusion that it is unnecessary for ESRD facilities to bill for KDE services. Up to 50 percent of patients with kidney failure do not receive pre-ESRD services. Thus, allowing facilities who employ individuals permitted to provide KDE to be reimbursed for these educational services would extend the availability of such services to the very patients who require them most. In these situations, it would be more efficient and less burdensome to allow facilities to bill for the KDE services as well.

The concern that permitting dialysis facilities who are participating in the ETC Model to support and provide KDE services is misplaced. If the goal of the Model is to increase access to home dialysis and transplant options, it does not make sense to stop dialysis facilities from using a critically important tool – patient education. There is no

evidence that allowing facilities to support or provide KDE services will result in unlawful or abusive relationships. One of the advantages of the current waivers is that it allows Stage V patients to access these services. Many of those patients have already selected a dialysis facility and should be able to access the full scope of educational services, including the KDE, to help them select the modality that is best for them. Moreover, allowing facilities to provide the benefit in the ETC Model would test whether the concern is warranted or not.

We also support extending the scope of clinical and qualified staff to include licensed social workers and registered dieticians/nutrition professionals who furnish services under the direction of an incident to the Managing Clinicians who is an ETC participant.

While these waivers are important, they fall far short of allowing for the necessary care coordination envisioned by the Administration and that the ETC Model seeks to encourage. The current application of the Stark/anti-kickback law remains a substantial barrier to coordinating care. This law and its corresponding regulations prohibit physicians from referring patients for certain designated health services paid for by Medicare to any entity in which they have a "financial relationship." Yet, for nephrologists and facilities to work together to increase the number of patients who select home dialysis and the number of patients referred for transplant, such referrals from physicians to facilities participating in the ETC Model should be occurring. We understand that oversight agencies are hesitant to waive these restrictions that were originally enacted to prevent fraud and abuse and protect the Medicare programs. However, many of these requirements were established decades ago in a more traditional fee-for-service environment and are not well suited for bundled payment systems or modern, coordinated care models. As such, waivers of Stark/anti-kickback laws are essential elements for any efforts to bring greater coordinated care to Medicare. KCP and our members reiterates our commitment to work closely with the Department to help ensure that such waivers would be as narrow as possible to effectuate the goals of the model.

VIII. Response to Questions about PD catheters, patient experience measures, and publishing quality outcomes.

PD Catheters. KCP supports CMMI using its authority to test alternative payment structures to address barriers to PD catheter access as part of the ETC Model. Specifically, we recommend that CMMI test a bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for PD catheter placement in line with AV Fistula reimbursement. Current reimbursement rates provide little incentive for surgeons to place a PD catheter. Even when a surgeon is willing to place it, he/she may have difficulty obtaining a place at a hospital to perform the surgery. We believe that creating a bonus for physicians that is not budget neutral to the ESRD PPS or the Monthly Capitated Payment (MCP) will help create an effective incentive to expand access to the procedure.

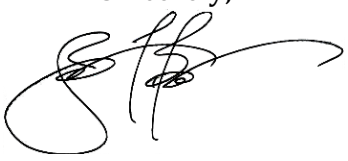
Home Dialysis Patient Satisfaction/Experience Measure. KCP continues to support patient satisfaction measures. We have asked CMS to encourage AHRQ expand the current In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS). While that measure has not yet been modified, a small group at the University of Washington (UW) has developed and initially tested a measure specific for home dialysis patients.[10] KCP is working with the UW team to identify ways to conduct a more complete testing so it could be submitted to the National Quality Forum (NQF) for approval and use in CMS ESRD quality program. We encourage CMMI to support this effort.

Reporting Quality Outcomes. KCP strongly supports transparency for individuals enrolled in the ETC Model and their care partners. To minimize confusion, we suggest that the reporting occur annually, consistent with the ESRD Quality Incentive Program (QIP) timeline. We recommend that the quality outcomes be available via a website, as well as posted at each facility aggregated in the HRR. Because the program is focused on aggregation at the HRR level, the data should be at that aggregated level rather than at the individual facility level.

V. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. We appreciate the RFI and efforts to address many outstanding concerns KCP has raised about the ETC Model. Kathy Lester will be reaching out to schedule a meeting, but please do not hesitate to reach out to her if you have any questions in the meantime. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

[10]Matthew B. Rivara, Todd Edwards, Donald Patrick, *et al.* "Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis." 16 CJASN 588-98 (2021).

Appendix: 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 Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma