



February 22, 2024

Elizabeth Fowler
Deputy Administrator
Centers for Medicare and Medicaid Services
Director
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

Dear Deputy Administrator Fowler:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals represented by the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model.

ASN supports the goals of the ETC Model to encourage greater use of home dialysis and kidney transplants for individuals in Medicare with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to these individuals. ASN also commends the Center for Medicare and Medicaid Innovation (CMMI) for its long-standing commitment to developing and testing models to improve care and outcomes for millions of Americans experiencing kidney diseases and furthering the goal of value-based care. It is notable that CMMI pursued a randomized study design with the intent of improving the quality of evidence regarding the model's impact.

However, the ETC Model is at a critical inflection point. ASN requests CMMI undertake additional rulemaking on the ETC Model to address concerns about the model's design and evaluation methodology as well as implications of the performance targets in the remaining years of the model. CMMI must view the ETC Model in the broader context of kidney care in the United States. This is a time of great change and tremendous stress on the kidney care system.

1. Medicare Advantage (MA) has grown dramatically, such that the majority of maintenance dialysis patients likely have MA coverage as opposed to fee-for-service (FFS). This movement from FFS to MA may have dramatic effects on the ETC Model, from which MA beneficiaries are barred.
2. Financial stresses in kidney care currently are substantial, with the ESRD bundled payment to facilities and Medicare reimbursement to nephrologists lagging behind inflation. These stresses have resulted in facility contractions and

closures affecting access to care for the most disadvantaged individuals, including those with only Medicaid coverage.

3. Participants (nephrologists and dialysis facilities) in the ETC Model are compared to non-ETC participants for the purposes of achievement thresholds on home dialysis and transplant metrics through the designation of ETC and non-ETC Hospital Referral Regions (HRRs). With education and other interventions designed to increase home dialysis and transplantation spanning all HRRs, regardless of ETC status, similar changes in performance are seen in both model participants and control groups.
4. Staffing and access issues remain, even for several years following the height of the COVID-19 pandemic, substantially impacting clinical capabilities. All these factors influence ETC performance and threaten model results.

In the remainder of this letter, ASN highlights the challenges raised by these circumstances and suggests potential next steps for CMMI to consider. Most notably, ASN is very concerned that the upcoming severe penalty phase of the ETC Model could significantly penalize already under-resourced dialysis units and health professionals, resulting in decreased access to home dialysis and transplantation, while exacerbating established disparities in kidney care. Since the COVID-19 pandemic began four years ago, rates of home dialysis, in general, and peritoneal dialysis, specifically, have been negatively impacted by the staffing and resource shortages at facilities.^{i ii}

ASN is aware that these recommendations could impact CMMI's efforts to compare participants in the ETC Model to those that are not in the model. As this letter will illustrate, ASN believes that impacts to the comparison effort have already occurred.

Recently, the two-year evaluation findings of the ETC Model were released. The "Findings at a Glance" reported that:

"Through the first two years of the ETC Model, there was no difference in the growth in home dialysis between the ETC areas and the comparison group. Overall transplantation increased, but there was no significant increase on transplant waitlisting or living donor transplantation. There are no differences in Medicare spending, no worsening or improving of underlying disparities, and no unintended consequences. Given the challenges and the complexity of increasing home dialysis and transplant rates and the early stage of the model implementation, it is early to form conclusions about possible longer-term impacts of the model."ⁱⁱⁱ

ASN is concerned that, based on these preliminary findings, CMMI may conclude that ongoing rulemaking is unnecessary or premature at this point. ASN respectfully disagrees and believes that now is a critical time for rulemaking, and, without addressing issues in the model through rulemaking, ASN believes that the model's impact and legacy are jeopardized by the looming widespread penalties. This

recommendation is not intended to undermine analyses that are dependent on the randomization strategy of the ETC Model, although we do maintain that these analyses are already affected by shared interventions in both the control and ETC groups. Rather, ASN recognizes the important goal of the model demonstrating some real successes without undue penalties on the majority of participants.

Critics of the ETC Model are already pointing to statements from the finding, such as:

“Home dialysis grew similarly across ETC areas and the comparison group, increasing 12% to 15.2% in ETC areas and 12.7% to 15.9% in the comparison group from 2017-2019 to 2021-2022, respectively. To date the ETC Model has led to an 8% increase in home dialysis training, though most of this change occurred in 2021.”

The report summary went on to state:

“The ETC Model did not result in any statistically significant differences in waitlisting and living donor transplant rates compared to beneficiaries receiving care outside of the model during the first two years. While the overall transplant rate increased 10% and the deceased donor transplant rate increased 11%, this growth occurred in 2021 was not sustained in 2022.”^{iv}

Based on challenges with ETC methodology and current dialysis health system infrastructure, ASN is not wholly surprised by these findings. However, as we will discuss in this letter, ASN believes the model can and should be adjusted for CY 2025.

Therefore, ASN urges CMMI to:

1. Reopen voluntary models to new applications, starting January 1, 2025
 - a) Revisit KCF and KCEs to make these models more feasible for small and medium sized practices
 - b) Incorporate data from MA patients (even if not included in cost data) to improve numerators and denominators in performance calculations and comparison efforts
2. Mitigate penalties in the ETC Model to avoid further disadvantaging under resourced dialysis units and exacerbating disparities
 - a) Remove the 10 percent “stretch goal” achievement threshold escalators to mitigate penalties in the ETC Model, given improvements in both ETC and non-ETC regions
 - b) Maintain the benchmarks at the Measurement Year (MY) 6 targets as the “peak”

3. Address confounding resulting from both Medicare Advantage and/or KCC beneficiaries
 - a) Incorporate data from MA and KCC beneficiaries (even if not included in payment adjustments) to increase the denominator sizes and give facilities credit for patients that switch to MA and/or participate in additional value-based models
 - b) Conduct sensitivity analyses stratified by participation in MA, KCC, other value-based models to understand potential directional impacts from non-ETC-based VBC programs
4. Give ETC participants credit for a kidney transplant for the life of the transplant (e.g. do not remove the beneficiary who gets a kidney transplant from the savings analysis after one year)
 - a) Credit preemptive transplant to clinicians while also robustly crediting living donation kidney transplants for those who have already initiated dialysis for both clinicians and facilities
 - b) Apply the KCC definition for successful transplant (a transplant that does not require dialysis, after excluding potential delayed graft function)
 - c) Continue both numerator and denominator credit in performance calculations even if the beneficiary transitions away from Medicare fee-for-service (FFS) coverage while the beneficiary has a functioning transplant
 - d) Explore a composite measure that includes not only patients who are waitlisted but also patients who receive a transplant
5. Increase home dialysis resources beyond the dialysis facilities
 - a) Use a regional data adjuster for home dialysis rates to account for region-wide investments in home dialysis, such as improved in-hospital PD care, as well as minimize the impact of unaffiliated PD-only facilities on other facilities participating in the model (ASN originally recommended that unaffiliated PD-only facilities be excluded from the model)
 - b) Use any savings in ETC to improve resources for home dialysis in non-home settings, such as investing in PD Centers of Excellence at nursing homes and LTACHs so that PD patients who require rehabilitation are not forced to transition to hemodialysis

The Case for Rulemaking

Without changes like removing the 10 percent “stretch goal” and crediting a kidney transplant for the life of the transplant, ETC participants anticipate that they will be facing significant penalties **despite** successfully facilitating greater access to home dialysis and kidney transplantation. The potential negative adjustments in the latter part of the Performance Payment Adjustment (PPA) period of -9 percent for managing clinicians and -10 percent for ESRD facilities are almost certain to affect numerous clinicians and facilities.

ASN members who participate in the ETC Model believe their data and trends suggest an acceptable ETC home dialysis policy would be to maintain the benchmarks to the MY6 targets as the “peak” with a 30% home dialysis rate as the 75th percentile and 45% home dialysis rate as 90th percentile (for stratum 2).

With kidney transplantation, nephrologists and dialysis providers regularly raise the fact that the model incentivizes, by virtue of its design, keeping patients who are on home dialysis on a transplant waitlist rather than helping them be successfully transplanted, highlighting that this as a ***misaligned incentive***. Additionally, there is very little incentive, and actually notable disincentives, under the model for nephrologists and dialysis providers to see to it that patients be pre-emptively transplanted or receive a living donor transplant. ASN urges CMMI to remove disincentives of this nature in upcoming rulemaking.

ASN has been contacted by numerous participants regarding the financial cliff they are facing for the final years of the model. According to the Measurement Year (MY) 6 benchmark reports of one nephrology practice assigned to the ETC is projected to lose approximately \$550,000. The size of this penalty jeopardizes continuity and quality of care for vulnerable kidney patients.

If CMMI does not address these problems, the ETC Model will likely not survive beyond its current term, will be considered unsuccessful, and will make it more difficult for CMMI to implement a different mandatory kidney model in the future. CMMI has an opportunity to use its upcoming rulemaking cycle to help ensure the ETC Model accomplishes its goals, which were embraced by the kidney community and gave hope to the millions of Americans living with kidney diseases.

ETC Areas, the Comparison Group, and Medicare Advantage

Before 2021, most beneficiaries with ESRD were unable to enroll in private Medicare Advantage (MA) plans. The 21st Century Cures Act permitted these beneficiaries to enroll in MA plans effective January 2021. Current estimates suggest that nearly 51% of Medicare beneficiaries with ESRD are now enrolled in MA plans^v. Since the ETC Model bars patients in MA from participation in the model, the flux of patients from traditional Medicare FFS to MA is having a substantial impact on practices participating in the model.

With well-deserved attention being focused nationally on home dialysis and kidney transplantation and the addition of the voluntary Kidney Care Choices (KCC) Model (as of performance year 2024, KCC had 282,335 beneficiaries, 5,512 healthcare team members, and 2,100 dialysis units), it is not surprising to see rates of home dialysis and transplantation growing in both ETC areas and the comparison group. ASN did support the concurrent creation of both the ETC and KCC. However, since inception in 2019, the kidney community has been concerned that the control group would also be impacted with both nephrologists and dialysis providers viewing the dual goals of home dialysis and kidney transplantation as hallmarks of high quality care for individuals facing kidney failure, including for participants in the KCC.

Given the impacts of MA and the KCC model on the care of beneficiaries in the ETC Model, ASN believes that the impact of the ETC on yielding different home dialysis and transplant waitlist rates in ETC HRRs and non-ETC HRRs is challenging and limited due to spillover effects. For example, one ETC group participating in both the ETC and KCC models located in North Carolina observed that their practice was participating in the KCC with another practice from the adjacent HRR that was not an ETC HRR. To date, both practices – the one in the ETC and the one not in the ETC – have increased their home dialysis rates.

ASN maintains that the concurrent KCC model and the prevailing thinking in favor of increasing home dialysis utilization among kidney care health professionals across the United States has led to a spillover effect that makes demonstrating relative improvement of the ETC HRR over the adjacent non-ETC HRR very unlikely, in contrast to how the model was originally envisioned. This does not mean that the ETC Model had no impact. To the contrary, the strong focus on home dialysis and transplantation across CMMI's models has effectively translated into a "rising tide lifts all boats" dynamic.

ASN advocates for greater transparency relating to MA and KCC beneficiary-related outcomes for patients in the ETC, including performance and reporting of stratified analyses. ASN believes CMMI also should assess home dialysis and transplant waitlist and transplant performance data with and without MA patients being included. We recognize that there may be statistical limitations to this approach, but it may nonetheless highlight directional impacts.

Finally, ASN notes that such a large group of shared participants, challenging health care work force shortages and steep inflation have left many ETC areas and others in non-ETC areas competing for ever-tightening resources, particularly experienced kidney care allied health professionals. The impact of resource constraints on home dialysis growth in ETC and non-ETC HRRs will be challenging to ascertain, but CMS should acknowledge these limitations.

Home Dialysis Challenges

A fundamental lack of incentives exists in the ETC Model to improve the infrastructure (such as surgeons, hospital systems, and rehabilitation and long-term care facilities) that is needed to facilitate home dialysis. Many surgeons remain unaware of the ETC Model, despite working closely with nephrologists who participate in the model. Even after being informed about the model, some surgery groups report that they are unable to increase their support staff to help patients get access to home dialysis, and those nephrologists maintain the ETC Model has no incentive for hospital systems to increase their operating room capacity.

Critically, there are also numerous reports from ASN membership about home dialysis patients who receive peritoneal dialysis needing to be transitioned to in-center hemodialysis in order to be discharged to a rehabilitation facility. This barrier to patient-centered continuation of peritoneal dialysis requires system-wide solutions with CMS support.

The lack of a workforce trained in home dialysis, years of focus on in-center treatment models, and a lack of physician and patient understanding of the benefits of home dialysis will take time to overcome. Expecting these systemic changes within a few years, coupled with harsh penalties, is unrealistic and potentially devastating to many providers. ASN urges CMMI to pursue rulemaking to avoid punitive impacts to providers and patients.

Transplant

In 2019, ASN articulated its support for a transplant rate metric due to concerns of the downsides of a waitlisting metric, namely incentivizing maintaining home dialysis patients on dialysis waitlisted as opposed to ensuring successful transplantation. ASN also has concerns that patients aligned to the ETC who are successfully transplanted and then become enrolled in a MA program are no longer counted within the ETC Model.

In the current model structure, it is more financially beneficial to ETC participants to have a patient on the waitlist but not transplanted, thus disincentivizing efforts to focus on helping a patient get a living donor transplant (often the fastest path to transplant due to wait times for deceased donor kidneys) – within the ethical boundaries of finding a living donor. ASN favors a composite measure that includes patients who are waitlisted as well as successfully transplanted.

In its September 16, 2019, comment letter on CMS-5527-P, ASN wrote the following:

“...we strongly support the use of an actual transplant rate as a metric in the ETC Model. This approach will require both nephrologists and dialysis organizations to take a much more proactive, focused approach to improving patient access to transplantation in ways that they have not been previously asked to do. This

approach also constitutes a fundamental shift and will necessitate greater cooperation with patients, their families and loved ones, transplant centers, Organ Procurement Organizations, and other stakeholders.

While we acknowledge that there are some aspects of the transplant process that are out of the control of nephrologists and dialysis organizations – such as the total number of deceased donor organs available for transplant nationwide or the suitability of a patient’s family and social network to serve as living donors – there are many aspects of the process that can and should be in their control – such as how they educate patients and families about living donation and how effectively they interact with transplant centers. The nephrology care community can and should make transplantation a more central part of routine care, practice, and modality selection than presently occurs, and a risk-adjusted transplant rate metric is an appropriate tool to engender this change.

While recognizing that successful transplantation requires the engagement of multiple stakeholder groups, ASN believes that aligning financial incentives and removing disincentives for dialysis units and nephrologists can be impactful. ASN urges CMMI to address these transplant-related recommendations in rulemaking this year.

ASN believes that it is critically important for CMS, HRSA, and the OPTN to work together collaboratively as they craft expectations for nephrologists, dialysis organizations, transplant centers, and OPOs, so that all stakeholders are aligned towards the same end—increased, equitable patient access to transplant—and are increasingly operating in a regulatory environment that intentionally fosters more “yes” responses to organ offers, in consultation with patient input. The Organ Transplant Affinity Group may help achieve this goal.

The need for inter-agency coordination is underscored, at this moment in time, by multiple known forthcoming policy transplant-related proposals and efforts in addition to a potential ETC rulemaking cycle: the Improving Organ Transplant Access (IOTA) model, an OPO proposed rule, and the OPTN Modernization Initiative. While the shift to continuous distribution for kidneys is on pause, the advancement of mandatory organ offer filters through OPTN is another moving part.^{vi}

The kidney and transplant community need the U.S. Department of Health and Human Services (HHS), to ensure these and other policy changes (including the ETC Model) evolve in an aligned and harmonious fashion to maximize patient access, and to ensure that access is equitable.

Equity

ASN appreciates CMS's efforts to address equity in the ETC Model and recognizes that the model does not directly address social determinants of health that greatly impact the goals of the model – namely the uptake of home dialysis and increased transplantation. Taking home dialysis for example, CMMI and ASN understand that many individuals do not have the appropriate housing, care partner(s), utilities, resources, and self-efficacy (to name a few factors) to undertake dialyzing at home. The lack of direct, programmatic steps in the model to address such factors challenges the ability for home dialysis to succeed in the model.

Inequities in home dialysis and kidney transplant rates are well known, and ASN applauds the Biden-Harris Administration's commitment to addressing inequities across health care. For kidney diseases, kidney failure incidence is 3.4 times greater in Black people compared to White people and is 2.7 times greater in Native Hawaiians and Pacific Islanders compared to White people. In contrast, home dialysis use is 40%-50% lower among Black and Latinx people compared to White people. The home dialysis rates for facilities with median levels of lower socio-economic status (SES) patients are significantly lower than among those with median levels of higher SES patients^{vii}. Responding to concerns about equity, in October 2021, CMS finalized a two-tiered approach to address disparities in home dialysis and transplant rates through the ETC Model's benchmarking and scoring methodology.

Specifically, CMS first added a Health Equity Incentive (HEI), namely "ETC Participants who demonstrate significant improvement in the home dialysis rate or transplant rate among their attributed beneficiaries who are dual-eligible for Medicare and Medicaid or Low-Income Subsidy (LIS) recipients can earn additional improvement points." Secondly, CMS structured changes to stratify benchmarks by the proportion of the same individuals covered under the HEI.^{viii} ASN believes the differences between the two strata need re-examining and maintain that it is difficult to dichotomize at 50 percent (as, for example, a facility with 49% may be indistinguishable from a facility with 51% dual-eligible beneficiaries). ASN urges CMMI to monitor the HEI to ensure that it is indeed effectively reaching those facilities for which it was intended.

ASN applauds CMMI's commitment to equity but is concerned that the lack of significant resources to assist those dual-eligible and LIS individuals to make the changes needed to increase their home dialysis rates prevents the ETC Model from significantly moving the needle in those areas. Consistent with CMMI's efforts to address equity mentioned above, ASN suggests consideration of upfront investment for facilities with a significant dual-eligible and LIS population in order to support facility-based investments in care delivery strategies to mitigate disparities.

Conclusion

CMMI's bold move to create the ETC Model is one that ASN strongly supported. With the confluence of COVID-19, patient migration to MA, and emphasis on home dialysis and kidney transplantation across the country, demonstrating improvement within the model is challenging. Therefore, ASN urges CMMI to undertake rulemaking in advance of CY 2025 to avoid a heavy penalty phase. To discuss this letter, ASN's recommendations concerning the ETC Model, or the society's request that CMMI undertake rulemaking in this arena, please contact David L. White, ASN Regulatory and Quality Officer, dwhite@asn-online.org.

Thank you.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

cc: Ellen Lukens, MPH
Pauline Lapin, MHS
Neomi Rudolph, MPH
Tom Duvall, MBA
Miriam Godwin, MPP

ⁱ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10577320/>

ⁱⁱ <https://thehill.com/opinion/healthcare/3499481-staffing-and-supply-chain-shortages-are-causing-deadly-disruptions-to-dialysis/>

ⁱⁱⁱ <https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt-aag>

^{iv} <https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt-aag>

^v <https://jamanetwork.com/journals/jama/fullarticle/2802316>

^{vi} Deviating from the Match Run to Save a Kidney. SRTR poster presentation, ATC 2023. <https://www.asn-online.org/policy/webdocs/23.3.15ASNOPTNPublicCommentProp.pdf>

^{vii} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8672226/>

^{viii} <https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model>