



September 15, 2019

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-5527-P: Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures

Dear Secretary Azar and Administrator Verma:

Kidney Care Partners (KCP) would like to reiterate our support and appreciation of the Administration's focus on patients living with chronic kidney disease (CKD) and kidney failure. As we have discussed with the Secretary, KCP and our members continue to seek ways to work with federal and state policy-makers to increase awareness and understanding about the critical role that their policies play in the lives of patients with kidney disease. The Medicare program, itself, has a unique role. Because the Congress extended Medicare coverage for all Americans living with kidney failure, known as End-Stage Renal Disease (ESRD), by granting them eligibility to enroll in Medicare based on their disease status and not their age, Medicare policy essentially drives the care and treatment options available for these patients.

As the Administration recognizes in the Department of Health and Human Services (HHS) "Advancing American Kidney Health," to effectively treat kidney failure, policies need to reach patients before their kidneys fail. In addition, Medicare policies need to promote patient choice and innovation. Thus, KCP strongly supports the three primary objectives of the initiative: (1) increasing efforts to prevent, detect, and slow the progression of kidney disease; (2) providing patients who have kidney disease with more options for treatment; and (3) increasing the availability of organs for transplant.¹

We wish to reiterate our commitment to work with the Administration to help achieve these objectives. KCP is uniquely situated to assist, because our members cover all aspects of the kidney care community – patients and patient advocates; physicians, nurses, and other health care professionals; dialysis facilities of all types and sizes providing services across the United States; and manufacturers seeking to develop and support innovative treatment options for patients.

¹HHS, "Advancing American Kidney Health" (July 2019).

As our July public statement indicated, KCP is excited to support the Administration in its efforts to redesign the Medicare benefit for patients with kidney failure to achieve these goals. Unfortunately, as we have reviewed the detailed proposals outlined in the proposed rule entitled, “Specialty Care Models To Improve Quality of Care and Reduce Expenditures,”² we are concerned that the ESRD Treatment Choices (ETC) model will not achieve the desired outcomes for patients, providers, or the Administration. In fact, our members are deeply concerned that unless the overarching framework and details of the model are revised, it will have the unintended, opposite effect. MedPAC has also highlighted “significant methodological concerns such that [the Commission] believe[s] CMS should not implement the proposed ETC Model.”³

Therefore, we ask that the Department and CMS address the core concerns outlined in this letter before implementing the ETC model. Without such modifications, we are deeply concerned that those patients, nephrologists, and facilities forced into the mandatory model will experience unintended consequences that will lead to issues with access to care and lower quality of care. These core concerns are related to five policies that we ask that CMS revise.

The core concerns are:

- The need for the ETC model to truly empower patients and provide them with the autonomy to make their own treatment choices without having them feel forced into a particular treatment modality.
- The need for waivers to the Stark and anti-kickback laws to allow for coordination among facilities and nephrologists.
- The need to eliminate the forced penalty, for which there seems to be no specific rationale for its size, along with a scoring methodology that results in facilities and nephrologists being cut year over year, even if their performance improves, given the existing shortage of nephrologists and chronic underfunding of the ESRD Medicare benefit as recognized by MedPAC.
- The need to reduce the scope of the program, which is proposed to encompass 50 percent of the United States using the Hospital Referral Regions (HRRs).
- The need to adjust the proposal to use organ transplant rates (rather than referral and/or waitlist measures) over which facilities and nephrologists have limited control, as well as holding these providers accountable for such outcomes when the

²84 *Fed. Reg.* 34478 (July 18, 2019).

³MedPAC, Letter to CMS Administrator Seema Verma (September 3, 2019).

Administration has not adequately addressed the shortage of organs through reforms to the Organ Procurement Organization rules and has not required transplant centers to standardize their waitlist protocols or address their organ discard rates, both of which are the central drivers of transplantation.

- The need to change the proposed policies to use comparative geographic areas to determine benchmarks and improvement goals, along with the unknown attainment benchmarks that appear to be based on an overly aspirational goal of 80 percent of patients selecting home dialysis or receiving a transplant.

KCP proposes in this letter solutions to each of these core concerns. We believe that the Administration should adopt the recommendations outlined in this letter to revise the ETC Model before implementing it. We cannot support implementing the ETC Model without these changes. Given the importance of this model and the urgent need to transform the approach to kidney diseases and kidney failure, as well as the potential unintended negative impact on beneficiaries, we ask that CMS engage in an iterative process with KCP and others in the kidney care community to revise the framework of the model and address other technical issues (such as those outlined in Section II and others that will arise as the framework is modified). Once that has occurred, we ask that CMS issue another rule that includes these modifications and provides the kidney care community with an opportunity to review the revised model one more time and make suggested tweaks before it is implemented.

Section I of this letter provides the detailed concerns around the core concerns and offers recommendations as to how CMS could begin to address these concerns and revise the framework of the ETC Model. Section II provides additional recommendations about a set of critical technical issues and supports the KCP's overarching framework recommendations.

In sum, if CMS were to adopt these recommendations, the framework would be as follows:

- The revised model would test a home dialysis track and transplant track in a separate, but parallel, set of demonstrations for three years with the option for extending the model for an additional one or two years.
- The revised model would honor patients' autonomy to select the modality best suited for them by revising the metrics used to evaluate provider performance under the model:
 - For home dialysis, the measure would still evaluate the home dialysis rate, but incorporate exclusions for patients for whom home dialysis is not clinically appropriate, as determined by their clinician, and patients, who after

documented education and with appropriate oversight, exercise their legitimate choices not to select home dialysis.

- For transplants, the measure should be a referral measure (such as the one under-development by CMS and consistent with the recommendations KCP has made for CMS to develop a measure that would relate to patient education, referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process (with which a facility can often provide assistance)). This measure should include an exclusion for patients for whom transplant is not clinically appropriate, as determined by their clinicians.
- Measures used in the revised ETC Model should be endorsed by NQF.
- The revised model would provide tools for coordinating care by providing Stark Law/anti-kickback waivers to allow facility health care professionals (such as dietitians 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.
- The revised model would incentivize transformation through a bonus system that would provide participating clinicians and nephrologists with a bonus of 3 percent each year if they met attainment benchmarks and/or showed significant improvement.
- The revised model would reduce the sample size and ensure a representative sample of clinicians and facilities by basing the sample on the percentage of Medicare ESRD facilities and using a constrained covariate randomization selection that provides an appropriate representative sampling of all types, sizes, and geographic distribution; KCP suggests the sample should be no more than 25 percent of Medicare ESRD facilities in a mandatory model.
- The revised model would rely upon a methodology that rewards attainment and improvement similar to the methodology created by the Congress in statute for the QIP rather than forced penalties; attainment and improvement would be determined using a method similar to the QIP rather than comparative geographic areas and attainment benchmarks based on other countries.
- The revised model would use mortality and hospitalization as monitoring measures, but instead of using standardize ratios, the measures would be standardized risk-adjusted rate measures with appropriate socio-demographic factors and endorsed by NQF.

I. Section I: KCP recommends revising the framework of the ETC Model in six core ways before implementing the program.

As we have discussed, KCP and its members continue to support efforts to redesign the Medicare ESRD benefit. We support the goal of promoting “patient choice regarding home dialysis and kidney transplantation” and “test[ing] the effectiveness of outcomes-based payment adjustments to health care providers to increase utilization of home dialysis and kidney/kidney-pancreas transplants.”⁴ As outlined in the following section, we believe that to be effective and truly support innovation and patient-centered care, CMS needs to change the ETC model framework before it is implemented to address the six major concerns below. Without these changes, the model is not appropriate. We understand that CMS prefers the mandatory model. However, even as supporters of mandatory models have indicated, “such programs must be designed carefully.”⁵ In that spirit, KCP urges CMS to adopt the following recommendations to address the concerns outlined below, as recommended, to reform that model as outlined in the introduction of this letter.

A. Concern: The ETC model should truly empower patients and provide them with the autonomy to make their own treatment choices without having them feel forced into a particular treatment modality.

Throughout the Department’s “Advancing American Kidney Health” report, the Administration consistently notes its commitment to “improving person-centered care.”⁶ The second objective of the initiative is to “[i]ntroduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life.”⁷ KCP has consistently supported efforts to improve patient education and shared decision-making opportunities as evidenced by our work to create the Kidney Disease Education (KDE) benefit and ongoing efforts to improve it. Thus, we agree with the Administration’s goal as described in the report:

“Looking forward, HHS will continue to strengthen patient voices in policy development, address the needs of vulnerable populations with portable dialysis technologies, and use payment incentives to support patients making choices about their kidney care modalities.”⁸

⁴HHS, *supra* note 1 at 15.

⁵S Levy, N Bagley, R Rajkumar, “Reform at Risk — Mandating Participation in Alternative Payment Plans” 378 *N Eng J Med* 1664-64 (May 2018).

⁶HHS *supra* note 1 at 14.

⁷*Id.* at 15.

⁸*Id.* at 14.

Protecting patients' autonomy to exercise their choice is critically important and foundational to all ethical health care. The Proposed Rule recognizes that there are many reasons patients may not select home dialysis. It states: "Whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference."⁹

The GAO also noted that selecting home dialysis is related to patient preferences. According to the GAO's report, patients often select home dialysis because it provides them with more flexibility than an in-center option allows; yet, "[o]n the other hand, successfully performing home dialysis requires patients to undergo training and assume other responsibilities that they would not otherwise have if they dialyzed in a facility."¹⁰ Additionally, some patients need a partner to help them dialyze at home, as well as the appropriate physical location and home resources (such as a grounded electrical outlet, special water systems and drains, etc).¹¹ Home dialysis may also be more difficult for patients who have physical limitations (such as poor vision or dexterity), as well as those with multiple comorbidities that a nephrologist may also need to manage in an in-center setting.¹² These are particularly true for home hemodialysis patients.

KCP, including the patient and patient advocacy members, is troubled by the absence of accounting for patient choice when it comes to selecting the best modality for their treatment of kidney failure. While KCP supports concepts like assignment for patient participation in innovative payment models, we have similarly supported policies that allow patients to exercise their choice when it comes to specific treatment choices. For example, KCP has historically supported immunization measures, but the measures always provide an exclusion that allow patients who wish to opt-out of such treatment to do so.

For example, not all patients are candidates for transplant. As one patient member of KCP has described, transplant center criteria heavily influence which patients receive transplants. Some centers in California, for example, refuse to consider patients who do not have a caregiver who can drive them to and from the transplant center for their follow-up visits. Consistent with our comments below, KCP believes CMS needs to do more to address such problems, but until that time, patients who may not qualify for transplant because of a clinical factor, such as infections or certain co-comorbid conditions, should not be included in the transplant measure. (Please note we provide specific recommendations on the clinical

⁹84 *Fed. Reg.* at 34536.

¹⁰GAO, "End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis," 7 (Nov. 2015).

¹¹NIDDK, "Home Hemodialysis" available at <https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/home-hemodialysis/Pages/home-hemodialysis.aspx#think> (last accessed July 18, 2016).

¹²*Supra*, note 10 at 8.

exclusions in Section II). Similarly, some patients are not candidates for home dialysis, based on their clinical condition.

We agree that education is a critical factor in determining whether a patient selects home dialysis or transplant, but it is not the only factor, as noted. Even though we understand that the ETC model cannot eliminate all of the barriers to patients selecting home dialysis, we are disappointed that the proposed model focuses only on education without proposing ways to address care partner support and assistance, socioeconomic factors, or other concerns that patients may have which stop them from selecting that treatment modality.

Because the model does not address these patient-driven concerns, we recommend that CMS revise the ETC model so that it will empower patients and promote shared decision-making by excluding from the home dialysis and transplant measures denominators patients for whom the modality is not clinically appropriate. For the home dialysis measures, we ask that CMS work with the community to develop a specific exclusion for patients who are exercising their informed, independent, affirmative choice not to receive home dialysis. These patients would remain in the model, but be excluded from the measures.

We believe that the Kidney Care Quality Alliance (KCQA) (which KCP launched in 2005 to create quality measures for value-based purchasing and other quality programs) could help CMS define the exclusions to ensure that the exclusions would be appropriately tailored to empower patients, but also protect against the potential for using the exclusions as an excuse for avoiding working with patients to help them solve resolvable barriers to home dialysis.

These measure exclusions would still allow CMS to test whether financial incentives would improve education about home dialysis at the nephrology and facility levels, while recognizing that other barriers may be driving some patients' decisions about which modality is best for them. In fact, the solution proposed by KCP would likely lead to a more accurate assessment of the question CMS is trying to test by eliminating the confounding variables that influence patient choice outside of provider education.

While KCP argues that the forced penalty should be eliminated, incorporating these exclusions are even more critical if CMS were not to adopt that recommendation. Excluding patients from the home dialysis and transplant measures would eliminate the substantial disincentive created by the forced penalties that would place the government in the position of telling nephrologists and facilities to have patients use modalities that are either clinically not appropriate for them to select or that are expressly against their will to use. The kidney care community witnessed a similar occurrence when CMS developed measures that penalized facilities if hemodialysis patients received a graft rather than a fistula access, in an effort to decrease the use of catheters. CMS policy encouraged surgical placement of fistula for all patients – even those who would have been better clinically suited for a graft. This problem

occurred when the maximum cut was only two percent. The maximum cuts proposed for the ETC Model are substantially greater.

While we appreciate and support the beneficiary protections CMS sets forth in the Proposed Rule, they are not sufficient to address this problem.

In addition, allowing for true patient choice would not undermine the goals of the model. We are not asking for a simple “check-the-box” form that allows participating providers to avoid working to increase the number of home dialysis patients or transplant recipients. The proposals regulating the model materials shared with beneficiaries and the right CMS would reserve to review such materials,¹³ provide counter-balances to address concerns that such an exclusion might allow for patients to be “talked out of” selecting home dialysis. CMS used a similar approach when it first implemented the Medicare+Choice (now the Medicare Advantage program) by implementing educational outreach requirements and reviewing these documents to make sure that patients had accurate information to make a decision. The audit and record retention policies¹⁴ and monitoring and compliance policies¹⁵ proposed for the ETC Model would serve a similar purpose as well.

B. Concern: The ETC Model should provide participants with the tools necessary to coordinate care and education, including waivers to the Stark and anti-kickback laws to allow for coordination among facilities and nephrologists.

Another core component of the ETC Model and the goal of patient-centered care is the objective to “improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure.”¹⁶ In “Advancing American Kidney Care,” HHS describes the ETC Model as a “payment model to encourage more coordinated care to delay kidney failure and ensure that people living with kidney failure have access to the best available care options.”¹⁷

KCP and its members, many of whom are participating in the ESCO model, strongly support care coordination efforts. We agree with MedPAC that this model “provide[s] a holistic approach to the care of beneficiaries with CKD, who often have multiple comorbidities in addition to kidney disease” and “hold[s] both dialysis facilities and managing clinicians jointly accountable for the outcomes...of beneficiaries with CKD, including rates of home dialysis and

¹³84 Fed. Reg. 34484.

¹⁴*Id.* at 34485.

¹⁵*Id.* at 34486.

¹⁶*Supra* note 1 at 4-5.

¹⁷*Id.* at 15.

transplantation.”¹⁸ MedPAC also recognizes the need to include transplant centers when transplantation is incorporated into such models as well.¹⁹

CMS recognizes that current laws create barriers to coordinate care and educational efforts for the ESRD populations. Expanding the KDE benefit is an important part of this program, but it should be extended even beyond what CMS has proposed. KCP supports the proposed waiver to the current restrictions in the KDE benefit that limit educational services to Stage 4 CKD patients and expands it to include beneficiaries with CKD Stage 5 and those in the first six months of receiving an ESRD diagnosis.²⁰ KCP also supports the waiver of the requirement that at least one of the KDE sessions be dedicated to management of comorbidities when the beneficiary receiving the educational services has CKD Stage 5 and is in the first six months of diagnosis,²¹ as well as the proposed flexibility as to when the outcomes assessment to measure beneficiary knowledge of CKD and its treatment is performed.²² While we also support the expansion of which professionals may perform the KDE services, we respectfully disagree with the conclusion that it is unnecessary for ESRD facilities to bill for KDE services. As noted in below, 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 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.

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. In the Proposed Rule, the Administration suggests that social workers and dieticians (for example) who work in facilities could assist nephrologists in the education envisioned by the ETC Model. However, under current law, such coordination may raise legal concerns.

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-

¹⁸ MedPAC, *supra* note 3.

¹⁹ *Id.*

²⁰ 84 *Fed. Reg.* at 34562.

²¹ *Id.*

²² *Id.* at 34563.

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. Given the enormity of the task at hand, KCP asks that the Secretary to coordinate the efforts of all parts of HHS, as well as other entities such as the Department of Justice, to ensure alignment around the goals of “Advancing American Kidney Care” and provide the necessary waivers to permit care coordination in the ETC Model without risk of civil and criminal sanctions. KCP and our members would welcome the opportunity 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.

C. Concern: The forced penalty (for which there seems to be no specific rationale for its size) along with the scoring methodology that results in facilities and nephrologists being cut year over year, even if their performance improves, will destabilize the already underfunded Medicare ESRD benefit.

KCP supports efforts to incentivize nephrologists and facilities to improve educational efforts and help patients who decide home dialysis and/or transplant are the best options for them. Our members have been consistently working to improve home dialysis selection through improved education, not only by urging passage of the KDE and trying to improve its use through legislative modifications, but also through the work of individual KCP members outside of the policy arena. MedPAC has recognized the impact of these efforts:

Between 2012 and 2017, beneficiaries’ use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 9.5 percent to 11.0 percent of dialysis beneficiaries. Since 2014, a shortage of dialysis solutions needed for the predominant home method, peritoneal dialysis, has slowed this modality’s growth.²³

However, KCP recognizes that more can and should be done. We support the ETC Model insofar as it would incentivize nephrologists and facilities through bonus payments when they demonstrate attainment of reasonable benchmark goals or significant improvement in the number of patients for whom they care who select home dialysis.

Similarly, KCP members have sought to address some of the barriers to transplant. We have encouraged CMS to develop a referral measure to hold facilities accountable for helping patients navigate the first steps of the transplant center criteria for getting on the waitlists. Specifically, KCP recommended as early as 2016 that CMS develop a measure that would relate to patient education, referral to a transplant center, initiation of the waitlist evaluation process,

²³MedPAC, *Report to the Congress*, “Chapter 6: Outpatient Dialysis Services: Assessing payment adequacy and updating payments,” 156 (March 2019).

or completion of the waitlist evaluation process (with which a facility can often provide assistance). We are, therefore, pleased that the Department has indicated in “Advancing American Kidney Care” that CMS is pursuing the development of such a measure.²⁴

We have also consistently urged CMS to work with the transplant community to develop standardized criteria for waitlisting patients with kidney failure and to limit behaviors that lead to cherry-picking patients for transplant. We are pleased that CMS recognizes these problems in the preamble, but are disappointed that the proposed modifications do not include these recommendations. With less than 20,000 organs available²⁵ and more than 100,000 patients on current waitlists,²⁶ nephrologists and facilities face substantial limits in what they can do to increase the number of kidney transplants. A more coordinated effort is needed that focuses on Organ Procurement Organizations, living donors, and transplant center criteria and policies.

KCP supports the ETC Model’s general approach for Years 1 through 3 that focus on a bonus-based incentive, although we recommend a fixed amount for all three years, based on attainment or improvement linked to historical performance (please see specific recommendations on benchmarking and scoring methodologies – including concerns about comparison geographic areas – in Section II).

We do not support the proposal that would penalize a pre-determined percentage of nephrologists and facilities as much as 11 or 13 percent, respectively. Given the already precarious economics of the Medicare ESRD program, as recognized consistently by MedPAC, such major cuts applied year over year to a specifically defined proportion of providers will undermine kidney care in the United States.

Figures 1 and 2 illustrate how these points are projected to affect payment over the duration of the ETC model:

Figure 1: Facility Performance Payment Adjustment

MPS	Performance Payment Adjustment Period				
	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
≤ 2	-4.0%	-4.5%	-5.0%	-6.0%	-6.5%
≤ .5	-8.0%	-9.0%	-10.0%	-12.0%	-13.0%

²⁴HHS, *supra* note 1 at 19.

²⁵Milliman, “2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion” (August 2017)

²⁶National Kidney Foundation, “organ Donation and Transplantation Statistics” *available at* <https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats>.

Figure 2: Clinician Performance Payment Adjustment

MPS	Performance Payment Adjustment Period				
	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
≤ 2	-3.0%	-3.5%	-4.0%	-4.5%	-5.5%
≤ .5	-6.0%	-7.0%	-8.0%	-9.0%	-11.0%

These penalties, coupled with the unknown, but seemingly impossible to meet benchmarks (please see concerns and recommendations outlined below in subsections D and E) in Years 4 through 6, turn the model into a simple payment cut. This contradicts MedPAC’s consistent annual recommendation to increase the ESRD PPS by the market basket amount. These payment adjustments are also inconsistent with the penalties Congress has imposed on providers when trying to incentivize certain behaviors. The maximum penalty under the ESRD QIP is two percent.²⁷ The maximum penalty under MIPS, a more comprehensive program covering multiple disciplines and focused on many more aspects of care is nine percent. The ETC Model penalties are substantially higher and unjustified. Severe penalties may drive behavior; they are likely to drive nephrologists and facilities out of the markets being tested and lead to closures, particularly in rural areas.

The Proposed Rule indicates that the goals of the ETC Model are to:

incentivize ESRD facilities and clinicians managing adult Medicare FFS beneficiaries with ESRD, referred to herein as Managing Clinicians, to work with their patients to achieve increased rates of home dialysis utilization and kidney and kidney-pancreas transplantation and, as a result, improve or maintain the quality of care and reduce Medicare expenditures.²⁸

Given the already precarious nature of the benefit, we fear that applying such substantial cuts will lead to the opposite effect and reduce the quality of care.

KCP members agree that Medicare expenditures for the total cost of care for beneficiaries with kidney disease can likely be reduced from current levels. Our members who have participated in the C-SNPs and ESCOs have demonstrated that coordinated care can work. However, Medicare should not be looking to find savings from the already underfunded ESRD PPS, if it seeks to, at a minimum, maintain current care levels and ideally improve them.

²⁷42 U.S.C. § 1395rr(h).

²⁸84 Fed. Reg. at 34535.

Medicare should instead focus on savings generated from improving quality and outcomes and reducing the need for other health care services that drive the total cost of care. The preamble to the Proposed Rule seems to recognize this fact and states:

Research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing incenter. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis.²⁹

A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis. Additionally, this review finds that beneficiaries who receive transplants experience a better quality of life than treatment with chronic dialysis.³⁰

CMS' goal should be to capture these savings rather than seek to impose a year-over-year cut on nephrologists and dialysis facilities. Restoring dollars to the underfunded Medicare ESRD program would allow nephrologists and facilities to improve care. Taking the dollars out as proposed would have the opposite effect of reducing the quality of care provided.

In addition, given that CMS is only testing one factor – patient education – among the many barriers to home dialysis and transplant, it is important that the incentives also be appropriately scaled. Because issues related to patient caregiver, socioeconomic status, OPO regulations, and transplant waitlist criteria are not being adequately addressed in the model, it is simply not appropriate to apply such large cuts.

Therefore, KCP strongly encourages CMS to eliminate all proposed penalties and focus on a reward-based system. (Please note the related recommendation to use a referral rather than a transplant rate measure that can measure nephrologist and facility performance). At the same time, CMS should track and report publicly on the savings achieved through reduced hospitalization, cardiovascular events, infection rates, increased transplantation, and other aspects of care that occur as a result of the ETC Model.

²⁹*Id.* at 34537 (citations omitted).

³⁰*Id.* at 34538 (citations omitted).

D. Concern: The sample size of the program encompassing 50 percent of the United States shifts the model from a demonstration to a policy change inappropriately.

KCP agrees the any model tested under the CMMI authority needs to be appropriately powered. However, we do not understand the approach set forth in the Proposed Rule. While the preamble seems to indicate in one place that CMS needs to include “approximately 50 percent of adult ESRD beneficiaries” to “improve the statistical power of the Model’s evaluation,”³¹ the analytics for determining the scope of the model indicate that CMS is selecting 50 percent of the Hospital Referral Region (HRR): “To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 153 HRRs in the intervention group, which represents 50 percent of the 306 HRRs in the US.”³²

Analytics performed by Discern on behalf of KCP support the policy that CMS confirmed the sample size calculation based on the HRRs specifically counting an HRR as “one,” as opposed to the hundreds or thousands of ESRD patients receiving services within the HRR.

KCP recommends that CMS take an alternative approach to using HRRs to conduct a sample size calculation. In accordance with our recommendation that allocation to the ETC intervention or comparison be done at the facility level, the corresponding sample size calculation would be revised.

As an illustration of this new sample size calculation, a two-sided comparison of two means was performed. This calculation of required sample size requires six parameters:

1. Power
2. Type I Error rate
3. Initial Group Mean
4. Post-intervention Group Mean
5. Standard Deviation
6. Sampling Ratio

The proposed rule and USRDS data provides five of the six needed numbers to make a sample size calculation:

³¹*Id.* at 34544.

³²*Id.*

Parameter	#
Power	0.80
Type I Error rate	0.05
Initial Group Mean	3.8558%
Post-intervention Group Mean	4.3071%
Standard Deviation	
Sampling Ratio	1

Even though the standard deviation of the organ transplant rates is not known at the facility level, state-level transplant rate data from USRDS provide an order-of-magnitude approximation of the relevant standard deviation. This standard deviation (1.21 percent) infers a needed intervention sample size of 114 facilities. Given their smaller size, we would expect a larger standard deviation at the facility level.

The table below provides a sensitivity analysis relative to the standard deviation. Even a facility-level standard deviation of 4.9 percent, more than four times the standard deviation at the state level, would only necessitate assignment of 25 percent of facilities to intervention

	Estimated Standard Deviation	Needed Intervention facilities
Standard deviation of Transplant rate per 100 dialysis patient years by state (USRDS)	1.21%	114
Standard deviation to require 25% assignment	4.9%	1,878
Standard deviation to require 50% assignment	7%	3,756

Therefore, KCP is recommending selection of no more than 25 percent of dialysis facilities nationwide for the intervention group, with stratification to ensure that all types, sizes, and locations of facilities are included.

Focusing on the ESRD facilities is preferable to the number of geographic designated areas for several reasons. First, a mandatory model with 50 percent of the HRRs included would eliminate the ability for CMS to use comparison groups. The consolidated nature of the ESRD industry means that dialysis organizations operate on a regional or national level. If roughly 50 percent of the facilities are included in the model, there would be no comparison group because the changes made to implement the model would be distributed to all facilities in an organization to make it operationally possible to capture the 50 percent in the model. Thus, there would be no way to establish a comparison group, as CMS envisions.

Second, the ETC Model is just that – a model that needs to be tested. Including 100 percent percent of the country based on HRR – with 50 percent being the intervention group

and 50 percent being the control group – constitutes a permanent policy change – and in this case one that imposes a massive payment rate cut. A better approach would be to use a smaller percentage – specifically, no more than 25 percent – to allow CMS to appropriately power the evaluation, while still having it be a test of innovation. The problem is intensified by mandating that Maryland be included automatically in the interventional group.

MedPAC also voices concern “that random assignment of HRRs would not generate equal distribution of home dialysis rates among participants in each group.” The Commission also expresses concern that using an HRR control group “would potentially put [mid-size and large dialysis organizations] in the awkward position of maintaining a status quo level of effort in control under HRRs while exerting additional effort to increase home dialysis rates in treatment HRRs.”³³

KCP also recommends addressing this issue by separating the home dialysis and transplant components of the ETC Model into different tracks. They could run parallel, but allow for a more focused test of developing and implementing best practices for each of these goals.

It is also important that CMS take into consideration the practice of having home-only facilities. CMS should allow for the aggregation of home-only facilities with in-center facilities when they are under common ownership. In addition, CMS should take into consider how to address facilities that do not offer the full set of modalities. For example, facilities that that are home-only (and do not have in-center options available) could create substantial problems for the model by cherry-picking patients who prefer home dialysis and leaving those for whom home dialysis is a not a clinical option to facilities that provide all modality choices.

In sum, KCP recommends that CMS reduce the sample size to no more than 25 percent and base it on the number of ESRD facilities attributed to the model rather than on the number of HRRs (or similar geographic designation). CMS should ensure that all types, sizes, locations of nephrologists and facilities are included in the sample using a covariant-based constrained randomization. In addition, KCP recommends randomizing clinicians at the group/TIN level as well. (Please note recommendations to use a referral rather than a transplant rate measure, especially in light of the mandatory nature and scope of the model).

³³MedPAC, *supra*, note 3.

E. Concern: The proposal to use organ transplant rates (rather than referral and waitlist measures) when the Administration has not adequately addressed the shortage of organs through reforms to the Organ Procurement Organization rules and has not required transplant centers to standardize their waitlist protocols, both of which are the substantial drivers of transplantation, is of great concern.

KCP agrees that the best option for many patients living with kidney failure is a kidney transplant. KCP members have asked CMS to design a measure that would accurately record facility-level performance on helping dialysis patients be referred for transplant and be able to get to their first appointment (KCP letter on the ESRD QIP Proposed Rule August 2016). We have also continued to urge CMS to work with the transplant community to develop a standardized set of waitlist criteria that would be applied evenly and consistently among all transplant facilities (KCP letter on the ESRD QIP Proposed Rule August 11, 2017).

Thus, we are pleased that in “Advancing American Kidney Health” the Department has identified increasing access to kidney transplant as one of its major goals.³⁴ We also agree with the objectives to: (1) “[i]ncrease the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate”³⁵; and (2) “[i]ncrease the number of living donors by removing disincentives to donation and ensuring appropriate financial support.”³⁶ We are also encouraged by the steps HHS plans to take to achieve these objectives and that it has outlined in that document:

- “HHS is updating the PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. The goal of the existing 2013 Guideline was to reduce risk of unintended HIV, HBV, and HCV transmission, while preserving availability of high quality organs.”
- “HRSA has funded the OPTN to expand the COIIN pilot project in 2020, allowing more kidney transplant programs to participate in this OPTN quality improvement activity focused on changing program waitlist management and organ acceptance practices.”
- “The Innovation Center’s ETC Model includes a learning collaborative operated by the Center for Clinical Standards and Quality (CCSQ), designed in collaboration with HRSA and informed by the HRSA OPTN COIIN, to reduce the disparity in performance among Organ Procurement Organizations (OPOs) and transplant centers with the

³⁴HHS, *supra* note 1 at 17.

³⁵*Id.*

³⁶*Id.* at 19.

goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers.”

- “HRSA, through the OPTN, is developing a new model to test accelerated placement of certain kidneys that are at high risk for discard.”
- “Per the 2019 OMB regulatory agenda, CMS is reviewing the OPO conditions for coverage and will be proposing changes to the standards used to evaluate OPOs to ensure proper data collection on the availability of transplantable organs and transplants.”³⁷

We support these steps and believe they are critical to achieving the Department’s overall objective.

However, the Administration has not yet implemented these policies, other than to propose a few changes around the edges in the Hospital Outpatient Proposed Payment System (HOPPS) proposed rule that is currently open for public comment and to propose the Learning Collaborative³⁸ in the ETC Model proposed rule. We appreciate that the Office of Management and Budget is reviewing a rule to assist with living donor compensation issues, but the actual contents remain unknown at this time. While positive steps, these are simply not enough to bring about the changes needed to support the proposed goal of holding nephrologists and facilities accountable for increasing the number of kidney transplants by more than 2,000 each year for the ETC Model.

OACT [Office of the Actuary at CMS] did not assume any change in its main projections but estimated that an additional 2,360 transplants would occur over the course of the proposed Model due to a lower discard rate for deceased donor organs. With 20,161 transplants currently conducted on an annual basis, this represents an 11.7 percent increase over 5 years.³⁹

Unfortunately, the ETC Model provides no changes for other relevant transplant organizations that suggests achieving this type of an increase is actually possible. There are several barriers that make these projects unrealistic at this time. First, the Department notes for example that the discard rate of kidneys procured is substantial.

From 2007 through 2017, the annual rate of kidneys procured but not transplanted has ranged between 18-20 percent. In 2017, the discard rate of 18.9 percent reflected 3,534 kidneys that were procured but not transplanted

³⁷*Id.* at 18-19.

³⁸84 *Fed. Reg.* at 34542.

³⁹*Id.* at 34544 (citations omitted).

into waiting patients. Some donor kidneys are not transplanted due to medically justifiable reasons; however, it is estimated that thousands of discarded kidneys could provide benefit to people on dialysis. Education about the appropriate clinical use of kidneys would help maximize the limited supply of donated organs used. Addressing the availability and utilization of kidneys is one of the ways HHS can help people living with ESRD through transplantation.⁴⁰

Second, the Department similarly recognizes that organ allocation and transplant center criteria are at the center of determining the number of transplants.

However, depending on the organ, some factors become more important, so there is a different policy for each organ. For example, some organs can survive outside the body longer than others, so the distance between the donor's hospital and the potential recipient's hospital may be given greater weight than other factors in certain situations.

After the OPO enters information about a deceased donor into the database, the computer system generates a list of patients who match the donor, by organ. Each available organ is then offered to the best-matched patient for evaluation by the patient's transplant team.

After a match is identified, the transplant team determines whether the available organ is medically suitable for the matched patient. Even if an organ is suitable, the transplant team may decline the organ offer, for example, if the patient is too sick to undergo a transplant, has an untreated infection, or is unavailable for transplant. In these situations, the organ is then offered to the next patient on the waiting list. During the organ matching process, organs are maintained on artificial support, and the hospital medical staff and the OPO procurement coordinator closely monitor the condition of the donated organs. After removal from the donor, organs remain viable for transplantation for only a limited period of time, which varies by organ type, so the OPO must arrange timely transportation of the organs to the hospitals of the intended recipients.⁴¹

Third, Figure 12 in the Department's report provides a list of the reasons recovered kidneys are not used.

⁴⁰HHS, *supra* note 1 at 17 (citations omitted).

⁴¹*Id.* at 28.

FIGURE 12

Reported reasons why recovered kidneys are not used for transplantation:

- infection
- organ trauma
- too old on pump
- too old on ice
- ureteral damage
- deceased organ
- vascular damage
- biopsy findings
- positive hepatitis
- donor social history
- poor organ function
- donor medical history
- organ not as described
- anatomical abnormalities
- warm ischemic time too long
- no recipient located – list exhausted
- recipient determined to be unsuitable for transplant in the operating room

SOURCE: OPTN/SRTR 2016 Annual Data Report: Deceased Organ Donation

In addition to these concerns, each transplant center has its own waitlist criteria that patients must navigate in order to get on the waitlist. It is the transplant center that ultimately determines which patients are accepted to be waitlisted. A good example of this problem has been summarized by IPRO, the ESRD Network for the South Atlantic. In a document prepared to help patients navigate the transplant process, it provides the following advice.

A kidney transplant is a possible treatment option for people on dialysis. However, not everyone who wants a transplant can be considered eligible to receive one. Only transplant center professionals can determine if a patient is a good candidate for a transplant.

Each transplant center uses its own set of standards for deciding if a patient is a good candidate for a kidney transplant. In some cases, a patient can be turned down by one transplant center, but found to be eligible at another transplant center.

The table on the following pages is a tool to help guide dialysis patients, their family members and care partners to the transplant centers that could most likely meet their needs.⁴²

Moreover, of the nine transplant centers in Georgia, South Carolina, and North Carolina, none has the same “absolute transplantation criteria.” Standardized transplant center waitlist criteria are necessary to level the playing field for patients, nephrologists, and facilities and to

⁴²IPRO, “South Atlantic Area Kidney Transplant Center Referral Guide” (on file with author; available upon request).

prevent cherry picking by transplant centers. To see the differences among transplant center criteria in just one area of the country, please review Appendix A.

Given the overwhelming control that OPOs and transplant centers have over the number of organs available, which patients are placed on a waitlist, and which patients actually receive a transplant, KCP asks that CMS implement the necessary changes in OPO and transplant center policies and accountability, including standardizing waitlist criteria, before holding nephrologists and facilities accountable for the number of kidney or kidney-pancreas transplants that occur.

In the meantime for the purposes of a revised model, CMS should expedite its work on the referral measure mentioned in the “Advancing American Kidney Care”⁴³ and obtain NQF endorsement for it. The measure should be more than a “check-the-box” metric. KCP has recommended one way such a measure could hold facilities more accountable. Specifically, CMS could develop a measure that would relate to patient education, referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process (with which a facility can often provide assistance). That measure could then be applied at the beginning of the ETC model. CMS should also work with transplant centers and other stakeholders in the kidney care community to develop standardized waitlist criteria. Once such standardized criteria are in place, CMS could develop a valid waitlist measure that would receive NQF endorsement. NQF has rejected the current waitlist measures so they should not be used in the ETC Model.

This approach would be preferred, until as MedPAC recommends, a more comprehensive model that incorporated transplant centers (and potentially OPOs) is developed.

F. Concern: The proposed policies determine benchmarks and improvement goals using comparison geographic areas, along with the unknown attainment benchmarks that seem to be unrealistic goals based on inappropriate comparisons to Hong Kong and other nations with substantially different public policies.

KCP has consistently supported efforts to incentivize improvements in the quality of care provided and being responsible for patient outcomes. At the suggestion of and with the full support of KCP, the Medicare ESRD program became the first Medicare program to incorporate value-based purchasing. Even during the first years of the QIP, the majority of the

⁴³HHS, *supra* note 1 at 19. “CMS has begun to develop and test new dialysis facility transplant referral measures, which, if approved, could be added to Quality Incentive Program (QIP) through rulemaking in the future and then via the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system and ultimately, Dialysis Facility Compare.”

measures to which facilities were held accountable were outcomes/clinical measures rather than process measures. Thus, our concerns about the proposals related to the determination of benchmarks and improvement goals should be viewed as an effort to help CMS establish goals that move the community toward more home dialysis and transplant in a manner that is achievable. It is not, as critics might suggest, an effort to reduce responsibility or accountability.

KCP supports the Department's general statements that:

1. We need to provide patients who have kidney failure with more options for treatment, from both today's technologies and future technologies such as artificial kidneys, and make it easier for patients to receive care at home or in other flexible ways...
2. We need to deliver more organs for transplants, so we can help more Americans escape the burdens of dialysis altogether...⁴⁴

Unfortunately, the proposal to use comparison geographic areas and attainment benchmarks with the aim of "hav[ing] 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant" will not allow CMS to drive improvement or accurately measure improvement and attainment toward the basic goals.

As noted above, using the comparison geographic areas to set the benchmarks for an achievement score as proposed does not account for the practical reality that large and medium dialysis organizations, especially if the interventional group comprises 50 percent of the HRRs as opposed to facilities, will apply a single policy nationwide. MedPAC has recognized this concern as well and the potential negative impact having control groups could have on the patients access to home dialysis in those areas outside of the ETC Model.⁴⁵ The comparison geographic areas' outcomes related to home dialysis will shift just as the model participants are demonstrating improvement. Simply put, these comparison geographic areas are not appropriate assuming best practices are applied nationwide.

In addition, KCP is deeply concerned that the attainment benchmarks proposed seems likely to be based on an overarching goal of having 80 percent of beneficiaries (which appear to be the prevalent patients, rather than incident patients) with kidney failure either being on home dialysis or having received a transplant. The basis for this goal appears to be other countries, specifically Hong Kong, where a PD First policy is mandatory, with patients unable to choose their kidney replacement therapy modality, and Scandinavian countries, where there

⁴⁴*Id.* ii.

⁴⁵MedPAC, *supra* 3.

are fewer than 20,000 patients with ESRD in total. These nations have very different population characteristics and health care systems, making direct comparisons challenging.

The United States has been at the forefront of providing dialysis to its residents following the commitment by the Congress in the 1970s to ensure that any American, regardless of age, race/ethnicity, other health care conditions/comorbidities, or ability to pay could receive treatment for kidney failure under the Medicare program. This means that the vast majority of the 764,341 patients with ESRD (as of the 3rd quarter of 2018 per the USRDS) depend upon Medicare for their life-sustaining treatments. Applying MedPAC's data that show 11 percent of US dialysis patients receive home dialysis, there are approximately 84,000 patients on home dialysis.⁴⁶ Thus, while Hong Kong may boast that 80 percent of its dialysis patients receive home dialysis, there are only about 4,000 patients actually receiving home dialysis.⁴⁷ These differences matter and impact the overall percentage of patients receiving home dialysis.

In addition to the determination of the benchmark for attainment, the methodology proposed is also deeply troubling because it would penalize nephrologists and facilities even if they show improvement over the previous year. KCP continues to believe that programs that "pay for performance" should be transparent and reflect the actual quality of the services provided. Forcing a pre-determined percentage of nephrologists or facilities into substantial payment cuts each year does not reflect the quality of care being provided, but rather functions as a way to cut dollars from the Medicare program in a way that is less than transparent.

Based on current clinical literature and the experience of clinicians who care for patients with kidney disease and kidney failure on a daily basis, it is simply not clear how any provider in the Medicare ESRD program with the rules governing organ transplant as they are today along with the need to honor patient choice could achieve an 80 percent goal of patients being on home dialysis and/or transplanted. The one study evaluating this question and cited in the ETC proposed rule evaluated 1303 patients seen in 7 nephrology clinics in the US and Canada with CKD stages 3-5 for reasons for ineligibility for hemodialysis, peritoneal dialysis and transplant, noting that, among these patients with nephrology care prior to kidney failure, approximately 80 percent were medically eligible for PD.⁴⁸ This study overestimates PD eligibility at the time that dialysis would be needed given: (1) limited data on social factors, (2) selection bias as evidenced by the extensive non-dialysis CKD care⁴⁹, and (3) an inability to account for significant

⁴⁶USRDS, 2018 ADR Reference Tables (citing 2016 data).

⁴⁷Leung, CB, *et al*, "Renal Registry in Hong Kong," *Kidney Int Suppl* 33-38 (2015).

⁴⁸84 *Fed. Reg.* at 34537 (citing Mendelssohn DC, Mujais SK, Soroka, SD, *et al.*, "A prospective evaluation of renal replacement therapy modality eligibility. 24 *Nephrology Dialysis Transplantation*, 555-561 (2009) (available at doi: <https://doi.org/10.1093/ndt/gfn484>).

⁴⁹Baer, *et al.* "Late referral of patients with end-stage renal disease: an in-depth review and suggestions for further actions," 3 *NDT Plus* 17-27 (2010).

illness and comorbidity more proximate to the need to initiate dialysis that would reduce PD eligibility. Critically, there was no account of patient choice.

In addition, CMS also notes that another study reported that only 42 percent of patients preferred PD when the option was presented to them.⁵⁰ This latter study supporting the 42 percent is somewhat higher than, but seems more aligned with, the experts in the U.S. kidney care community have suggested is possible. It is also important to recognize that the literature demonstrates that only about 50 percent of patients that chose a home therapy actually end up on this modality.⁵¹

We recognize that the 80 percent goal includes transplants as well. But, as noted already, without drastic changes to the organ procurement and use policies, as well as the standardization of transplant center waitlist criteria, there is very little nephrologists or facilities can do to increase the number of organs available for transplant or the number of patients on a waitlist. Thus, with the current percentage of transplants, which CMS states is close to 30 percent based on 2018 USRDS data, at a national level and not a provider level, it is difficult to see how that rate could be substantially increased.

This is not to say that KCP believes the status quo should prevail, but benchmarks that seek to incentivize care should be grounded in the practical aspects of how they can or cannot be achieved. The danger of using international comparisons out of context or small studies without the context of the broader literature to set attainment benchmarks is that the goals are so disconnected from the realities of providing care that nephrologists and facilities simply cannot achieve them. Similarly, a methodology that always results in a portion of providers being heavily penalized regardless of performance undermines the incentives CMS is trying to create. Under the ETC Model, provider reimbursement is then cut by \$30 million per year on average reducing the funds available to care for patients with kidney failure. The field of nephrology is already experiencing a shortage of physicians; the ETC Model with unattainable benchmarks and substantial cuts is likely only to make this problem worse. Facilities that are already operating at a deficit under Medicare will not be able to sustain such cuts either and will likely close. Given that the methodology always results in a predefined percentage of nephrologists and patients being heavily penalized, the ETC Model creates a downward spiral that could unintentionally create severe quality of care and access to dialysis treatments problems.

⁵⁰*Id.* (citing Maaroufi A, Fafin C, Mougél S, Favre G, Seitz-Polski P, Jeribi A, Vido S, Dewismi C, Albano L, Esnault V, Moranne O., "Patient preferences regarding choice of end-stage renal disease treatment options," 37 *American Journal of Nephrology*, 359–369 (2013).

⁵¹Scott E. Liebman, David A. Bushinsky, James G. Dolan, and Peter Veazie, "Differences between Dialysis Modality Selection and Initiation" 59 *Am J Kidney Dis.* 550–557 (2012).

KCP wants a model that incentivizes home dialysis and transplant modalities to succeed. A better approach would be to base the methodology on that the Congress established in the ESRD QIP. In that program, CMS assigns a total performance score (TPS) to facilities based on their performance on a set of clinical and reporting measures. It sets the benchmarks for these measures using a comparison period (often a full year) during which data is gathered on all dialysis facilities for that measure. Data collected during the comparison period is used to create performance standards. CMS describes this methodology as applied for Payment Year 2019 as follows:

Facility performance will be evaluated against each measure; a facility receives a score based on the higher of its achievement or improvement on a measure. The comparison period for the PY 2019 clinical measures was CY 2015 for achievement and CY 2016 for improvement.

Facilities receive achievement points on a measure based on where they fall on the achievement range. The achievement range begins at the achievement threshold, which is defined as the 15th percentile of facilities during the comparison period. It ends at the benchmark, which is defined as the 90th percentile of facilities during the comparison period. A facility will receive an achievement score of 0 if its performance on that measure falls below the achievement threshold, 1 – 9 if its performance falls within this range, and 10 points if it is at or above the benchmark.

Facilities may receive improvement points on a measure based on where they fall on the improvement range. The improvement range begins at the facility's prior performance rate on the measure during the improvement period (facility comparison rate) and ends at the benchmark. A facility will receive an improvement score of 0 if its performance falls below the facility's comparison rate, 0 – 9 if its performance falls within this range, and 10 if it is at or above the benchmark.⁵²

While the methodology would need to be adjusted slightly to address the small set of measures and the goals of the ETC Model, adoption of this methodology has several advantages. First, it is proven; while CMS has used this methodology for nearly a decade, the performance of dialysis facilities across the nation has improved. Second, it is well known to the kidney care community, including patients and their advocates, so would provide a level of transparency which is lacking in the ETC Model's methodology. Third, using it would create consistency among programs, particularly important given that the QIP will still apply to facilities and that some of the measures in the ETC and QIP overlap with one another. KCP

⁵²CMS, "ESRD QIP Payment Year 2019 Program Details" (available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2019-Program-Details-v1_0.pdf)

would welcome the chance to talk through any questions CMS might have about how applying this methodology to the ETC Model could work and is committed to finding a way to address the problems created by the benchmark and scoring methodology outlined in the Proposed Rule. (Please note recommendations to use a referral rather than a transplant rate measure to ensure that the measures are actionable by model participants).

G. Section I Conclusion

In sum, KCP reiterates our initial comments made at the announcement of the “Advancing American Kidney Health” Initiative that we share the goal of the Administration to improve the quality of life of all patients living with kidney failure. We want to partner with the Administration to achieve this goal as effectively, safely, and efficiently as possible. We agree that increasing the number of patients on home dialysis and assisting patients with securing a transplant are critical components of achieving this goal. We recognize that there is an important role for nephrologists and facilities to play in this effort. Thus, while the ETC Model is well-intentioned, CMS should address the concerns outlined above before implementing the model. Even though we believe each of these problems can be addressed and have offered concrete recommendations to achieve these solutions, it may simply take more time than a January 1, 2020, or April 1, 2020, start date would allow. We do not ask that CMS take an infinite amount of time to address these concerns, but ensure that they are in fact addressed before the program is implemented.

II. Section II: KCP also recommends other modifications to the proposed ETC model to allow it to achieve the Administration’s overarching goals.

Once these core concerns are addressed, KCP also asks CMS to refine other policies within the ETC to allow for the smooth implementation of the model as well. These are related to the:

- The rationale for not using HRRs for determining participants.
- The rationale for using a covariant-based constrained randomization for determining participants.
- The rationale for having the National Quality Forum review the home dialysis and transplant measures.
- The need for the technical information about the reliability adjustment and aggregation proposal, which have not been specified in the proposed rule, and allow for comment to determine if such an adjustment is necessary.
- The rationale for using the standardized risk-adjusted rate measures with appropriate socio-demographic factors to measure mortality and hospitalization.

A. The rationale for not using HRRs for determining participants.

KCP is concerned that the use of the HRRs does not accurately reflect the practice and referral patterns for nephrologists and facilities caring for patients with kidney failure.

HRRs were created as part of the Dartmouth Atlas of Health (2019), which defines them as follows:

Hospital referral regions (HRRs) represent regional health care markets for tertiary medical care. Each HRR contains at least one hospital that performs major cardiovascular procedures and neurosurgery. HRRs were defined by assigning Hospital Service Areas to the region where the greatest proportion of major cardiovascular procedures were performed, with minor modifications to achieve geographic contiguity, a minimum population size of 120,000, and a high localization index. The process resulted in 306 hospital referral regions.⁵³

While the Proposed Rule suggests that HRRs correlate with organ transplantation patterns,⁵⁴ that statement is not consistent with the KCP members' experience for either home dialysis or transplant. We were not able to locate a source to verify the statement in the preamble. At least one set of researchers evaluating HRRs and Health Service Areas (HSAs) has suggested that "HSAs and HRRs are geographic units commonly used in health services research yet vary in their ability to describe where patients receive hospital care."⁵⁵ As this article's findings suggest, and the experience of the KCP members attests for dialysis patients in particular, there is substantial patient movement across HRRs and county boundaries because the services areas of nephrologists and facilities is not linked to the referral patterns for the conditions around which HRRs were constructed.

An example of this problem can be seen from the USRDS map⁵⁶ that shows patient populations by HSAs.

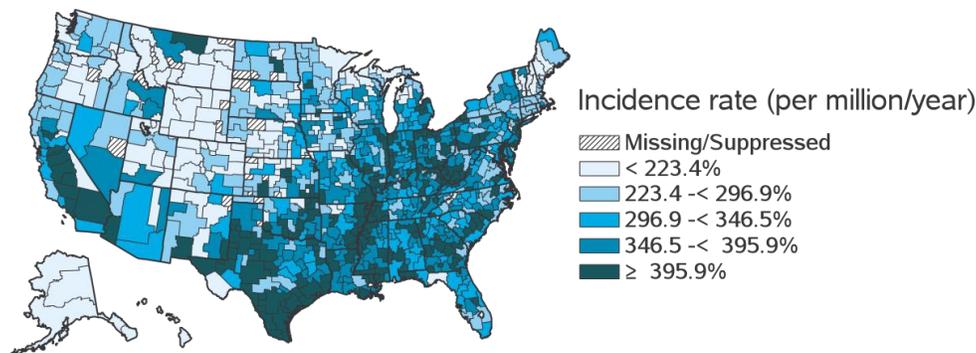
⁵³<https://www.arcgis.com/home/item.html?id=62969fa5bc3c4e3abd045cd62332c58c>.

⁵⁴ 84 *Fed. Reg.* at 34544.

⁵⁵Kilaru, Austin S., Wiebe, Douglas J., Karp, David N., Love, Jennifer, Kallan, Michael J., Carr, Brendan G., "Do Hospital Service Areas and Hospital Referral Regions Define Discrete Health Care Populations?" 53 *Medical Care* 510–516 (June 2015).

⁵⁶USRDS, Annual Report Data Report, Vol 2 300 (2018).

vol 2 Figure 1.3 Map of the standardized incidence rate of ESRD, by Health Service Area, in the U.S. population, 2012-2016



Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, HSA, and unknown/other race. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

As this chart shows that the distribution of patients is not uniform geographically. The same is true of home dialysis and transplant. A similar problem would occur with HRRs. Thus, the use of the HRRs with random assignment would not generate an equal distribution of patients necessary to test the model. MedPAC has made a similar point in its comment letter on the proposed model.⁵⁷

We appreciate that CMS provides the alternative of using CBSA as a geographic unit of selection and then assigning rural counties to the nearest CBSA to try to create geographic diversity, but this option is also problematic. CBSAs are a third the size of HRRs, which would increase problems of splitting single facilities/provider groups into intervention and control groups. Even smaller regional operations would have facilities across multiple CBSAs if this designation were used. That problem also significantly aggravates issues identified with the reliability adjustment (which we discuss in detail below). In particular, there would be a small number of dialysis facilities in an HRR (see chart below). Thus, dividing the geographic areas into 929 units would mean an even smaller number of facilities would be included in the aggregation group and would likely introduce a large number of facilities with no other dialysis facilities in the same CBSA.

The Proposed Rule is also silent as to how CMS would attribute the rural areas to CBSAs. KCP is not aware of a standard method for doing so. Without having a chance to review and comment on the rural assignment algorithm, we have concerns about transparency and the proposal could result in additional problems that have yet to be identified.

Thus, for these reasons KCP recommends that CMS base the sample used for the model on the Medicare ESRD facilities and not the HRRs or another geographic designation. As

⁵⁷MedPAC, *supra* note 3.

discussed below in subsection II.B., using a covariant-based constrained randomization, would allow to effectively test the impact of the proposed model and ensure that all types, sizes, and locations of nephrologists and facilities participate in the model.

B. The rationale for using a covariant-based constrained randomization for determining participants.

KCP believes that the stratified randomization at the regional level is not sufficient to create fully comparable groups to evaluate the effect of the intervention. We believe an equitable allocation, which would in turn enable rigorous evaluation, would seek to balance the distribution of factors known to be linked to home dialysis rate and kidney transplantation. A brief review of literature identified several factors with regular associations. Numbers in the body of the table indicate unique findings within peer-reviewed analyses of home dialysis and organ transplantation rate.⁵⁸ For example, six findings of a negative relationship between ethnic/racial minority and home dialysis rate have been found (indicating that ethnic/racial minority patients are less likely to be treated with home dialysis):

Factor	Home Dialysis			Organ Transplant			Total
	Association type			Association type			
	-	None Found	+	-	None Found	+	
Ethnic/racial minority	6	0	0	5	0	0	11
Higher Socioeconomic Status (SES)	0	2	2	0	0	2	6
More Education	0	1	2	0	0	2	5
Rurality	2	0	0	0	0	0	2
% Patients employed full or part-time	0	0	1	0	0	0	1
Distance from donation service area (DSA)	0	0	0	1	0	0	1
Facility size	0	0	1	0	0	0	1
Late dialysis work shift	1	0	0	0	0	0	1
Older age	1	0	0	0	0	0	1
Percentage of housing units occupied by owner	0	1	0	0	0	0	1

The four most common findings (ethnic/racial minority, higher SES, more education, and rurality) are recommended for inclusion in the proposed randomization methods below, as these data are available and can be readily determined.

⁵⁸See Appendix B

KCP suggests using covariate-based constrained randomization. Under this method, a number of covariates are selected and multiple randomizations are performed to identify a randomization that effectively balances allocation on those covariates. This is done by identifying a number of known covariates and specifying the acceptable level of difference between the intervention and control groups. For example, the percentage of African-Americans in each of the two groups must be within 5 percent. A large number of independent randomizations are performed, and those meeting all of the caliper criteria are identified as candidate randomizations. From these candidate randomizations, one randomization is chosen at random. An example of the known covariates and caliper criteria that could be used in the ETC model are in the table below.

Covariate	Proposed Measure	Caliper Criteria
Ethnic/racial minority	Percent non-white	+/- 0.25%
Higher SES	Per capita income	+/- 0.25%
More education	Percent college graduate	+/- 0.25%
Rurality	Percent rural census tracts	+/- 0.25%

While this covariate-based constrained randomization may be performed within the regional stratification that CMS has identified, evidence supporting a regional association with key outcomes was not found. This method could be used with the patient-specific approach suggested above in subsection II.A.

C. The rationale for having the National Quality Forum review the home dialysis and transplant measures

As CMS has recognized, one of the most important ways to improve the lives of any patient, especially patients with a chronic diseases, is to empower them by providing accurate information about provider performance and to give patients the tools they need to make informed health care choices. KCP has long agreed with CMS that paying for value over volume is also central to achieving this goal.⁵⁹ As the NQF – the Congressionally mandated consensus-based entity upon which CMS relies for evaluating quality measures – has stated in its own report to the Congress, “The presence of high-quality performance measures is essential in providing information and insight on how providers are responding to the needs and preferences of patients and families with regards to healthcare delivery.”⁶⁰

⁵⁹CMS, “Report to the Congress: Identification of Quality Measurement Priorities—Strategic Plan, Initiatives, and Activities” 4 (March 1 2019).

⁶⁰NQF, “NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services” 24 (March 1, 2019).

These principals also apply when CMS is establishing innovative models and using measures to evaluate participants. For such models to be truly evaluated, the measures used must provide accurate information about the care being provided by the entity or individuals serving the patients. Both CMS and the NQF have recognized that fact and in the words of NQF, “the increased use of performance measures for public reporting and payment purposes underscores the need to ensure that these measures fairly and accurately assess quality.”⁶¹ CMS recognized this critical principal when, in 2015, it developed the “Principles and Approaches to Enhance Accuracy and Accountability for Value Based Purchasing and Alternative Payment Models.” This project developed an Attribution Model Selection Guide for measure developers and program implementers to enhance accuracy and fairness in assigning accountability for health outcomes.⁶² “The use of measures that are unreliable or invalid undermines confidence in measures among providers and consumers of healthcare.”⁶³

In addition to measures being valid and reliable to provide accurate information to patients, the measures being used Medicare innovation models must also be meaningful. We applaud CMS’ Measures that Matter initiative’s “focus on core issues that are essential to providing high quality care and improving patient outcomes while reducing the cost and burden associated with quality measurement.”⁶⁴

Applying these principals to the ETC model is critically important as well. Thus, CMS should submit both of these measures with the KCP recommended modifications, to NQF for review. CMS should be sure that the metrics it is using to determine payment adjustments are reliable and valid and meet the other scientifically accepted criteria applied by the NQF.

As part of this process, CMS should provide transparency with regard to both measures by publishing full specifications and algorithms, which were not included as part of the Proposed Rule.

As noted above, KCP recommends that CMS adopt exclusions to these measures. For the home dialysis measure, KCP recommends including exclusions for patients for whom home dialysis is not clinically appropriate. It should also exclude patients who select not to receive home dialysis after having been appropriately educated about the modality. (Please see Section I for more specific details.) We also recommend developing ways to document patients who are homeless or experiencing housing insecurity, which creates the most prominent socio-demographic barrier to home, as well as patients who have been documented as non-compliant with their medical regimen. These are important factors, but KCP recognizes that they are not measurable at this time.

⁶¹*Id.* at 17.

⁶²CMS, *supra* note 59, at 48.

⁶³NQF, *supra* note 60, at 18.

⁶⁴CMS, *supra* note 59, at 1.

In addition, for the transplant measure, KCP recommends shifting it to a referral measure, for the reasons outlined in Section I. In addition, the exclusions for the measure (and similarly for any future potential waitlist or rate measures) should take into account clinical criteria that result in a patient not being qualified for a transplant. KCP reviewed a “South Atlantic Area Kidney Transplant Center Referral Guide (produced by IPRO), which shows that of the nine transplant centers in Georgia, North Carolina, and South Carolina. Not one has the same “absolute exclusion criteria,” which underscores the point made in Section I.E. regarding the need for a standardized, level playing field for waitlist criteria.

Based on the absolute exclusion criteria used by these nine centers, KCP recommends the following additional exclusions from the transplant rate measure denominator:

- Advanced COPD
- Active malignancy
- Active or untreatable infection
- Myocardial Infarct within prior 6 months
- BMI >45 (the highest level among the nine centers)
- Cirrhosis/advanced Liver Fibrosis
- Active tuberculosis
- Active substance use

Once these exclusions are added, CMS could then submit the measure for NQF review. All measures used in the ETC should receive NQF endorsement before used to adjust payment amounts to participants.

D. The need for the technical information about the reliability adjustment and aggregation proposal, which have not been specified in the proposed rule, and the need for a comment period to determine if such an adjustment is necessary.

KCP understands that reliability adjusters are used by groups including Leapfrog, NQF, the Agency for Healthcare Quality and Research (AHRQ), and CMS within the Hospital Compare and Hospital Value-Based Purchasing programs. A small body of research has suggested that reliability adjustments effectively reduces statistical noise and improves the ability of measurements in one period to predict subsequent performance. Others point out that the issue of shrinkage may reduce the ability to distinguish performance outliers. The reliability adjustment approach suggests that these performance outliers are “false positives,” in that they likely do not represent a meaningful deviation from average performance.

For many measures that CMS includes in Hospital Compare, including 30-day readmission rates, performance among facilities typically follows a bell-shaped distribution. However, among dialysis facilities, the home dialysis rate follows a distribution that could be

fairly characterized as a zero-inflated beta distribution. The important implication of this observation is that the variance of this distribution is relatively large. In other words, between-facility variance is large. Consequently, the ratio of between-facility variation to within-facility variation is also large. Applying a uniform reliability adjustment to a non-normal distribution would likely introduce noise into any resulting measurement instead of improving accuracy. Additionally, this method may elicit adjusted home dialysis rates that reflect the facility much more than the respective aggregation group.

Unfortunately, it is difficult for KCP to comment as to whether the reliability adjustment as proposed should be adopted in the final rule because the Proposed Rule does not provide sufficient information describing the methodology or application of a reliability adjuster in the ETC Model for stakeholders to evaluate and provide informed comment. We asked CMS to release the technical document that explains the measure and scoring methodology, including the detailed methodology for calculating the individual transplant and home dialysis scores, including the reliability adjustment. KCP is disappointed, as are many in the kidney care community, that this information was not provided in the Proposed Rule or through other channels, creating an unfortunate lack of transparency.

This lack of information also makes it difficult to assess the aggregation proposals, which are tied to the decision to use a reliability adjustment.

Without the information necessary to provide sufficient notice about the reliability adjuster or the aggregation proposals, we believe CMS should release the technical documents requested and provide an additional opportunity for the community and stakeholders to provide comments on the proposal.

E. The rationale for using the standardized risk-adjusted rate measures with appropriate socio-demographic factors to measure mortality and hospitalization.

KCP supports the monitoring mortality and hospitalization as part of the ETC Model. However, consistent with our comments outlined in previous letters to CMS about the ESRD QIP, KCP asks CMS to use a true risk-standardized rate measure, because the ratio measure has relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. A ratio that is then multiplied by a national median is not a true risk-standardized rate. The confusion around the ratio measure and misclassification of facilities create an unnecessary burden on facilities, as well as patients who are interested in understanding the actual performance of facilities and cannot.

In addition, CMS should address the problem of small facilities having scores that are highly subject to random variability. KCP would welcome the opportunity to provide our more detailed analysis about how this problem could be addressed for these measures.

Thus, for both measures, CMS should use the mortality and hospitalization rate, respectively, and appropriately risk adjust the hospitalization measure using race/ethnicity, as CMS currently does for the standardized mortality ratio. It should also build off of its contracted work with NQF and develop socio-demographic adjusters, consistent with KCP's 2018 ESRD QIP comment letter recommendations. While CMS submits the new measure to the NQF for endorsement, it could use this improved readmissions rate measure in the QIP.

III. Conclusion

KCP appreciates the opportunity to work with the Department and CMS to transform the Medicare ESRD benefit. However, because Medicare is essentially the single payer upon which patients with kidney failure must rely to receive life-saving treatments, it is essential that the ETC Model not be implemented as proposed and instead be reformed consistent with the recommendations outlined in this letter.

The KCP believes that together, we can achieve the goals outlined in "Advancing American Kidney Health." Based on our previous conversations, we were frankly surprised by the design of the proposed ETC model and hope that we and our members can work with CMS closely during the coming weeks and months to revise the model as outlined in this letter to allow for the smooth implementation and testing of the central tenants of improving access to home dialysis and transplant upon which we all agree. If implemented as proposed however, the ETC model will result in severe unintended consequences for all involved. Therefore, we ask that the Department and CMS take a little more time to get this program right.

As a next step toward achieving this goal, we request the opportunity to meet with you and your teams about our concerns and recommended solutions. Our counsel in Washington, Kathy Lester, will be in contact to schedule this meeting. In the meantime, please do not hesitate to reach out to her at klester@lesterhealthlaw.com or (202) 534-1773 if you have questions about our concerns or recommendations as presented in this letter.

Sincerely,



Allen Nissenson
Chairman, Kidney Care Partners

cc: Adam Boehler, Deputy Administrator for Innovation Policy and Director, CMMI
Amy Bassano, Deputy Director CMMI
Tom Duvall, CMMI

Appendix A: IPRO Referral Guide Summary Chart

	GEORGIA		
	Augusta University Medical Center Transplant Program	Emory Transplant Center	Piedmont Hospital Transplant Institute
ABSOLUTE EXCLUSION CRITERIA			
Active or untreatable infection	X	X	
Malignancy or history of cancer		X – Active Malignancy Only	
Body Mass Index - kg/m ² (BMI)	>42	>45	>45
Age	>80		
Myocardial infarction or active myocardial ischemia			
Advanced Coronary Artery Disease (CAD)	X	X	X
Cerebrovascular accident within the last 3 months			
Severe peripheral vascular disease		X	
Advanced chronic obstructive pulmonary disease (COPD)	X	X	X
Incomplete immunization series			
Active Tuberculosis (TB)		X	
Cirrhosis / Liver Disease / Oxalosis	X		
Liver biopsy with stage ≥3 fibrosis			
Current Positive T cell Crossmatch			
Sickle Cell Disease			
Good Pasture's Syndrome			
Wagener's Granulomatosis			
Active Systemic Lupus Erythematosus			
Active Vasculitis / Glomerulonephritis			
Psychiatric illness not controlled with medication	X	X	X
Lack of social support for financial resources	X	X	X
Non-Compliance with Medical Regimen	X	X	
Active smoker			
Active substance abuse (drug or alcohol)	X	X	X
Miscellaneous	Yes self referral	Yes self referral	Yes self referral

Absolute Exclusion Criteria: A list of medical conditions that would prevent a person from being eligible for a transplant. (Every transplant unit has its own set of exclusions.)

NO. CAROLINA					SO. CAROLINA
Carolinas Medical Center Renal Transplant Program	Duke University Hospital Transplant	UNC Hospital Transplant Program	Vidant Medical Center	Wake Forest Baptist Hospital Medical Center	Medical University of South Carolina Transplant Center
X			X	X	X
X – Active Malignancy Only				X – Active Malignancy Only	X
>40	>40	>40	>42	>45	>40
		>80		>85	
Within 6 mo's.	Within 6 mo's.				
X		X			X
X					
X					
X	X – Only if severe	X	X – Only if severe	X – Only if severe	X
X					
X		X			
X				X	
X					
X					X
					X
					X
					X
X					X
X	X		X	X	X
X	X		X	X	
X	X		X	X	X
		X			
X	X	X	X	X	X
No self referral	Yes self referral and Chronic SNF	Yes self referral	Yes self referral	Yes self referral	Yes self referral

Appendix B: Research Summary

Home Dialysis Determinants Evidence

Source Title	Year	Predictor	Association	Dependent factor	Description
Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis	2010	Facility size	Positive	use of home dialysis	A facility with greater than 62 patients was the characteristic associated with the largest magnitude (8.2%) of increase in home dialysis use.
Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis	2010	% Patients employed full or part-time	Positive	use of home dialysis	As the percent of the dialysis population employed increases, the percent of dialysis patients receiving home dialysis also increases at about the same rate.
Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis	2010	Older age	Negative	use of home dialysis	As a facility's percentage of patients between the ages of 18 to 54 years old increased, so did the percentage of patients receiving home dialysis. Each 1% increase in this age group resulted in a 0.13% increase in the percentage of patients receiving home dialysis therapy.
Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis	2010	Rurality	Negative	use of home dialysis	Facilities located in a more rural area, a geographically larger zip code area, or high-population-density zip codes were associated with lower use of home dialysis.
Dialysis Facility and Patient Characteristics Associated with	2010	Late dialysis work shift	Negative	use of home dialysis	Late shifts (starting at 5pm or later) were available in 23% of independent clinics compared with 18.7% of chains (P 0.0033) The average facility with a late shift had a 4.4% lower

Source Title	Year	Predictor	Association	Dependent factor	Description
Utilization of Home Dialysis					rate of patients on home dialysis compared with those without a late shift
Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis	2010	Ethnic/racial minority	Negative	use of home dialysis	Each absolute 1% increase in the black population within a zip code was associated with an absolute 0.03% decline in the percent of patients on home dialysis
Socioeconomic Differences in the Uptake of Home Dialysis	2014	Higher SES	positive	use of PD	Patients from the most advantaged quartile of areas were less likely to commence peritoneal dialysis (0.63 OR; 0.58, 0.69)
Socioeconomic Differences in the Uptake of Home Dialysis	2014	Higher SES	positive	use of in-center HD	Patients from the most advantaged quartile of areas were more likely to use in-center hemodialysis than patients from the most disadvantaged areas (1.19 OR; 1.10 to 1.30).
Socioeconomic Differences in the Uptake of Home Dialysis	2014	Higher SES	None found	use of home HD	SES was not associated with uptake of home hemodialysis.
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	Ethnic/racial minority	negative	rates of transfer from home to in-center dialysis	The adjusted risk was also higher for patients treated in units located in neighborhoods with a higher proportion of black residents. (% of Black residents) HR of experiencing a transfer: Quartile 1 (<0.2%) 1.00 Quartile 2 (0.2% to 1.0%) 1.03 (0.98 to 1.08)

Source Title	Year	Predictor	Association	Dependent factor	Description
					Quartile 3 (1.0% to 6.8%) 1.08 (1.03 to 1.14) Quartile 4 (≥6.8%) 1.14 (1.07 to 1.22)
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	Higher SES	None found	rates of transfer from home to in-center dialysis	Hazard ratio (HR) of transfer by per capita income in relation to those in the first quartile: *Quartile 1 (<\$18,229) 1.00 *Quartile 2 (\$18,229-\$21,934) 0.98 (0.93 to 1.03) *Quartile 3 (\$21,394-\$26,468) 0.94 (0.88 to 1.00) *Quartile 4 (≥\$26,469) 0.94 (0.87 to 1.02)
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	Percentage of housing units occupied by owner	None found	rates of transfer from home to in-center dialysis	Hazard ratio (HR) of transfer by household units occupied by owner in relation to those in the first quartile: *Quartile 1 (<55%) 1.00 *Quartile 2 (55% to 65%) 0.97 (0.93 to 1.01) *Quartile 3 (65% to 73%) 0.98 (0.93 to 1.03) *Quartile 4 (≥73%) 0.99 (0.94 to 1.05)

Source Title	Year	Predictor	Association	Dependent factor	Description
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	More Education	Positive	rates of transfer from home to in-center dialysis	Hazard ratio (HR) of transfer by % of more than 25 years with high school diploma in relation to those in the first quartile: *Quartile 1 (<77%) 1.00 *Quartile 2 (77% to 85%) 1.06 (1.01 to 1.12) *Quartile 3 (85% to 90%) 1.06 (0.98 to 1.13) *Quartile 4 (≥90%) 1.12 (1.02 to 1.21)
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	More Education	None found	rates of transfer from home to in-center dialysis	Hazard ratio (HR) of transfer by % of more than 25 years with a college degree in relation to those in the first quartile: *Quartile 1 (<18%) 1.00 *Quartile 2 (18% to 24%) 1.04 (0.98 to 1.09) *Quartile 3 (24% to 34%) 1.05 (0.98 to 1.12) *Quartile 4 (≥34%) 1.02 (0.93 to 1.11)
NEIGHBORHOOD LOCATION, RURALITY, GEOGRAPHY, AND OUTCOMES OF PERITONEAL DIALYSIS PATIENTS IN THE UNITED STATES	2011	Rurality	negative	rates of transfer from home to in-center dialysis	Hazard ratio (HR) of transfer by rurality relative to urban environment: *Urban, 1.00 HR *Large rural, 1.00 HR (0.93 to 1.06) *Small rural, 1.01 HR (0.86 to 1.19) *Remote rural, 1.33 HR (1.05 to 1.69)
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	Negative	use of PD	Adjusted OR comparing use of PD between ethnic minorities and whites: *Black, 0.53(0.50, 0.56) *Hispanic, 0.57(0.53, 0.61) *Asian, 0.82(0.72, 0.93) *Other, 0.60(0.52, 0.68)

Source Title	Year	Predictor	Association	Dependent factor	Description
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	negative	use of home hemodialysis	Adjusted OR comparing use of home HD between ethnic minorities and whites: *Black, 0.40(0.36, 0.44) *Hispanic, 0.25(0.21, 0.30) *Asian, 0.53(0.41, 0.69) *Other, 0.44(0.33, 0.57)
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	negative	higher transfer rates from home hemodialysis into in-center HD	Only blacks had a statistically significant higher OR of transfer from home HD to in-center HD when compared to whites *Black, 1.41 (1.12, 1.77)
Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study	2002	Ethnic/racial minority	negative	Use of PD over HD	Whites were 1.90 (1.65 to 2.20) times more likely to undergo PD treatment versus PD than their non-white counterparts after adjusting for various other clinical factors.
Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study	2002	More Education	positive	Use of PD over HD	Those with college education were 2.74 (2.10 to 3.57) times more likely to undergo PD treatment versus PD than those with only elementary education.

Organ Transplant Determinant Evidence

Source Title	Year	Predictor	Association	Dependent factor	Description
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	negative	kidney transplant after PD	Adjusted OR comparing kidney transplant among those in PD between ethnic minorities and whites: *black, 0.54 (0.47, 0.62) *Hispanic, 0.52 (0.44, 0.62) *Asian, 0.88 (0.69, 1.12) *Other, 0.77 (0.58, 1.03)
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	negative	Kidney transplant after home HD	Adjusted OR comparing kidney transplant among those in home HD between ethnic minorities and whites: *black, 0.57 (0.40, 0.83) *Hispanic, 0.84 (0.46, 1.53) *Asian, 0.81 (0.36, 1.83) *Other, 0.51 (0.16, 1.62)
Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States	2016	Ethnic/racial minority	negative	Kidney transplant after in-center HD	Adjusted OR comparing kidney transplant among those in in-center HD between ethnic minorities and whites: *Black, 0.39 (0.36, 0.42) *Hispanic, 0.52 (0.49, 0.58) *Asian, 0.78 (0.66, 0.91) *Other, 0.70 (0.61, 0.82)

Source Title	Year	Predictor	Association	Dependent factor	Description
The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes	2010	Higher SES	positive	access to transplant	Patients in the highest SES quartile had increased access to transplant compared with those with lowest SES, driven strongly by 76% higher likelihood of living donor transplantation (adjusted hazard ratio [aHR] 1.76, 95% confidence interval [CI] 1.70 to 1.83)
The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes	2010	Higher SES	positive	time of waitlist death	Waitlist death was lower among high SES compared with low SES candidates (HR 0.86, 95% CI 0.84 to 0.89)
The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes	2010	Distance from donation service area (DSA)	negative	donor transplant access	Inter-DSA travel was associated with a dramatic increase in deceased donor transplant access (HR 1.94, 95% CI 1.88 to 2.00).

Source Title	Year	Predictor	Association	Dependent factor	Description
Access and Outcomes Among Minority Transplant Patients, 1999–2008, with a Focus on Determinants of Kidney Graft Survival	2010	Ethnic/racial minority	negative	Ratio of % transplant to % active waitlist patients (2008)	<p>White, 1.22 (ex: 61% of all kidney recipients were white, 50% of all waitlist patients were white; $61\%/50\% = 1.22$)</p> <p>African American, 0.91 Hispanic/Latino, 0.85 Asian, 0.72</p> <p>***This ratio is a crude indicator of equity in kidney transplants. A ratio of 1 means that amongst all ethnic groups, the group in observation received the same proportion of kidney transplants as there were people on the waitlist for that particular group relative to all other groups.</p>
Racial Ethnic Differences in Rates and Determinants of Deceased Donor Kidney Transplantation	2011	Ethnic/racial minority	negative	Transplant rates from time of initiating dialysis	<p>Annual transplant rates from the time of dialysis initiation (1995-2006 with a follow-up through 2008):</p> <ul style="list-style-type: none"> *AIANs (2.4% [2.2 to 2.6%]) *Blacks (2.8% [2.8 to 2.9%]), *Pacific Islanders (3.1% [2.9 to 3.4%]) *Hispanics (3.2% [3.1 to 3.3%]), *Whites (5.9% [5.8 to 5.9%]) *Asians (6.4% [6.2 to 6.6%]).

Source Title	Year	Predictor	Association	Dependent factor	Description
Educational Level as a Determinant of Access to and Outcomes After Kidney Transplantation in the United States	2008	More Education	positive	Placed on transplant waitlist	After multivariate adjustment, college graduates experienced almost 3 times greater rates of wait-listing (hazard ratio, 2.81; 95% confidence interval, 2.21 to 3.58) compared with patients without a high school degree
Educational Level as a Determinant of Access to and Outcomes After Kidney Transplantation in the United States	2008	More Education	positive	Kidney transplant	College graduates also experienced greater rates of kidney transplantation (hazard ratio, 3.06; 95% confidence interval, 2.38 to 3.92) compared with patients without a high school degree.

Appendix C: Kidney Care Partner Members

American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
Ardelyx
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
Dialysis Clinics, Inc.
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Renal Administrators Association
Nephrology Nursing Certification Commission
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care