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End-Stage Renal Disease Treatment Choices (ETC) Model

Third Annual Evaluation Report, Calendar Years 2021–2023

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End-Stage Renal Disease Treatment Choices (ETC) Model: Third Annual Evaluation Report, Calendar Years 2021–2023

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Glossary of Terms

Acronym	Definition
ACO	Accountable Care Organization
APM	Alternative Payment Model
AFS	Annual Facility Survey
AHRF	Area Health Resource File
AKI	acute kidney injury
AR	annual report
BMI	body mass index
CAHPS	Consumer Assessment of Healthcare Provider
CATI	computer assisted telephone interviewing
CAPD	continuous ambulatory peritoneal dialysis
CBSA	Core-Based Statistical Area
CCN	CMS Certification Number
CCPD	continuous cycling peritoneal dialysis
CEC	Comprehensive End-Stage Renal Disease (ESRD) Care
CI	confidence interval
CKD	chronic kidney disease
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease of 2019
CY	calendar year
DCE	dialysis care experience
DiD	difference-in-differences
DDD	difference-in-difference-in-differences
ECE	extraordinary circumstance exception
ED	emergency department
EHR	electronic health record
E/M	Evaluation and Management
EQRS	End-Stage Renal Disease Quality Reporting System
ESRD	end-stage renal disease
ETC	ESRD Treatment Choices
FFS	fee-for-service
FMC	Fresenius Kidney Care
HD	Hemodialysis
HDPA	Home Dialysis Payment Adjustment
HRR	Hospital Referral Region
ICD	International Classification of Diseases
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
ICHD	in-center hemodialysis

Acronym	Definition
IRF	inpatient rehabilitation facility
KCC	Kidney Care Choices Model
LIS	Low-Income Subsidy
LTCH	long-term care hospital
MA	Medicare Advantage
MBSF	Master Beneficiary Summary File
MCP	Monthly Capitation Payment
MD	Maryland
MPS	Modality Performance Score
MSSP	Medicare Shared Savings Program
MY	Measurement Year
NF	nursing facility
NGACO	Next Generation ACO
NPI	National Provider Identifier
PCP	primary care physician
PD	Peritoneal dialysis
PHE	public health emergency
PPA	Performance Payment Adjustment
PPPM	per patient per month
PROMIS	Patient-Reported Outcomes Measurement Information System
QoC	quality of care
QoL	quality of life
RQ	research question
RUCC	Rural-Urban Continuum Code
SD	standard deviation
SMD	standardized mean difference
SMR	standardized mortality ratio
SNF	skilled nursing facility
SRTR	Scientific Registry of Transplant Recipients
TDAPA	Transitional Drug Add-on Payment Adjustment
TPNIES	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
U.S.	United States

1. Introduction

The Centers for Medicare & Medicaid Services (CMS) launched the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model on January 1, 2021. The ETC Model is intended to encourage greater use of home dialysis and kidney transplantation, while reducing Medicare expenditures and preserving or enhancing quality of care (QoC) for patients with ESRD. In addition, starting in the second year of the model, January 1, 2022, CMS amended the model design to promote greater access to home dialysis and transplantation among patients who are dually eligible for Medicare and Medicaid or recipients of the Part D Low Income Subsidy.[1]

The Lewin Group, with our partners Arbor Research Collaborative for Health and the University of Michigan Kidney Epidemiology and Cost Center, was contracted by CMS to conduct the evaluation of the ETC Model.

For this third annual report (AR3), we employed a mixed-methods research design that incorporates both quantitative and qualitative data to assess the impacts of the ETC Model during the first 3 years of the model (Calendar Year [CY] 2021–2023). Key outcomes of interest include use of home dialysis, waitlisting for a kidney transplant, living donor and deceased donor transplantation, utilization of services, Medicare payments, and QoC. To estimate impacts of the model on these key outcomes, we used a difference-in-differences (DiD) framework to compare changes in outcomes observed over time for patients included in the ETC Model with a comparison group of patients who were not included in the ETC Model. For this report, we also conducted the following analyses:

- Examined potential impacts on home dialysis patient experience of care and patient quality of life (QoL) using data from patient surveys that were fielded to samples of patients in ETC areas and the comparison group.
- Assessed the potential implications of the model for patient subpopulations of interest using mixed methods. We used quantitative data to compare model impacts observed among patient subgroups of interest relative to other patients across a range of selected outcomes. Based on quantitative findings, we conducted case studies to improve our understanding of factors that affect patient access to home dialysis and transplantation and how ETC participants work to improve patient access to these treatments. The case studies involved semi-structured interviews with patients with ESRD, ESRD facilities, and Managing Clinician practices in a sample of ETC areas with a disproportionately high percentage of dually eligible patients.
- Assessed whether ETC participant Modality Performance Scores (MPS), which are used to determine the Medicare payment adjustments to participating ESRD facilities and Managing Clinicians, differ based on the extent to which they treat patients from patient subgroups of interest.

[1] CMS adopted two modifications to the ETC Model that were effective on January 1, 2022. First, the performance of ETC participants on home dialysis and transplant rates was assessed separately based on how many dually eligible beneficiaries and Part D LIS recipients they treated. Second, ETC participants could earn more favorable payment adjustments when demonstrating significant improvement in rates of home dialysis or transplantation among dually eligible beneficiaries and Part D LIS recipients. For further details, see p.4.

- Examined whether the model led to different patterns in modality transitions involving home dialysis, including both patients with ESRD starting home dialysis and home dialysis patients switching to in-center hemodialysis (HD) or receiving a kidney transplant.
- Examined the net impact of the Medicare payment adjustments to ETC participants, accounting for both the Home Dialysis Payment Adjustment (HDPA) amounts (positive only) and Performance Payment Adjustment (PPA) amounts (can be positive or negative) reported in Medicare claims.

1.1. Overview of the ETC Model

The ETC Model is a mandatory model that is underway in about one-third of hospital referral regions (HRRs) throughout the United States.[2] The model is designed to encourage greater use of home dialysis and kidney transplantation among Medicare patients with ESRD as well as preemptive kidney transplantation among Medicare patients who have not yet initiated dialysis. The ETC Model is designed to achieve these goals by establishing financial incentives related to home dialysis and transplantation for ESRD facilities and Managing Clinicians selected to participate in the model based on their geographic location. Managing Clinicians include nephrologists and other qualified practitioners who furnish and bill ESRD-related physician services under the Medicare Monthly Capitation Payment (MCP). The ETC Model incentives take the form of adjustments to the Medicare payment amounts that participating ESRD facilities and Managing Clinicians would otherwise receive for providing care to patients with Medicare fee-for-service (FFS) coverage.

The ETC Model waives certain requirements that clinicians had to fulfill to furnish and bill Kidney Disease Patient Education Services. The goal of this waiver is to support patients in more advanced stages of disease in making informed decisions about their ESRD treatment. Further, CMS is operating a voluntary collaborative, the ETC Learning Collaborative to increase the supply of donor organs for transplantation by identifying and coordinating best practices among transplant centers, organ procurement organizations, donor hospitals, and patients and donor family members.

The ETC Model design includes several key features that involve the primary mechanisms for achieving the goals of the model and are essential to consider when evaluating the impacts of the model. These features include (1) randomized selection and mandatory participation, (2) Medicare performance-based payment adjustments, and (3) the modified payment adjustments that were effective January 1, 2022. We discuss each of these features below.

Randomized selection and mandatory participation. To identify ETC Model Participants, CMS selected a random sample of 31% of HRRs in the United States among all 50 states and the District of Columbia, stratified by the four U.S. census regions. This method of randomization was used to avoid selection bias and to ensure a broad representation of participants. In addition, CMS also included in the ETC Model four HRRs where at least 20% of the component ZIP Codes are in Maryland, in conjunction with the ongoing Maryland Total Cost of Care Model. ETC Model

[2] The ETC Model selection process was limited to the 50 states and the District of Columbia and did not include Puerto Rico and other U.S. Territories.

Participants include ESRD facilities and Managing Clinicians who were identified based on their location in the selected HRRs.

Performance-based Medicare payment adjustments. The ETC Model incorporates two distinct payment adjustments for ETC participants that are designed to achieve the goals of the model: the HDPA and the PPA.

The HDPA, which is in effect for the first 3 years of the ETC Model (CY 2021–2023), represents an upward adjustment to Medicare payments for participating ESRD facilities and Managing Clinicians that is specifically designed to promote the use of home dialysis for the treatment of ESRD. The HDPA is applied on a claim-by-claim basis for the provision of home dialysis services reported on FFS dialysis claims submitted by ESRD facilities and MCP claims submitted by Managing Clinicians. The HDPA was largest during the first year of the model and declined thereafter. Specifically, the HDPA for each year is as follows:

- 3% positive payment adjustment during 2021
- 2% positive payment adjustment during 2022
- 1% positive payment adjustment during 2023

The PPA is designed to promote greater use of both home dialysis and kidney transplantation. Like the HDPA, the PPA also applies to both ESRD facilities and Managing Clinicians who are ETC participants. The PPA adjusts Medicare FFS payments for outpatient dialysis facility and provider Monthly Capitation Payment claims based on the performance of ETC participants on a combination of measures of home dialysis, transplant waitlisting, and living donor transplant rates. Performance is measured based on a combination of levels of achievement relative to historical benchmarks and of improvement relative to the participant's past performance. Participants receive the higher of the achievement score or the improvement score for both the home dialysis rate and the transplant rate.

The resulting home dialysis rate score and transplant rate score are then combined to determine the Modality Performance Score (MPS), with the home dialysis rate score constituting two-thirds of the MPS and the transplant rate score constituting one-third of the MPS. The MPS determines the PPA for each participant.[3]

The initial Measurement Year (MY) for the PPA spanned January 1, 2021, to December 31, 2021, while the PPA was applied to Medicare payments to ETC participants starting on July 1, 2022. As shown in **Exhibit 1**, the range of potential PPAs increases over time for both facilities and Managing Clinicians.

ETC Model Payments and Scoring

- Home Dialysis Payment Adjustment (HDPA)
- Performance Payment Adjustment (PPA)
- Measurement Year (MY)
- Modality Performance Score (MPS)

[3] The achievement benchmarks corresponding to each MY and other details on the calculation of the PPA are available at https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model.

Exhibit 1. MYs and Range of Potential PPAs, by PPA Period

PPA Period	MY	Time Period for Payment Adjustments	ESRD Facilities		Managing Clinicians	
			Min.	Max.	Min.	Max.
1	1/1/2021–12/31/2021	7/1/2022–12/31/2022	–5.0%	+4.0%	–5.0%	+4.0%
2	7/1/2021–6/30/2022	1/1/2023–6/30/2023				
3	1/1/2022–12/31/2022	7/1/2023–12/31/2023	–6.0%	+5.0%	–6.0%	+5.0%
4	7/1/2022–6/30/2023	1/1/2024–6/30/2024				
5	1/1/2023–12/31/2023	7/1/2024–12/31/2024	–7.0%	+6.0%	–7.0%	+6.0%
6	7/1/2023–6/30/2024	1/1/2025–6/30/2025				
7	1/1/2024–12/31/2024	7/1/2025–12/31/2025	–9.0%	+7.0%	–8.0%	+7.0%

Note: ESRD = End Stage Renal Disease; MY = measurement year; PPA = Performance Payment Adjustment. The Model is proposed to end December 31, 2025, which eliminates PPA periods 8, 9, and 10.

Source: Centers for Medicare & Medicaid Services. (2023, February). *End-Stage Renal Disease Treatment Choices (ETC) Model Performance Payment Adjustment report user guide (Measurement Years 1-2).* https://innovation.cms.gov/media/document/etc-ppa-report-user-guide

Modified payment adjustments. CMS amended the model in the second year (CY 2022) to provide additional support to ETC participants treating patients who are dually eligible for Medicare and Medicaid or who are enrolled in a Part D prescription drug plan and receive the Low Income Subsidy (LIS).[4] First, starting with MY3, which began on January 1, 2022, the PPA achievement benchmarks were stratified based on the percentage of attributed patient-years during the MY for FFS patients who were dually eligible for Medicare and Medicaid or who were recipients of the Part D LIS. CMS made this change in recognition of the historically lower home dialysis and transplant rates among patients with lower socioeconomic status, among other patient characteristics.[5,6,7]

In addition, CMS modified the PPA scoring methodology to allow ETC participants to receive a higher improvement score if they achieved sufficient improvement in home dialysis and transplant rates among attributed patients who were dually eligible for Medicare and Medicaid or Part D LIS recipients.[8] We provide more details about these modifications to the PPA in **Appendix B, Section B.8**. Together, these two refinements to the original ETC Model design that took effect in CY 2022 represent novel features of a health care payment model that were designed to promote improvements in care among patients who have historically had lower levels of access to care.

4 Centers for Medicare & Medicaid Services (CMS). Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. 86 *Fed. Reg*. 213, November 8, 2021.

5 Turenne M, Baker R, Pearson J, Cogan C, Mukhopadhyay P, Cope E. Payment reform and health disparities: Changes in dialysis modality under the new Medicare dialysis payment system. *Health Serv Res*. 2018 Jun;53(3):1430-1457.

6 Patzer RE, McClellan WM. Influence of race, ethnicity, and socioeconomic status on kidney disease. *Nat Rev Nephrol* 2012 Sep;8(9):533-541.

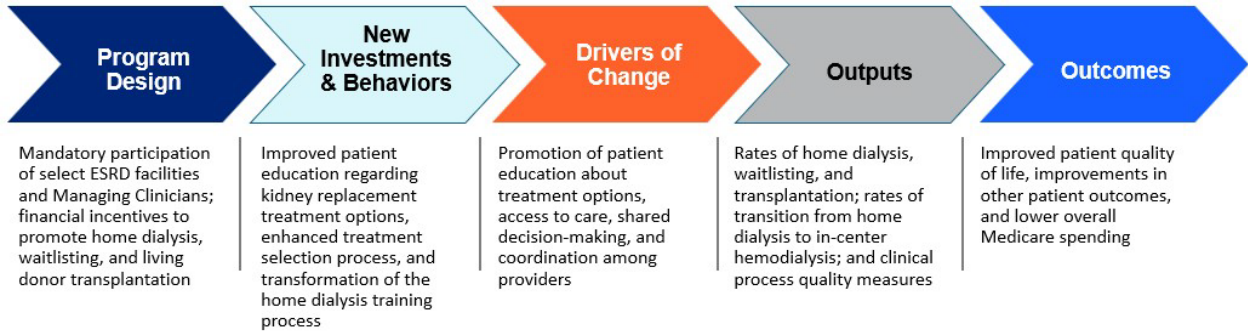
7 Murphy KA, Jackson JW, Purnell TS, Shaffer AA, Haugen CE, Chu NM, Crews DC, Norman SP, Segev DL, McAdams-DeMarco MA. Association of socioeconomic status and comorbidities with racial disparities during kidney transplant evaluation. *Clin J Am Soc Nephrol* 2020 Jun;15(6):843-851.

8 Through this modification to the PPA scoring methodology, ETC participants can earn 0.5 bonus points towards their improvement score for home dialysis or transplantation.

1.2. Theory of Action, Hypotheses, and Research Questions

We developed a detailed logic model that reflects the theory of action for the ETC Model and guided our evaluation design (see **Appendix A**). The logic model illustrates the conceptual framework for the process through which the ETC Model is expected to affect behavior and how changes in behavior (*drivers of change*) could lead to observable changes in outcomes. We apply the logic model and the embedded hypotheses to guide our analyses of the research questions for the evaluation. A high-level overview of the structure of the logic model is shown in **Exhibit 2**. Below we discuss the research questions addressed in this report.

Exhibit 2. ETC Logic Model (Abbreviated)



1.2.1. Who Participates in the ETC Model?

In promoting greater use of home dialysis and kidney transplantation, the ETC Model establishes separate incentives for two types of providers located in the selected ETC HRRs: ESRD facilities and Managing Clinicians. To provide context for the evaluation, we describe characteristics of the model participants as well as a comparison group of providers located in HRRs not selected for the model. We also describe characteristics of ETC markets and of patients who are attributed to model participants in relation to the markets and patients included in the comparison group. We use these analyses both to assess levels of balance in establishing the comparison group for the evaluation and to monitor the characteristics of ETC participants, the markets in which they are located, and attributed patients throughout model implementation.

1.2.2. What Were the Impacts of the ETC Model?

We used quantitative data to examine potential impacts of the model on several outcomes, including home dialysis use, transplantation, service utilization, Medicare payments, QoC, patient experience of care, and patient QoL. We first assessed whether the model's design to encourage home dialysis, transplant waitlisting, and transplantation affected the use of these renal replacement therapies. Given the model's incentives, changes in the use of these renal replacement therapies are of interest as potential outcomes that are most directly affected by the model. Increasing the use of home dialysis, transplantation, or both is also the primary mechanism by which we would expect any impacts on other outcomes of interest, such as QoC, patient experience of care, patient QoL, and cost of care. For AR3, we examined potential impacts of the model separately in each of the first 3 years of the model as well as cumulative impacts observed during the combined CY 2021–2023 period.

Dialysis modality. Home dialysis is a major focus of the model design and the evaluation. Home dialysis use in a given month determines whether the HDPA is applied to an ETC participant's

claim for that month, while previous levels of home dialysis use among attributed patients are given a weight of two-thirds in determining an ETC participant's PPA for a given period during model implementation. In addition to examining overall changes in the use of home dialysis, we separately explored impacts on the two major forms of home dialysis, peritoneal dialysis (PD), which is the most common form of home dialysis, and home hemodialysis (HD). PD involves the use of a peritoneal catheter that is placed in a patient's abdomen and used to instill dialysis solution into the peritoneal cavity, which draws waste products and excess fluid from the patient's body. Home HD is similar to in-center HD in that it involves the use of a dialysis machine to pump the patient's blood through a filter, or dialyzer, that is outside the patient's body and removes wastes and excess fluid. However, both home HD and PD allow patients to perform dialysis treatments at home and provide greater flexibility with the timing and frequency of their treatments.[9] While home dialysis training does not directly affect the payment adjustments of participants under the model, it may serve as a potential indicator of future home dialysis use as well as the future performance of participants. As such, we examined whether the model is associated with a change in how frequently patients with ESRD undergo training for home dialysis.

It is also possible that any early effects of the model on home dialysis use will be more likely to occur among certain subgroups of patients. We explored this possibility by examining impacts among patient subgroups defined based on the duration of ESRD, patient age, and whether the patient was treated at an ESRD facility with an established home dialysis program. As discussed further in **Section 1.2.3.**, we also examined whether the model had a different impact on patient subpopulations of interest in the context of preexisting differences in ESRD patient care and outcomes referred to earlier in this report.

Another consideration in understanding potential impacts of the ETC Model is that the overall frequency of home dialysis use among patients with ESRD will be the result of both gains in home dialysis use (among patients initiating dialysis for ESRD) and losses in home dialysis use (among patients switching from home dialysis to in-center HD). We therefore also separately examined whether the model led to changes in different types of transitions to and from home dialysis, including changes in the frequency with which patients transitioned away from home dialysis for specific reasons (e.g., transplantation, death).

Waitlisting and transplantation. The other major aspect of performance measurement under the ETC Model, kidney transplantation, has two dimensions: waitlisting for a deceased donor transplant and living donor transplantation.[10] The performance of participating ESRD facilities and Managing Clinicians along these dimensions in CY 2021 and later years is used in determining the PPAs that are being applied since July 2022. Thus, we assessed whether there is evidence of changes in transplant-related events in the first 3 years of the model.

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[9] For further information regarding the different types of dialysis, see https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis#whatis and https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis.

[10] There are two exceptions to note. For ESRD facilities, attributed patients for performance measurement under the model include those who received a transplant after initiating outpatient dialysis for ESRD. For Managing Clinicians whose attributed patients include preemptive living donor transplant recipients but do not include patients undergoing dialysis for ESRD, performance under the PPA is calculated based on living donor transplants only.

Patients who are waitlisted for a deceased donor kidney transplant (or a combined kidney and pancreas transplant) can be assigned to either active or inactive status, which model participants may have limited influence in determining. However, active waitlisting may be a more clinically relevant measure of access to transplants by focusing on candidates who are considered ready for transplant, which is not the case for candidates placed in an inactive status. A change in waitlisting of patients in active status may be more likely to have implications for quality of care and patient outcomes. Therefore, in addition to examining whether the ETC Model is associated with changes in overall waitlisting rates, we separately examined rates of active and inactive waitlisting for a transplant.

Utilization and Medicare payments. Changes in the use of home dialysis or transplantation could have important implications for service utilization more broadly as well as overall Medicare payments for patients with FFS coverage. Patterns in utilization and Medicare payments may differ with the use of home dialysis and transplantation compared with in-center HD or in the event that they are affected by any changes in QoC (as discussed further below). We examined changes in major types of utilization that may also be important indicators of both quality and efficiency, including acute care hospitalizations, emergency department (ED) visits (based on measures of overall ED visits, regardless of whether they led to an acute care hospitalization, and outpatient ED visits), and hospital readmissions.

In this report, we explore several potential sources of changes in Medicare payments due to the ETC Model. In addition to examining overall Medicare Parts A & B payments among FFS patients with ESRD, we examined major components of Part A & B payments as potential drivers of any changes in overall payments as well as Part D payments for patients enrolled in a stand-alone Part D plan. These analyses of Medicare payments do not account for the application of the ETC payment adjustments, including the HDPA and the PPA, and are used to assess whether there are any gross savings under the model. To explore the prospect of any net savings under the ETC Model when also accounting for effects of the HDPA and the PPA, we also examined the relative magnitude of these payment adjustments to ESRD facilities and Managing Clinicians during CY 2021–2023.

Quality of care. Changing patterns in home dialysis and transplantation could have important implications for QoC. There is potential for the effects of the model to be either positive or negative with respect to specific aspects of quality. For example, the ETC Model may enhance quality of care by encouraging greater consideration of home dialysis modalities and transplantation, which may benefit many patients, and by establishing incentives to reduce the frequency of treatment complications that might limit the long-term use of home dialysis modalities. At the same time, it is important to monitor for any potential unintended consequences with respect to quality of care when encouraging a shift in how dialysis modalities are being used to treat patients with ESRD.

In this report, we examine several indicators of QoC that capture important outcomes for patients with ESRD and potential complications of ESRD treatment. Mortality is an important outcome for the assessment of model impacts, given the high mortality risk for patients with ESRD undergoing dialysis. Other QoC indicators include measures of dialysis-related infections, including both peritonitis infections in PD patients and vascular infections in HD patients; measures of other

potential treatment complications, including hospitalizations with vascular access complications or ESRD complications; and measures of the adequacy of dialysis based on Kt/V.[11]

Patient experience of care. The model could have important implications for patient experience of care. Given the model's focus, the experiences of patients using home dialysis is of particular interest. By encouraging greater use of home dialysis, the model's incentives may positively affect how providers educate and otherwise support patients, not only in selecting a dialysis modality but also in initiating and maintaining home dialysis for those who choose to use home dialysis. Since CMS was not already surveying Medicare patients on home dialysis to collect data on their experience of care, we fielded a patient experience of care survey during 2024 for patients using a home dialysis modality in both ETC Model areas and in the comparison group. In this report, we use patient survey responses to examine potential differences in the experience of home dialysis patients in the ETC and comparison group.

The model could also have positive or negative implications for the experience of patients undergoing in-center HD, which continues to be the predominant renal replacement therapy. For example, if the model encourages better education and communication about home dialysis and transplantation as treatment options, patient experience could be more favorable among ETC patients than comparison patients, even among those electing or continuing in-center HD. However, there is also a risk that shifting focus toward alternative modalities could divert attention and resources away from the care of in-center HD patients and consequently result in an unintended adverse impact on in-center HD patient experience of care. To account for these possibilities, we continued to examine measures of in-center HD patient experience using data routinely collected as part of the ESRD Quality Incentive Program, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS®) survey.

Patient quality of life. The ETC Model has the potential to improve patient QoL by improving patient education and understanding of treatment options for ESRD, engaging patients more actively in shared decision-making, and promoting greater access to alternative forms of treatment that may allow patients greater independence and flexibility. Since data on patient QoL are not routinely collected, we fielded a QoL survey to patients in the ETC Model areas and in the comparison group during 2024 for each of the following groups of patients: patients with ESRD dialyzing at home, patients with ESRD dialyzing in-center, and kidney transplant recipients. As part of this report, we analyzed patient survey responses to assess whether there were differences in patient QoL between ETC and comparison patients.

[11] Kt/V values reported by ESRD facilities are used to measure the dose of dialysis, where K represents dialyzer clearance of urea, t represents dialysis time, and V represents the patient's total body water volume.

1.2.3. Did the ETC Model Have Differential Impacts for Patient Subpopulations of Interest?

With the ETC Model adopting modifications to the PPA starting in CY 2022[12] that provide additional support to ETC participants treating patients who are dually eligible for Medicare and Medicaid or recipients of the Part D LIS, there is stronger potential for the model to promote growth in home dialysis and transplant among these patients. A potential challenge for ETC participants is the ability to address ongoing barriers to home dialysis and transplantation that may have previously contributed to lower use of home dialysis and transplantation among some patient groups. We used multiple approaches in AR3 to evaluate the potential implications of the model for access to home dialysis and transplantation among patients who are likely to face greater barriers to care. First, we examined whether the impacts of the ETC Model in the first 3 years of the model differed among several patient subgroups of interest, including the populations targeted by the model's incentives (dually eligible patients and Part D LIS recipients), and patients in rural versus urban areas. We estimated impacts for these patient subgroups and assessed whether they differed from those observed for corresponding reference populations. In addition to assessing the relative impacts of the model on the use of home dialysis, waitlisting, transplantation, and changes in home dialysis modality transitions and complications, we examined other selected indicators of utilization and QoC.

There may also be patterns in the performance of ETC participants and in the corresponding ETC payment adjustments that have future implications for differences in patient access to home dialysis and transplantation. For example, higher overall performance among ETC participants that disproportionately treat patient subpopulations of interest may indicate progress in addressing barriers to home dialysis and transplantation under the model, and an increase in payments to these providers through the ETC payment adjustments could support additional gains for their patients in future years. Alternatively, lower overall performance among participants that disproportionately treat patient subpopulations of interest may reflect widening gaps in home dialysis and transplant rates under the model. These gaps may be based on factors such as type of insurance, or result from negative payment adjustments, and limit resources participants have to devote to initiatives designed to address barriers to care. To explore these issues, we compared MPS and corresponding PPA percentage amounts among ETC participants based on the dual eligibility status, Part D LIS status, and rural versus urban location of their attributed patients.

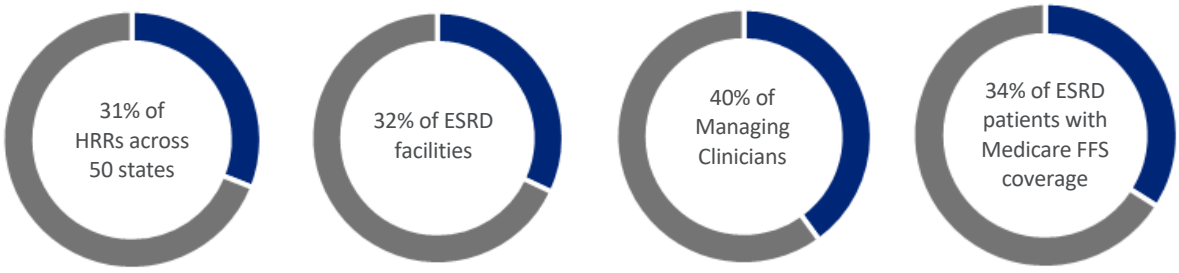
As part of our mixed-methods approach, we also conducted case studies to improve our understanding of any ETC participant efforts to address barriers to home dialysis use and transplantation and factors that may prevent or facilitate growth in home dialysis use and transplantation among patients who may generally have lower levels of access to care. In carrying out these case studies during 2024, we conducted interviews with a sample of ESRD facilities, Managing Clinician practices, and patients in four ETC Model areas with a disproportionately high percentage of dually eligible patients. The case study areas include both urban and rural areas and

[12] As summarized in **Section 1.1.** and described further in **Appendix B Section B.8.**, the PPA calculation methodology was modified in two ways: (1) when assessing achievement, CMS uses different achievement benchmarks for ETC participant home dialysis and transplant rates based on the percentage of their patient months attributed to dually eligible beneficiaries and Part D LIS recipients; and (2) when assessing improvement, CMS provides ETC participants with an opportunity to earn additional improvement points if there was sufficient improvement over time in their home dialysis and transplant rates among dually eligible beneficiaries and Part D LIS recipients.

are diverse with respect to geographic location and the performance of ETC participants. We integrate findings from these case studies with findings from the quantitative analyses described above to assess the potential implications of the model for patient access to home dialysis and transplantation.

2. Who Participates in the ETC Model?

Key Findings: Participant Characteristics



- Selected geographic areas and comparison geographic areas exhibited high degree of balance with the exception of select market level characteristics. The ETC areas had a higher penetration of patients enrolled in Medicare Advantage plans and a greater alignment with the CEC Model than the comparison areas in the pre-implementation period.
- With the implementation of the 21st Century Cures Act in 2021, enrollment of patients with ESRD in Medicare Advantage plans increased similarly in both groups. From 2017-2019 to 2021-2023, enrollment increased from 5.8% to 24.0% in ETC areas and from 7.5% to 24.3% in comparison areas.
- With the increasing enrollment of patients with ESRD in MA plans, there was a similar shift over time in case mix among Medicare FFS patients with ESRD in ETC and comparison areas. Between 2017-2019 and 2021-2023, FFS patients in both groups were less likely to be female, dually eligible, and recipients of the Part D LIS. While overall balance between the two groups across patient and ETC participant characteristics was maintained during CY 2021–2023, ETC areas showed greater alignment of Medicare patients with the Kidney Care Choice (KCC) Model than the comparison areas.

Note: ESRD = end-stage renal disease; FFS = fee-for-service; HRR = hospital referral region. ETC Model Participant characteristics were calculated based on CY 2021–2023 data. CEC: Comprehensive ESRD Care Model. KCC: Kidney Care Choices Model.

The selection process for the ETC Model resulted in the inclusion of 95 HRRs in the ETC areas. The HRRs consisted of 91 that were selected at random from the four U.S. census regions (out of 306 HRRs in the United States) and four HRRs for which at least 20% of the component ZIP Codes are located in Maryland. Together, the selected 95 HRRs account for 31% of the HRRs in the United States. Reflecting the random selection of HRRs within regional strata, the ETC areas are geographically distributed throughout the country (see **Exhibit 3**). The ETC areas include 40 states, and the comparison geographic areas include 43 states. Seven states fall entirely in the ETC areas,[13] 10 states fall entirely in the comparison areas,[14] and 33 states are split between the two groups. All Medicare-certified ESRD facilities and Managing Clinicians in the ETC areas must participate in the ETC Model.

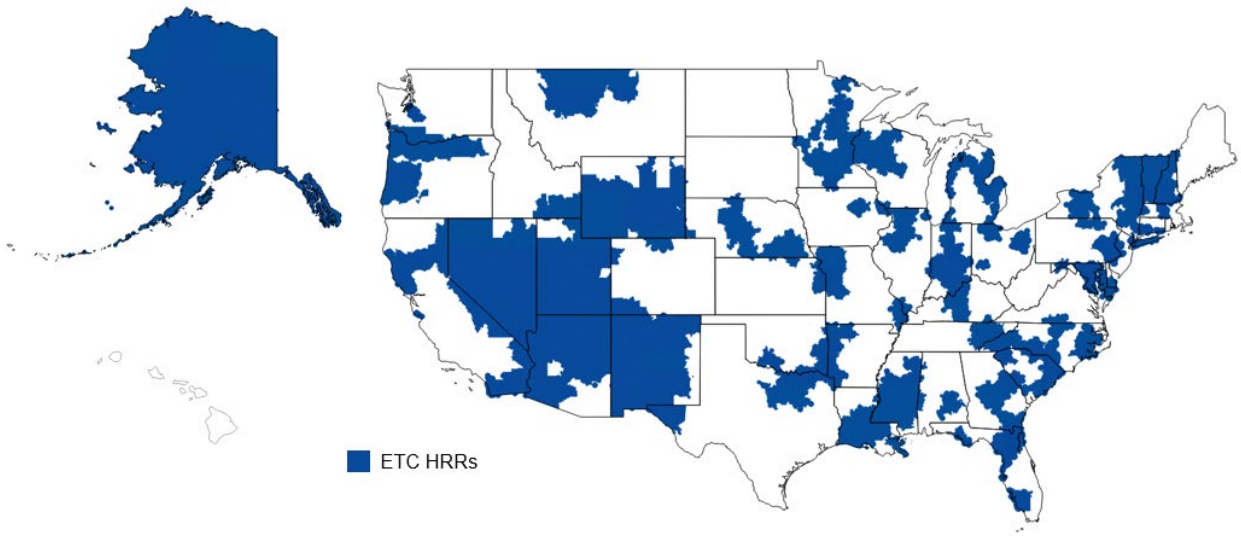
[13] Alaska, Maryland, Nevada, New Hampshire, New Mexico, Vermont, Wyoming
[14] Delaware, Hawaii, Idaho, Kansas, Maine, North Dakota, Rhode Island, South Dakota, Virginia, West Virginia

In this section, we describe the following:

- Characteristics of patients, ESRD facilities, Managing Clinicians, and HRRs in the selected and comparison geographic areas in the pre-ETC period (CY 2017–2019) and the first 3 years of the model (CY 2021–2023)
- Characteristics of patients with Medicare FFS coverage and patients enrolled in Medicare Advantage (MA) in the post-ETC period (CY 2021–2023)

As noted in **Exhibit 4** - **Exhibit 7**, the selected and comparison geographic areas in the pre-ETC period exhibited a high degree of balance across diverse patient, provider, and market characteristics, which informed the development of the comparison group. Because expanded eligibility of patients with ESRD for MA in 2021 could have led to differences in FFS patient case mix between the selected and comparison geographic areas, we also examined characteristics of patients, facilities, and Managing Clinicians in the post-ETC period. Additionally, we examined trends in MA enrollment as a share of all ESRD Medicare patients over CY 2017–2023 and compared characteristics of Medicare FFS patients with ESRD against MA patients with ESRD during the post-ETC period (CY 2021–2023).

Exhibit 3. Map of ETC HRRs



Note: HRR = hospital referral region.

2.1. Methods

Participation in the ETC Model is mandatory for ESRD facilities and Managing Clinicians in the selected HRRs. We constructed a patient-month–level dataset for analysis that included one observation per Medicare FFS patient per month (PPPM) for CY 2017–2023 for patients with ESRD and preemptive living donor transplant recipients who meet the eligibility criteria for the ETC Model. The dataset included patient characteristics and primary utilization, payment, and quality outcomes from 2017–2023 Medicare claims, transplant, and waitlisting outcomes from the

2017–2023 Scientific Registry of Transplant Recipients (SRTR) files,[15] facility-level characteristics from the 2017–2023 ESRD Quality Reporting System (EQRS), and market-level characteristics from the 2019 Area Health Resource Files (AHRF). We considered 2017–2019 as the pre-ETC period and excluded 2020 from the study (see **Appendix B, Sections B.1–B.3** for further details about data sources, the study population, and the study period).

Key Points

- Mandatory participation of ETC participants in the selected HRRs
- Examined balance between 95 ETC HRRs and 211 comparison HRRs on patient, ETC participant, and market characteristics

We assessed balance between the 95 HRRs selected for the ETC Model with the 211 HRRs in the comparison geographic areas based on the characteristics of ESRD facilities, Managing Clinicians, markets, and patients. We computed standardized mean differences (SMDs) and compared the absolute value against a threshold of 0.2 to identify any imbalance between the two groups. For more details on this analysis, see **Appendix B, Section B.4**.

2.2. Results and Discussion

2.2.1. Characteristics of ETC Participants

ESRD facilities. Outpatient ESRD facilities located in the ETC areas are designated as ETC participants. Facilities located in the comparison geographic areas comprise the comparison group (hereafter referred to as comparison areas).

ESRD Facilities and Managing Clinicians

Findings | The measured characteristics of ESRD facilities and Managing Clinicians showed balance between ETC and comparison groups.

ESRD facilities and Managing Clinicians in both groups observed a decline in the number of FFS dialysis patients and an increase in the total number of home dialysis patients over time.

Randomization at the HRR level appears to have yielded intervention and comparison groups with similar average ESRD facility characteristics. In **Exhibit 4**, we describe select characteristics of the ETC and comparison facilities in the pre-ETC period. About 32% of ESRD facilities are ETC participants, similar to the share of selected HRRs. Comparisons of ETC and comparison facilities over a broad range of characteristics revealed overall balance, as confirmed by consistently small SMD scores (see **Appendix B, Exhibit B-12**).

[15] The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. This evaluation was submitted to a functioning institutional review board (IRB) and determined IRB exempt.

Most characteristics of ESRD facilities were relatively stable between the pre-ETC and post-ETC periods, for both the ETC and comparison groups. Exceptions include a decline over time in the number of FFS dialysis patients and an increase over time in the total number of home dialysis patients regardless of insurance, which were observed in both groups.

Exhibit 4. ESRD Facility Characteristics by ETC Participant Status, CY 2017–2019 (Pre-ETC Period) and CY 2021–2023 (Post-ETC Period)

Variable		ETC Mean		Comparison Mean	
		Pre-ETC	Post-ETC	Pre-ETC	Post-ETC
		N = 2,512	N = 2,591	N = 5,227	N = 5,402
Number of HD Stations		17.4	17.3	17.5	17.5
Facility Ownership	DaVita	37.7%	37.3%	39.5%	39.4%
	Fresenius	39.1%	38.8%	34.9%	34.6%
	Independent/Nonchain For-Profit	3.5%	4.4%	5.1%	5.6%
	Other For-Profit	9.9%	10.8%	8.4%	8.9%
	Nonprofit	9.7%	8.8%	12.2%	11.5%
Facility Patient Volume (Medicare FFS Patients)[1]	≤50	36.7%	50.3%	39.3%	53.1%
	>50 and ≤75	21.2%	25.4%	21.8%	26.3%
	>75 and ≤100	18.0%	13.5%	17.1%	12.0%
	>100	24.0%	10.8%	21.8%	8.6%
In-Center HD Service Provided		94.8%	94.1%	92.9%	92.8%
Peritoneal Dialysis Service Provided		50.5%	50.3%	54.1%	54.0%
Home HD Training Service Provided		28.9%	28.7%	30.5%	30.3%
Facility Has Shift after 5:00 p.m.		15.9%	15.0%	16.4%	15.5%
Total In-Center Dialysis Patients		57.4	53.6	59.0	54.7
Total Home Dialysis Patients		7.6	9.7	8.1	10.0
Total Patients Receiving Any Dialysis Care[2]		65.0	63.3	67.1	64.7
Facility Region	Northeast	14.7%	15.0%	13.3%	13.5%
	Midwest	20.3%	19.5%	21.2%	20.4%
	South	47.3%	47.6%	45.2%	44.9%
	West	17.8%	17.9%	20.3%	21.2%
Facility RUCC	Metro	83.0%	83.3%	83.4%	84.3%
	Urban	16.3%	16.0%	15.9%	15.0%
	Rural	0.64%	0.69%	0.69%	0.65%

Note: Pre-ETC period = CY 2017–2019. Post-ETC period = CY 2021–2023.

[1] Facility volume is based on number of unique Medicare FFS patients treated in a year. Facility attributes averaged, with equal weight given to all facilities in each group.

[2] Obtained from the CMS 2744 form, this corresponds to the total number of patients receiving any dialysis in any setting at the end of the survey period.

ESRD = end-stage renal disease; FFS = fee-for-service; HD = hemodialysis; RUCC = Rural-Urban Continuum Code.

Managing Clinicians. The ETC areas include about 40% of Medicare Managing Clinicians nationwide. Displayed in **Exhibit 5** are select average characteristics of Managing Clinicians during the pre-ETC and post-ETC periods.

The ETC and comparison areas were balanced overall with respect to the predominant clinician specialty (nephrology) and most other observed characteristics. Similar to the ESRD facilities, both the ETC and comparison areas show declines between the pre-ETC and post-ETC periods in the average number of FFS patients treated by Managing Clinicians per month and increases in the percentage of patients using home dialysis modalities.

Exhibit 5. Managing Clinician Characteristics by ETC Participant Status, CY 2017–2019 (Pre-ETC Period) and CY 2021–2023 (Post-ETC Period)

Characteristic		ETC		Comparison	
		Pre-ETC	Post-ETC	Pre-ETC	Post-ETC
		N = 6,650	N = 6,379	N = 9,539	N = 9,678
		Mean	Mean	Mean	Mean
Demographics	Mean Age, Years	48.7	49.3	49.7	50.3
	Male	64.7%	60.3%	65.8%	62.3%
Specialty	Nephrology	75.3%	71.8%	74.3%	71.1%
	Nurse Practitioner	11.9%	14.9%	10.6%	13.3%
	Internal Medicine	8.0%	7.2%	9.3%	9.0%
	Physician Assistant	2.1%	2.5%	2.2%	2.5%
	Certified Clinical Nurse Specialist	0.11%	0.04%	0.23%	0.20%
	Other	2.5%	3.5%	3.3%	3.9%
Average Patient Volume and Characteristics	Number of FFS Dialysis Patients per Month	28.6	18.9	28.3	18.7
	Average Age	61.4	63.2	61.8	63.5
	Male	56.8%	57.6%	57.1%	58.0%
	Dually Eligible	47.2%	44.7%	48.3%	46.2%
Average Number of FFS Patients Treated per Month by Dialysis Modality	In-Center HD	25.4	16.1	25.0	15.8
	Peritoneal Dialysis	2.6	2.2	2.8	2.3
	Home HD	0.54	0.57	0.51	0.51
	Other	0.01	0.01	0.01	0.01
Percentage of FFS Patients Treated per Month by Dialysis Modality	In-Center HD	88.5%	85.6%	87.2%	84.3%
	Peritoneal Dialysis	9.6%	11.4%	10.8%	12.7%
	Home HD	1.9%	2.9%	2.0%	2.9%
	Other	0.05%	0.08%	0.06%	0.08%

Note: Results displayed are based on yearly averages and cover CY 2017–2019 for the pre-ETC period and CY 2021–2023 for the post-ETC period. FFS = fee-for-service; HD = hemodialysis.

2.2.2. What Are the Characteristics of the Markets in Which Facilities and Providers Participate in the ETC Model?

Market-Level Characteristics

Findings | ETC HRRs had lower MA penetration and greater alignment of Medicare patients with the Kidney Care Choices (KCC) Model.

All other measured characteristics showed balance between ETC and comparison HRRs.

Randomization for the ETC Model was done at the HRR level, stratified by the four census regions (Northeast, Midwest, South, and West). Accordingly, we compared select market characteristics for the ETC and comparison areas (see **Exhibit 6**). When comparing the calculated SMDs against the 0.2 threshold value, there was balance across a diverse set of characteristics, such as median age, high school education, poverty, and measures of health system capacity. ETC areas also had lower MA penetration and greater alignment of Medicare patients with the KCC Model. A detailed balance table is included in **Appendix B, Exhibit B-14**.

Exhibit 6. Market (HRR)-Level Characteristics by ETC Status, CY 2017–2019 (Pre-ETC Period)

Characteristic		ETC Mean	Comparison Mean
		N = 95	N = 211
Demographic Characteristics	Median Age, Years, 2010	38.8	38.4
	Persons above Age 25 without a High School Diploma	9.0%	9.0%
	MA Penetration	31.1	33.7
	Poverty	13.0%	13.0%
Market-Level Capacity (Number per 100,000 Population)	Short-Term General Hospitals	2.4	2.5
	Long-Term Care Hospital	0.11	0.12
	Short-Term General Hospitals with HD	0.38	0.41
	Nonfederal Transplant (that is, Transplant Surgeons)	0.03	0.04
	Nonfederal PCP, Patient Care	67.3	66.7
	Nonfederal PCP, Hospital Resident	6.1	6.3
Market Characteristics	ACO Patients (%)	31.0%	28.9%
	Comprehensive ESRD Care Model Patients (%)	0.14%	0.09%
	Kidney Care Choice Patients2 (%)	0.31%	0.25%

Note: County-level data are based on publicly available Area Health Resources Files. HRR market attributes averaged (equal weight to all HRRs) in each group[2] Corresponds to the percentage of Medicare FFS beneficiaries in the county who are in the KCC Model based on data for 2022–2023. ACO = Accountable Care Organization; ESRD = end-stage renal disease; HD = hemodialysis; HRR = hospital referral region; MA = Medical Advantage; PCP = primary care physician.

2.2.3. What Are the Characteristics of Patients Attributed to ETC Model Participants?

Medicare beneficiaries with ESRD requiring dialysis treatment are attributed to the ETC Model if they are treated in participating ESRD facilities or by participating Managing Clinicians and do not meet a set of defined exclusion criteria. ETC eligibility and exclusion criteria and attribution status are determined monthly for each patient and the unit of analysis for most analyses for the ETC Model evaluation is the patient-month (see **Appendix B, Section B.2**).[16]

2.2.3.1. Balance of Patient Characteristics

Characteristics of Patients Attributed to ETC Participants

Findings | In the pre-ETC period, there was balance between ETC and comparison areas across a wide range of patient characteristics. However, there were more patients aligned to the CEC and KCC Models in ETC areas.

We observed similar declines in the number of Medicare FFS patients in both the ETC and comparison areas during CY 2017–2023.

We assessed balance in the ETC and comparison areas across a wide range of patient characteristics that include demographics, duration of ESRD, health insurance, alignment with Alternative Payment Models, primary cause of ESRD, other health conditions, and pre-ESRD nephrologist care (see **Exhibit 7** and **Appendix B, Exhibit B-11** for more details). During CY 2021-2023, 34% of Medicare FFS beneficiaries with ESRD were attributed to ETC participants.

In the pre-ETC period, patients in the ETC and comparison groups had a similar average age (62 years), had an average of 5.2 years since ESRD onset, and were balanced in terms of the primary cause of ESRD, nephrology care prior to ESRD, dual eligibility, and Part D LIS eligibility (see **Exhibit 7**). The two groups were also balanced across claims-based and ESRD-related comorbidities (see **Appendix B, Exhibit B-11**).

Patients in the ETC areas exhibited a higher likelihood of alignment to CMS Innovation Center kidney models than comparison area patients. In the pre-ETC period, ETC patients were more likely to have been aligned to the CEC Model than patients in comparison areas (20% of ETC vs. 12% of comparison patient-months). In the post-ETC period a higher proportion of ETC patient-months were aligned with Managing Clinicians who volunteered to participate in the KCC Model compared to comparison patients (52% of ETC vs. 42% of comparison patient-months in the post-ETC period).

[16] The exceptions involve analyses of mortality, which employ patient-level time-to-event models, and analyses of in-center HD patient experience of care, which are based on facility-level data from the ICH-CAHPS survey. We describe these analyses further in **Section 4**.

For CY 2021–2023, we observed comparable changes in both groups relative to the pre-ETC period:

- Between 2017 and 2023, enrollment of patients with ESRD in Medicare Advantage (MA) plans increased from 5.8% to 24.0% in ETC areas and from 7.5% to 24.3% in comparison areas (see **Section 2.2.3.2.** for details). Consequently, the number of FFS patients declined by 34% in ETC areas (from 115,971 in 2017 to 76,715 in 2023) and by 35% in the comparison areas (from 229,963 in 2017 to 150,098 in 2023).
- Both groups showed similar trends in patient case mix between the pre-ETC and post-ETC periods, which include an increase in average age; a decrease in the percentage of dually eligible patients and Part D LIS recipients; and an increase in the percentage of patients receiving nephrology care prior to ESRD.
- Given the similar trends between the ETC and comparison areas, there continued to be overall balance in patient characteristics between the two groups (**Exhibit 7** and **Appendix B, Exhibit B-11**).

Exhibit 7. Medicare FFS ESRD Patient Characteristics by ETC Status, CY 2017–2019 (Pre-ETC Period) and CY 2021–2023 (Post-ETC Period)

Characteristic			ETC Mean		Comparison Mean	
			Pre-ETC N = 3,116,487	Post-ETC N = 2,172,797	Pre-ETC N = 6,165,610	Post-ETC N = 4,267,259
Patient Characteristics	Mean Age, Years		61.7	63.4	62.0	63.6
	Median Age, Years		63.0	65.0	63.0	65.0
	Female		43.2%	42.3%	42.9%	41.9%
	Time from Start of ESRD (Years)		5.2	5.4	5.2	5.3
	Dually Eligible (Full or Partial Benefits)		47.2%	44.5%	48.6%	46.9%
	Part D Benefit Enrollment		81.6%	78.5%	81.9%	79.1%
	Part D LIS (among Part D Enrollees)		67.8%	61.2%	69.2%	63.0%
	Medicare Shared Savings Program		22.3%	19.3%	22.3%	23.6%
	Alternative Payment Models	CEC	20.3%	2.4%	12.4%	1.1%
		KCC Provider Alignment[1]	49.1%	52.4%	39.8%	42.3%
		NGACO	2.9%	0.8%	3.5%	0.8%
Health Conditions at Start of Dialysis (Data Source: EQRS 2728 form)	Primary Cause of ESRD	Diabetes	42.9%	41.8%	44.6%	43.1%
		Glomerulonephritis	11.5%	11.0%	11.0%	10.3%
		Hypertension	31.4%	31.0%	30.1%	30.0%
		Other	14.1%	16.2%	14.3%	16.6%
	Health Status at Start of ESRD	Diabetes	51.3%	52.4%	52.4%	53.6%
		Congestive Heart Failure	21.5%	20.5%	21.7%	20.6%
		Atherosclerotic Heart Disease	10.2%	9.1%	9.9%	9.0%
	Nephrologist Care Prior to ESRD Therapy	Less than 6 Months	12.4%	14.3%	12.5%	14.5%
		6–<12 Months	19.1%	19.5%	18.3%	18.9%
		12 Months or Longer	29.2%	32.3%	28.3%	31.2%
		Not under Care of Nephrologist prior to ESRD	20.8%	17.0%	21.3%	18.0%
		Unknown	18.5%	16.9%	19.6%	17.5%

Note: Pre-ETC period = CY 2017–2019. Post-ETC period = CY 2021–2023. A patient may contribute up to 12 observations per year to this patient-month summary.

[1] Percentage of patient-months aligned with a clinician who later volunteered for KCC anytime between 2022 and 2023.

CEC = Comprehensive ESRD Care; ESRD = end-stage renal disease; EQRS = End-Stage Renal Disease Quality Reporting System; KCC = Kidney Care Choices; LIS = Low-Income Subsidy; NGACO = Next Generation ACO.

2.2.3.2. Upward Trend in Medicare Advantage Enrollment

Medicare Advantage

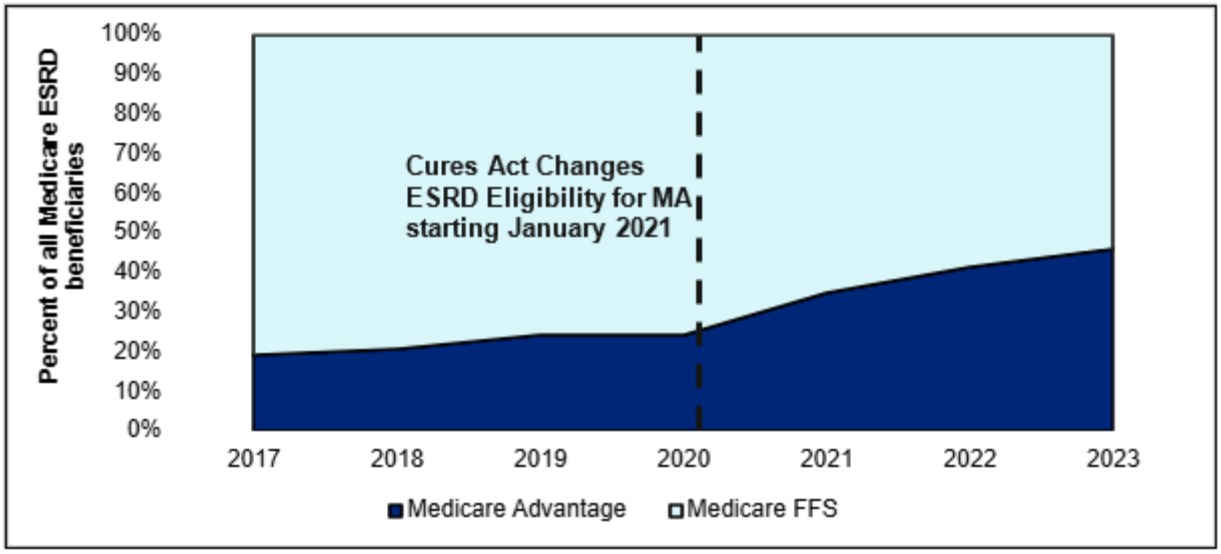
Potential Impacts | New MA enrollment rules that took effect in 2021 lifted restrictions on the ability of patients with ESRD to enroll in MA plans, which has potential implications for the ETC study population.

Findings | The ETC patient sample size has steadily declined since 2021 due to greater enrollment of beneficiaries with ESRD in MA plans.

Beneficiaries remaining in FFS Medicare have different demographic and socioeconomic characteristics than those who enrolled in MA.

The ETC Model began in 2021, coinciding with the implementation of the 21st Century Cures Act, which changed the rules governing the enrollment of patients with ESRD in Medicare managed care plans (MA). Prior to 2021, MA was only available to beneficiaries who were Medicare eligible based on age or disability and enrolled in an MA plan prior to the onset of ESRD. Most patients with ESRD were covered by the Traditional Medicare (FFS) program. Starting in 2021, all new and existing ESRD beneficiaries had the option of selecting MA. The rate of growth in MA accelerated in 2021, matched by a decline in Medicare FFS enrollment of all beneficiaries with ESRD (not restricted to ESRD beneficiaries in the ETC Model) from approximately 80% in 2021 to approximately 55% by 2023 (see **Exhibit 8**).

Exhibit 8. Increasing Enrollment in MA among Medicare Beneficiaries with ESRD, CY 2017–2023



Note: Data obtained from Medicare Beneficiary Summary Files to classify ESRD dialysis patients either as FFS or MA (see **Appendix B B.4.1.1** for more details). This figure represents all beneficiaries with ESRD, not restricted to ESRD beneficiaries in the ETC Model. ESRD = end-stage renal disease; FFS = fee-for service; MA = Medicare Advantage.

The rates of enrollment in MA plans increased similarly in both groups, rising from 5.8% in 2017-2019 to 24.0% in 2021-2023 in ETC areas and from 7.5% to 24.3% in comparison areas. The beneficiaries who selected MA were more likely to be female and dually eligible for Medicare and Medicaid (see **Exhibit 9**). MA patients are older than FFS patients, but the age gap is narrowing as

more new patients select MA. Similarly, fewer MA patients qualified for Medicare on the basis of ESRD (vs. age or disability), but this trend is changing as more patients with ESRD select MA.

Exhibit 9. Patient Characteristics by Medicare Enrollment Status in the Post-ETC Period (CY 2021–2023)

Patient Characteristics		Beneficiaries with ESRD Enrolled in Medicare FFS (CY 2021–2023)	Beneficiaries with ESRD Enrolled in MA plan (CY 2021–2023)
		N = 11,253,938	N = 7,703,061
Mean Age, Years		62.6	66.4
Female		40.5%	43.9%
Dual Eligibility (any status)		40.2%	50.5%
Reason for Medicare Eligibility	Age with ESRD	45.8%	59.0%
	Disability with ESRD	28.3%	31.4%
	ESRD Only	25.9%	9.6%

Note: ESRD = end-stage renal disease; FFS = fee-for-service; MA = Medicare Advantage.

The large, nonrandom shift of beneficiaries from FFS to MA enrollment has potential implications for the ETC Model and the evaluation. The ETC sample size is smaller than initially planned. As a result, the number of outcome events (home dialysis, waitlisting, and transplantation) is smaller than would be the case if the FFS population were stable. However, as noted (see **Appendix C**), sample size and power calculations continue to indicate that the ETC Model is sufficiently powered to detect important differences in key outcomes. Also as indicated by the balance of patient characteristics above (see **Exhibit 7**), the shift in enrollment among beneficiaries with ESRD from FFS to MA appears to be comparable for the ETC and comparison groups. The extensive set of covariates included in the impact specification offers further protection against potential group imbalances (see **Appendix B, Exhibits B-11–B-13 and B-20**).

2.3. Conclusion

The ETC Model design includes random selection at the HRR level and mandatory participation of ESRD facilities and Managing Clinicians in the selected HRRs. These features are relatively unique among health care demonstration models and help assure that the study will yield findings that are representative and scalable. In fact, the selection process yielded a geographically broad and diverse selected sample (see **Exhibit 3**). Overall, ETC and comparison areas were reasonably balanced. Of the 175 characteristics assessed at the ESRD facility, Managing Clinician, market, and patient level, only seven showed an imbalance based on a SMD greater than 0.2. Although the overall level of balance between the ETC and comparison groups was high, the model evaluation will adjust for multiple facility, Managing Clinician, market, and patient characteristics, including those that are not completely balanced.

The ETC Model excludes patients enrolled in MA plans and focuses on enrollees in the Traditional Medicare (FFS) program. The relatively large shift of beneficiaries from FFS to MA that has occurred so far during the first three years of the ETC Model has affected the study sample size and patient characteristics, although statistical power was preserved. Despite changes in patient case mix between the pre- and post-ETC periods, the overall balance between the ETC and comparison groups has been maintained. It will be important to continue to assess balance in patient characteristics and monitor MA enrollment trends for each year of the ETC Model.

3. What Were the Impacts of the ETC Model?

Key Findings: Model Impacts

Domain	Outcome	Cumulative ETC Model Impact, CY 2021–2023
Dialysis Modality Measures	Home Dialysis	
	Peritoneal Dialysis	
	Home Hemodialysis	
	In-Center HD^	
	In-Center HD	
	In-Center Self-Dialysis	
	Nocturnal Hemodialysis	
	Home Dialysis Training	↑
	Home Dialysis Gains^^	
	Home Dialysis Losses^^	
Transplantation	Overall Waitlisting	
	Active Status	
	Inactive Status	
	Overall Transplants	↑
	Deceased Donor	↑
	Living Donor	
	Living Donor (Dialysis and Preemptive)	
Utilization	Acute Care Hospitalization	
	Readmission	
	Outpatient ED use	
	Total ED use	
Medicare Payments	Total Part A & B[1]	
	Total Part A	
	Part A Acute Care Hospitalization	
	Part A LTCH and IRF	
	Other Part A	
	Total Part B[1]	
	Part B Dialysis[1,2]	
	Other Part B	
	Part D	
Quality	Peritonitis	
	ESRD Complications	
	Vascular Access Complications	
	Vascular Infection	
	Kt/V	
	Mortality[3]	

Key:		Favorable at p<0.10		Unfavorable at p<0.10		No Change

Note: See footnote 17 for full notes to Key Findings table.

This section summarizes quantitative findings of the impact of the ETC Model on dialysis modality, transplant waitlisting, kidney transplantation, utilization, Medicare payments, quality of

care, and in-center HD patient experience of care over the first 3 years of the model, CY 2021–2023.[17] New in this report, we include findings from patient experience of care from two newly fielded surveys—a home dialysis care experience survey and the Patient-Reported Outcomes Measurement Information System (PROMIS-29) QoL survey (see **Section 5.**). Additionally, we also examined measures of modality transitions (to characterize the sources of modality gains and losses contributing to home dialysis prevalence), total ED visits, modality-specific outpatient dialysis payments, and Kt/V as a quality measure.

3.1. Methods

Key Points

- Examined 46 measures across several domains, including modality, transplantation, utilization, cost, and quality of care
- Examined both HDPA and PPA payment adjustments made to ETC participants during CY 2021–2023

To estimate the impacts of the model, we used a difference-in-differences (DiD) framework to compare changes in outcomes for patients observed over time in the ETC areas with patients in a comparison group consisting of HRRs that were not selected for inclusion in the ETC Model. The DiD framework offers a quasi-experimental design and enables us to control for changes common to all patients over time, as well as for unmeasured differences between the ETC and comparison areas that do not change over time. All attributed and eligible patients receiving care from ESRD facilities and Managing Clinicians in a given month within the ETC HRRs comprised the treatment groups, while those receiving care in the HRRs not selected in the model formed the comparison group. We defined 3 years prior to the start of the model, CY 2017–2019, as the pre-ETC period and excluded 2020 from the study period.

We produced yearly and aggregate (cumulative) DiD impact estimates for CY 2021–2023, based on a patient-month–level analytic file created using Medicare enrollment and claims data along with EQRS, facility-level, transplant registry and market data sources. We adjusted for patient, facility, and market characteristics in DiD models (see **Appendix B, Exhibit B-20**) to account for potential confounders and residual imbalance that existed between the two groups despite randomization. Notably, given the overlapping goals of the ETC and KCC Models, we controlled for participation of Managing Clinicians in the KCC Model[18] in 2022 and 2023 in the DiD analysis. Each impact estimate, based on a DiD model, reflects the difference in the risk-adjusted mean outcome for patients in the ETC group before and after model implementation relative to the same difference over time for patients in the comparison group.

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[17] Notes for key findings graphic on previous page: Arrows indicate the direction of the statistically significant cumulative impact estimate. Detailed impact estimates for each outcome are included in the body of the report. ^In-center HD includes in-center hemodialysis, in-center self-dialysis, and in-center nocturnal dialysis. ^^Components of home dialysis gains (new patient gains, established patient gains, gains after failed transplant) and home dialysis losses (loss to in-center HD, loss to transplant, loss to death or withdrawal) were also examined (see **Appendix B, Section B.5.2**). [1]Does not include ETC payment adjustments. [2]Examined modality-specific outpatient Part B dialysis payments (in-center, home hemodialysis, peritoneal and home dialysis). [3]The post-ETC and pre-ETC hazard ratios of mortality obtained from risk-adjusted Cox proportional hazards model were similar. CAHPS = Consumer Assessment of Healthcare Providers and Systems; ED = emergency department; HD = hemodialysis; IRF = inpatient rehabilitation facility; LTCH = long-term care hospital; PROMIS = Patient-Reported Outcomes Measurement Information System.

[18] Implemented in 2022.

Details on the DiD methodology, including data sources, methods for identifying attributed and eligible patients, approaches used to test the parallel trends assumption, and unadjusted means of outcome measures and impact estimates are included in **Appendix B**. We discuss the evaluation's statistical power to detect impacts in **Appendix C.**

We assessed whether the impact of the ETC Model is heterogeneous among different subgroups of interest using a difference-in-difference-in-differences (DDD) model, adjusting for the same set of patient, facility, and market risk-adjusters as in the DiD model (see **Appendix B.8** and **Exhibit B-20**). We evaluated mortality as time-to-event using the Cox proportional hazards model. Using an intent-to-treat approach, we evaluated mortality risk separately in the pre-ETC period (CY 2017–2019) and the ETC intervention period (CY 2021–2023 for this report). We include details on mortality analyses in **Appendix D.** In addition to conducting impact analyses, we examined the two distinct types of the ETC Model payment adjustments, the HDPA and the PPA, to describe the net payment impacts of the model. We provide the sum of the payment adjustments during CY 2021–2023 by type and year. We include details on the net ETC payment adjustment methodology in **Appendix B**.

In this report, we present DiD analyses of 46 claims-based, SRTR-based, and ICH CAHPS measures, along with regression analyses of three measures of the home dialysis care experience survey and eight PROMIS-29 outcomes of patient QoL, as noted above. New in AR3, along with patient experience of care measures from two newly fielded surveys this year, we also examined measures of modality transitions (to characterize the sources of modality gains and losses contributing to home dialysis prevalence), total ED visits, modality-specific outpatient dialysis payments, and Kt/V as a quality measure. **Exhibit 10** shows the list of outcome measures included in this section.

Exhibit 10. ETC Model Evaluation Outcome Measures

Domain	Evaluation Measure
Dialysis Modality Point Prevalence Measures (%)	▪ Percent of patients receiving home dialysis (PD or home HD) in a given month ▪ Percent of patients receiving PD in a given month ▪ Percent of patients receiving home HD in a given month ▪ Percent of patients receiving in-center HD (in-center HD or self-administered dialysis or nocturnal) in a given month ▪ Percent of patients receiving in-center HD in a given month ▪ Percent of patients receiving in-center self-administered dialysis in a given month ▪ Percent of patients receiving nocturnal HD in a given month ▪ Percent of patients receiving home dialysis training in a given month
Modality Transition	▪ Monthly patient gains to home dialysis expressed as a percentage of patients receiving home dialysis in the corresponding month ▪ Monthly patient losses from home dialysis expressed as a percentage of patients receiving home dialysis in the corresponding month
Transplant Waitlisting	▪ Percentage of eligible patients on the transplant waitlist in a given month—overall ▪ Percentage of eligible patients on the transplant waitlist in a given month—active status ▪ Percentage of eligible patients on the transplant waitlist in a given month—inactive status
Transplant (per 1,000 patient-months)	▪ Percentage of patients receiving a living or deceased donor[1] kidney transplant in a given month ▪ Percentage of patients receiving a deceased donor[1] kidney transplant in a given month ▪ Percentage of patients receiving a living donor[1] kidney transplant in a given month ▪ Percentage of patients with a preemptive living donor transplant in a given month (dialysis and preemptive)[2]

Domain	Evaluation Measure
Utilization	▪ Percentage of patients with at least one acute care hospitalization in a given month ▪ Percentage of patients with a hospital readmission in a given month ▪ Percentage of patients with at least one outpatient ED visit (without hospitalization) in a given month ▪ Percentage of patients with at least one outpatient ED visit (without hospitalization) or an outpatient ED visit (with hospitalization) in a given month
Standardized Medicare Payments	▪ Total Parts A & B payments PPPM ▪ Total Part A payments PPPM ▪ Part A acute care hospitalization payments PPPM ▪ Part A LTCH and inpatient rehabilitation facility payments PPPM ▪ Other Part A payments PPPM ▪ Total Part B payments PPPM ▪ Part B dialysis payments PPPM ▪ In-center Part B dialysis payments PPPM ▪ Home dialysis Part B dialysis payments PPPM ▪ Home HD Part B dialysis payments PPPM ▪ PD Part B dialysis payments PPPM ▪ Other Part B payments PPPM ▪ Part D payments PPPM
QoC	▪ Percentage of PD patients with at least one diagnosis of peritonitis in a given month ▪ Percentage of HD patients with at least one vascular infection in a given month ▪ Percentage of patients with at least one hospitalization with a noninfectious vascular access complication in a given month ▪ Percentage of patients with at least one ESRD-related hospitalization in a given month ▪ Percentage of patients who have a Kt/V > 1.2 (for in-center HD patients) or Kt/V > 1.7 (for PD patients) ▪ Mortality

Note: All measures were analyzed at the patient-month level except for the hospital readmission measure, which was analyzed at the index discharge level. Mortality rate is expressed as death per 100 patient-years and analyzed as a time-to-event model. Transplant and waitlisting measures were restricted to patients less than 75 years old. Dialysis modality indicators except home dialysis training are mutually exclusive (primary modality in a patient-month). Home dialysis: PD or home HD. In-center HD includes in-center hemodialysis, in-center self-dialysis, and nocturnal.

[1] Among dialysis patients.

[2] Among dialysis patients and pre-dialysis preemptive transplant patients. Components of home dialysis gains (new patient gains, established patient gains, gains after failed transplant) and home dialysis losses (loss to in-center HD, loss to transplant, loss to death or withdrawal) were also examined (see **Appendix B, Section B.5.2**).

ESRD = end-stage renal disease; HD = hemodialysis; LTCH = long-term care hospital; PD = peritoneal dialysis; PPPM = per patient per month; PROMIS = Patient-Reported Outcomes Measurement Information System; QoC = quality of care.

3.2. Results and Discussion

In the United States, in-center HD has been the predominant treatment modality, supported by a large network of facilities, providers, and vendors. Alternative treatments have long been available, but a relatively limited subset of patients have used them. Specifically, both home dialysis and kidney transplantation offer potential advantages over in-center HD. The home dialysis modalities, PD and home HD, allow patients to control their own treatment at home. Potential advantages include scheduling flexibility, decreased travel time, increased independence, and the benefits associated with self-care. Both home dialysis and transplantation have been associated with higher

QoL and lower health care payments.[19,20] Transplantation provides a clear survival advantage to patients who meet the waitlist eligibility criteria.[21]

In our case study interviews, patients on home dialysis cited many positive benefits of this treatment choice, the most common of which was the ability to do other activities during the day. This aspect of home dialysis contributed to improved QoL. Examples of activities included shopping, working, doing housework, exercising, and spending time with family and friends.

Despite these advantages, there is a growing consensus that these modalities are underused relative to their potential. This section shows the impact of the ETC Model on home dialysis, waitlisting, transplantation, and other related outcomes as of the third year of the model.

> *"I'm still able to go to my kid's games, sports, spend time with him, go fishing…That was the number one thing that was put out to me like, 'Hey, you can still have that life you had before.' Obviously, it's a little different, sure. But to be able to wake up in the morning, get off the treatment, shut it down, get ready for my day. If I have stuff going on, appointments, like I said, my boy, it still gives me that ability. That's why I chose it, and that's why I like it…I'm not being tied up three days a week, having to go to the treatment, to the in-clinic for, I don't know, six to eight hours."*
>
> *– Rural home dialysis patient*

3.2.1. What Was the Impact of the ETC Model on Home Dialysis?

Home Dialysis

Potential Impacts | The ETC Model incentivizes expansion of home dialysis and is expected to increase the use of home dialysis among patients with ESRD on dialysis in ETC areas.

Findings | The model has not shown an impact on home dialysis as of the third year of the model.

The proportion of patients receiving home dialysis training each month grew faster in ETC areas than in comparison areas.

Patients on home dialysis in ETC areas were more likely to receive a transplant than patients in comparison areas.

The ETC Model aims to promote patient education and choice in dialysis modality, with the expectation that home dialysis use will grow and reliance on in-center HD will decline. The major home dialysis modalities are PD and home HD. PD is much more common and involves removal of fluids and toxins across the peritoneal membrane. Home HD involves removal of fluids and toxins from the blood stream, similar to in-center HD but performed at home by the patient

[19] Jung, HY, Jeon Y, Park Y, Kim YS, Kang SW, Yang CW, Kim NH, Choi JY, Cho JH, Park SH, Kim CD, Kim YL. Better quality of life of peritoneal dialysis compared to hemodialysis over a two-year period after dialysis initiation. *Sci Rep* 2019 July;9(1):10266.

[20] Kaplan JM, Niu J, Ho V, Winkelmayer WC, Erickson KF. A comparison of U.S. Medicare expenditures for hemodialysis and peritoneal dialysis. *J Am Soc Nephrol* 2022 Nov;33(11):2059-2070.

[21] Wolfe RA, Ashby VB, Milford EL, Ojo AO, Ettenger RE, Agodoa LY, Held PJ, Port FK. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. *N Engl J Med* 1999 Dec;341(23):1725-1730.

(usually with assistance). Each home dialysis modality offers distinct advantages and disadvantages. The decision is based on patient, provider and facility factors and preferences.

The ETC Model did not have a statistically significant impact on home dialysis use through the first 3 years of the model (see **Exhibit 11**). Home dialysis grew steadily from CY 2017–2019 to CY 2021–2023 in both ETC and comparison groups, increasing from 12.0% to 15.6% for the ETC group and from 12.7% to 16.3% in the comparison group (see **Appendix B, Exhibit B-21 and B-22**).

Starting in January 2021, model participants (ESRD facilities and Managing Clinicians) are eligible to receive the HDPA, a positive payment adjustment meant for the first 3 model years, to address start-up costs associated with home dialysis expansion. Beginning in 2022, the ETC Model also awarded partial credit to model participants for in-center self-administered HD and in-center nocturnal dialysis on the grounds that these options promote self-care. Participants are also eligible for the PPA, a positive or negative payment based on home dialysis and transplant performance, starting in July 2022.

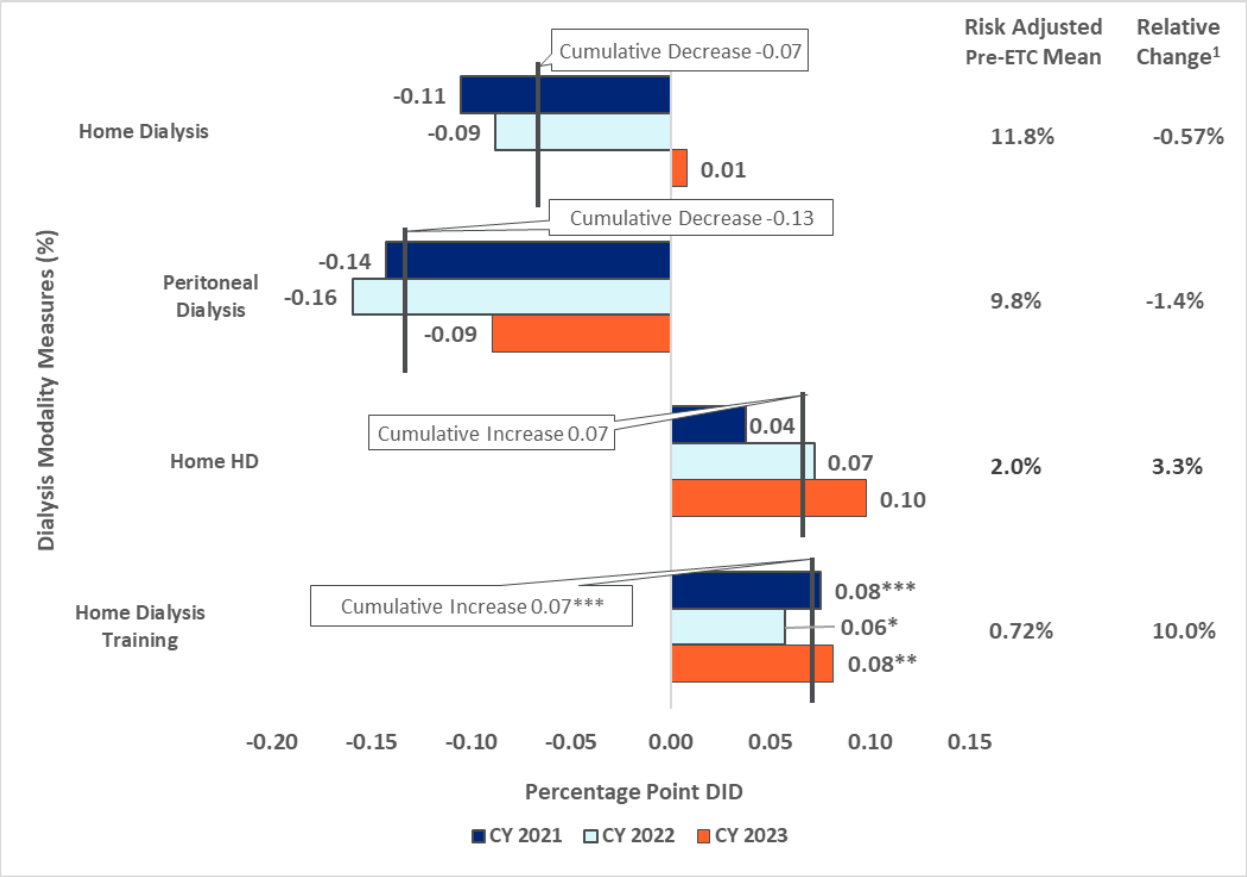
The impact of the ETC Model on home dialysis was evaluated in several ways. The primary analysis focused on the relative rate of growth in the prevalence of ESRD dialysis patients treated with home dialysis. Prevalence was expressed as the percent of ESRD beneficiary-months treated with home dialysis by year for ETC and comparison areas. Home dialysis prevalence was modeled within a DiD framework. The same approach was used to examine PD and home hemodialysis separately. New home dialysis patients require training, which is specifically captured in Medicare claims records. Accordingly, we examined trends in home dialysis training as a potential harbinger of home dialysis penetration. The percent of dialysis patients treated with home modalities is a dynamic function of patient accrual (gains) and patient departures (losses). The evaluation included an examination of the specific sources of gains and losses in home dialysis, as described below.

The percentage of patient-months engaged in home dialysis training increased at a higher rate in the ETC group (0.73% to 0.84%) relative to the comparison group (0.76% to 0.80%), resulting in positive and statistically significant yearly and cumulative DiD estimates. The 3-year estimate of 0.07 percentage points translates to a 9.8% increase relative to the pre-ETC mean of 0.73%. In terms of patients, we estimate an additional 720–1,441 home training patients[22] in the ETC group (see **Exhibit 11** and **Appendix B, Exhibit B-22**).

This finding potentially complements the analysis of home dialysis gains and losses (new in this report) that we have undertaken to explain the mechanism of home dialysis growth, which is the expected outcome of the ETC Model.

[22] Assuming patients having one to two home training sessions per month. On average, this equals 360 patients per year receiving home dialysis training.

Exhibit 11. Increase in Home Dialysis Training in ETC Areas and No Impact on Home Dialysis Use



Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021, CY 2022, and CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see Appendix B, Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. All dialysis modality measures except for home dialysis training are based on primary modality in a patient-month and are mutually exclusive. Home dialysis: peritoneal dialysis or home HD. In-center HD includes in-center hemodialysis, in-center self-dialysis, and nocturnal.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding).

CY = calendar year; DiD = difference-in-differences; HD = hemodialysis.

Home dialysis gains and losses. We classified the main sources of home dialysis gains as new ESRD dialysis patients who start home dialysis, established dialysis patients who switch to home dialysis, and patients who resume home dialysis after a hiatus (such as after a failed transplant). The major paths of loss include switching to in-center HD (which is generally considered to represent home dialysis failure), death, transplantation, and a miscellaneous category that includes recovery of kidney function and loss-to-follow-up. For example, two patient groups with a similar proportion of home dialysis may have different gain/loss patterns. One group may show higher rates of accrual and loss than the other, resulting in similar prevalence. Furthermore, home dialysis losses may occur for reasons that may be considered desirable (transplantation) or undesirable (death, withdrawal, or modality switches). This analysis examines the gain/loss patterns that determine the proportion of patients using home dialysis, offering insight on possible model impact.

There was evidence of greater losses to transplantation in the ETC group for CY 2022 and CY 2023 as well as cumulatively (see **Appendix B, Exhibit B-22**). The cumulative estimate of 0.08 percentage points corresponds to a 14.5% relative increase over the pre-ETC mean, which translates into an additional 306 patient losses from home dialysis to transplantation. There were no differences in other sources of loss, including switches to in-center HD.

With respect to home dialysis gains, we found significantly higher DiD estimates in CY 2021 for home dialysis gains from in-center HD and failed transplants. This result for CY 2021 aligns with an increase in home dialysis training observed for that same year (**Exhibit 11**), though the positive impact on training extended also to CY 2022 and CY 2023. Overall, our detailed analysis of home dialysis gains did not establish a clear corresponding source of gains to offset the observed loss of home dialysis patients to transplantation. This may be due to multiple challenges with attempting to balance specific types of home dialysis gains and losses, such as intermittent lapses in beneficiary eligibility and ESRD facility attribution that are part of the ETC Model design and transitions between FFS and MA coverage. If the ETC Model had achieved greater home dialysis growth in the ETC group compared to the comparison group, the analysis would have revealed the contribution and source of increased gains (new vs. established patients) or decreased losses (fewer switches to in-center HD, fewer deaths). The gain/loss analysis offers less insight given the apparent lack of ETC impact on home dialysis prevalence to date.

Considering the complexities and limitations that arise when examining different types of modality transitions in detail, we find a possible signal that the ETC Model stimulated a small increase in home dialysis gains. However, these gains were largely offset by increased losses to transplantation. The offsetting gains and losses resulted in no overall difference in home dialysis prevalence (the net result of gains and losses). The apparently higher rates of gain and loss to transplant among ETC patients are relatively small and need to be monitored to see whether this pattern is sustained. Increased losses to transplantation among home dialysis patients should be seen as a positive outcome in terms of patient survival and QoL. The finding is consistent with the overall observation of increased growth in transplantation in the ETC group (not just among ETC home dialysis patients, see **Section 3.2.3.**).

We also examined the possibility of an early signal of increased home dialysis attributable to the ETC Model by focusing on younger patients with ESRD and ESRD facilities with an established home dialysis program. The DDD analysis showed no significant differences in the change in home dialysis use between the ETC and comparison groups across younger patient subgroups or facilities with established home dialysis programs (see **Appendix B, Exhibits B-49 and B-50 and Appendix B, Section B.8)**.

As of the third year of the model, the proportion of patients receiving home dialysis has increased steadily in both the ETC and comparison groups, continuing an upward trend that began in 2010. There is some indication of a slight increase in the accrual of home dialysis patients, offset by increased losses due to transplantation in the ETC group.

Home dialysis expansion is a major goal of the ETC Model. However, the model incentives have not stimulated additional growth in home dialysis prevalence in ETC areas relative to the comparison areas. There are some plausible reasons for lack of model effect. Home dialysis was already growing before the start of the ETC Model. As reported in **AR2**, we learned in interviews with ESRD facility staff and Managing Clinicians that they had not substantially changed practices

directly in response to the ETC Model. Often their current efforts to increase home dialysis and transplantation built on prior efforts that were already underway before the model began. In addition, faster growth may have been limited by facility resources. In this year's case studies on patient access to care, Managing Clinicians reported that they did not have sufficient resources to address barriers to home dialysis and transplant among certain patient subpopulations (see **Section 4.2.3.6.**).

The patient sample was affected by the large movement of patients from the traditional Medicare FFS program to MA managed care plans starting in 2021 (see **Section 2.2.3.2.**). The movement of patients from FFS to MA during the model period resulted in application of ETC incentive payments to a smaller number of dialysis patients treated by facilities and Managing Clinicians, thus reducing the financial impact of the ETC Model on the participating providers. As we reported in **AR2**, an interview participant from an ESRD facility noted that most of its new patients are enrolled in either an MA plan or other managed care plan, and as a result, its efforts to implement the ETC Model are not resulting in financial gain. In the case studies conducted for this report, we heard from Managing Clinicians that model incentives are not substantial enough to motivate change (see **Section 4.2.3.6.**).

3.2.2. What Was the Impact of the ETC Model on the Kidney Transplant Waitlist?

Transplant Waitlisting

Potential Impacts | The ETC Model incentivizes expansion of the kidney transplant waitlist and is expected to increase the percentage of dialysis patients on the transplant waitlist in ETC areas relative to comparison areas.

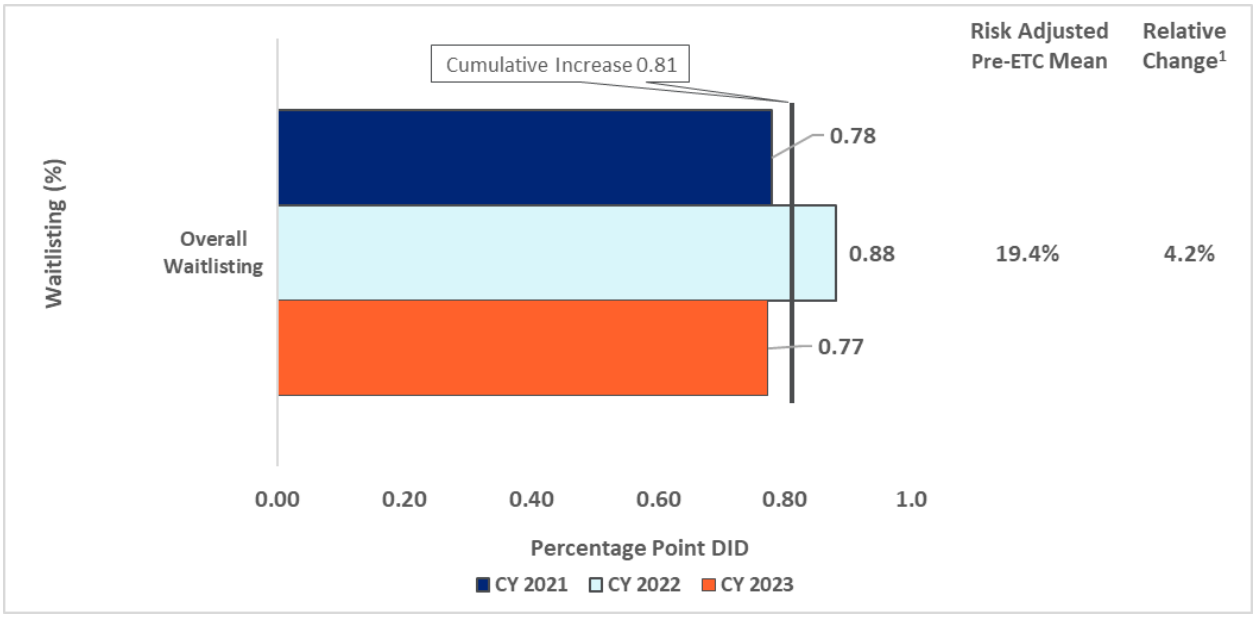
Findings | The model has not shown an impact on the waitlisting measures as of the third year of the model.

The ETC Model incentivizes dialysis providers to guide more patients to kidney transplantation. Important early steps in the transplant process include referral to a transplant center and placement on the transplant waitlist. Patients who have been evaluated and meet the criteria for a transplant are usually added to the waitlist in active status, meaning they qualify to receive a kidney transplant if a suitable organ becomes available. Patients who develop a medical complication or other temporary contraindication to transplant may be moved to inactive status until the situation is resolved.

The ETC Model did not have a statistically significant impact on transplant waitlisting overall (**Exhibit 12**), active, or inactive status (see **Appendix B, Exhibit B-22**). Participants usually make the initial referral to a transplant center and play an important role in coordinating pretransplant testing and evaluations needed for waitlist eligibility. However, transplant evaluations and waitlist decisions rest with the transplant centers. The transplant centers do not participate in ETC incentives but play a decisive role in the waitlisting process. Several factors could explain the lack of impact on waitlist expansion including different incentive structures for transplant centers. Based on findings from the case studies, some patients may encounter barriers navigating the transplant process. In our interviews with dually eligible beneficiaries and Part D LIS recipients, respondents reported barriers they encountered navigating the transplant process that they could

not overcome. These included lack of transportation to transplant centers, lack of financial resources to cover travel costs (see **Section 4.2.3.2.**), and inadequate education and communication between patients, providers, and transplant centers (see **Section 4.2.3.4.**). Providers reported that these barriers hampered their ability to increase waitlisting (see **Section 4.2.3.4.**).

Exhibit 12. No Impact on Transplant Waitlisting



Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021, CY 2022, and CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see Appendix B, Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding). Waitlisting and transplant measures are restricted to patients with age <75 years.

CY = calendar year; DiD = difference-in-differences

3.2.3. What Was the Impact of the ETC Model on Kidney Transplants?

Kidney Transplantation

Potential Impacts | The ETC Model provides financial incentives for the expansion of living donor kidney transplantation (including preemptive transplants) with the aim of increasing living donor transplants in ETC areas.

Findings | The ETC Model had no impact on living donor transplants.

Deceased donor transplants grew more rapidly in ETC areas, despite the absence of financial incentives.

Total transplants (living and deceased donor) increased at a faster rate in the ETC group than the comparison group.

The ETC Model incentivizes ESRD facilities and Managing Clinicians to increase the rate of living donor transplantation among patients undergoing dialysis for ESRD. Managing Clinicians

are also incentivized to increase preemptive transplants among patients with chronic kidney disease (pre-dialysis). The rationale holds that dialysis providers play an important role in helping their patients understand and facilitate living donor organ donations. In contrast, there is no explicit incentive to increase deceased donor organ transplantation, which is the more frequent donor source. As with waitlisting, the ETC Model evaluates transplant rates for dialysis patients under the age of 75 years, in addition to the general model exclusions described in **Appendix B, Exhibit B-4**.

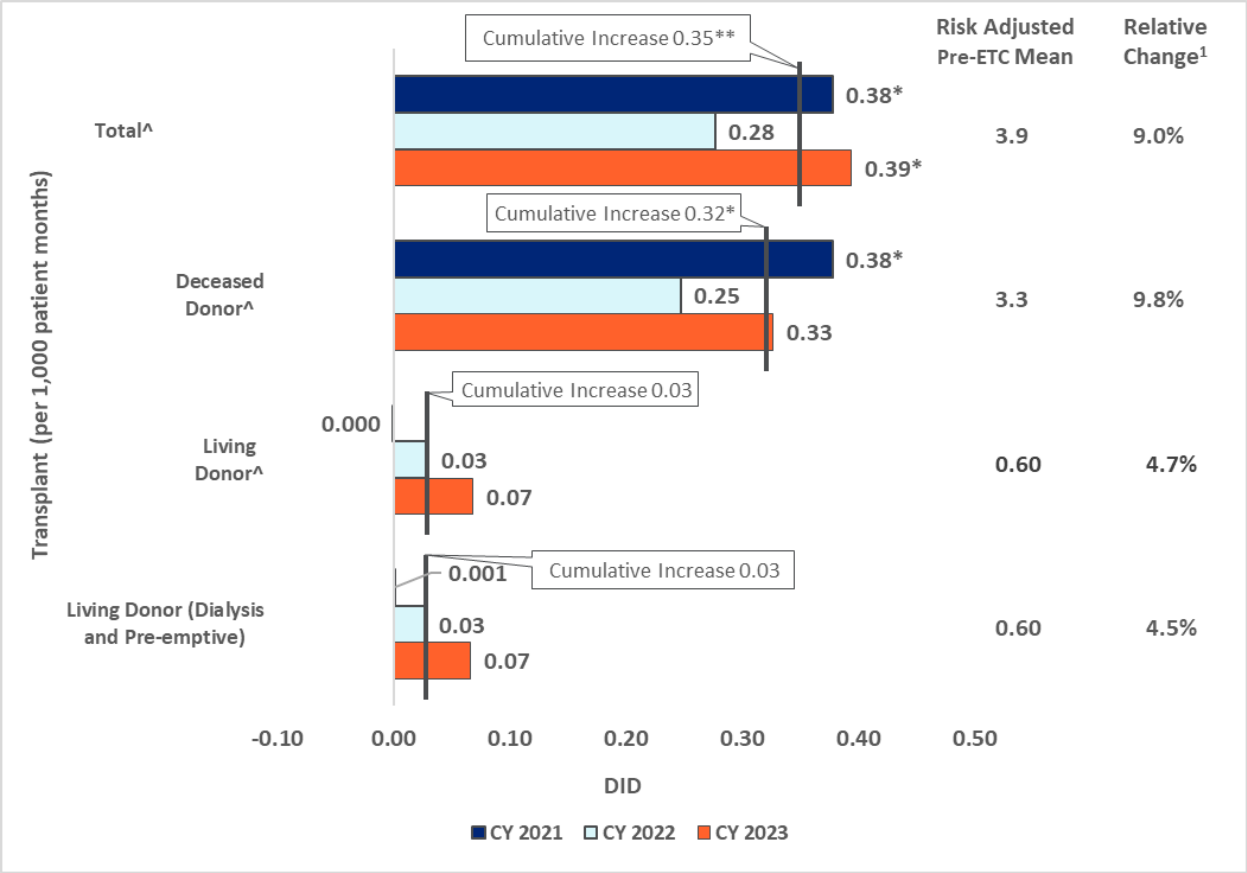
Living donor transplants increased modestly in both the ETC and comparison groups (see **Exhibit 13**). The DiD estimate was small and not statistically significant, indicating no difference in the rate of growth between ETC and comparison areas. The findings were similar when preemptive transplants were included.

Deceased donor transplants increased in both the ETC and comparison areas. The yearly (CY 2021–2023) and cumulative DiD estimates were positive in all years, indicating faster growth in the ETC areas. The statistically significant cumulative DiD estimate of 0.32 per 1,000 patient-months reflects a 10% relative increase over the pre-ETC mean of 3.3 transplants per 1,000 patient-months. We estimate that the ETC group experienced about 501 additional transplants from 2021 to 2023.

Total transplants increased in both the ETC and comparison areas, showing a similar growth pattern to the deceased donor transplants. The yearly (CY 2021–2023) and cumulative DiD estimates were positive in all years, indicating faster growth in the ETC areas. The DiD estimate was statistically significant in CY 2021 and CY 2023 as well as cumulatively. The statistically significant cumulative DiD estimate of 0.35 per 1,000 transplant-months reflects a 9% increase over the pre-ETC mean of 3.9 transplants per 1000 patient-months, translating to about 550 additional transplants (183 per year) in the ETC group from 2021 to 2023.

The ETC Model did not have the expected impact on living donor transplants through CY 2023. In contrast, the ETC group experienced greater growth in total transplants, which was largely driven by deceased donor transplants. The transplant increase was significant in CY 2021 and CY 2023, suggesting persistence of the finding. The mechanism of the ETC effect on deceased donor transplants is unclear. ETC does not directly incentivize deceased donor transplants. ETC incentivizes waitlisting, which could facilitate deceased donor transplantation. However, the ETC Model had no measurable impact on waitlisting. The relative increase in deceased donor transplants could potentially be explained by chance differential organ procurement organization (OPO) and transplant center performance in ETC versus comparison group areas that may be unrelated to the model incentives.

Exhibit 13. Relative Increase in Total Transplants Driven by Increase in Deceased Donor Transplants in ETC Areas



Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021, CY 2022, and CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see Appendix B, Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding). ^Among dialysis patients. Waitlisting and transplant measures are restricted to patients with age <75 years.

CY = calendar year; DiD = difference-in-differences.

3.2.4. What Was the Impact of the ETC Model on Utilization?

Utilization

Potential Impacts | The ETC Model may influence efforts to sustain long-term home dialysis and reduce complications, potentially leading to quality improvements and a decline in utilization of services.

Findings | The ETC Model had no impact on acute care hospitalizations, readmissions, or ED visits.

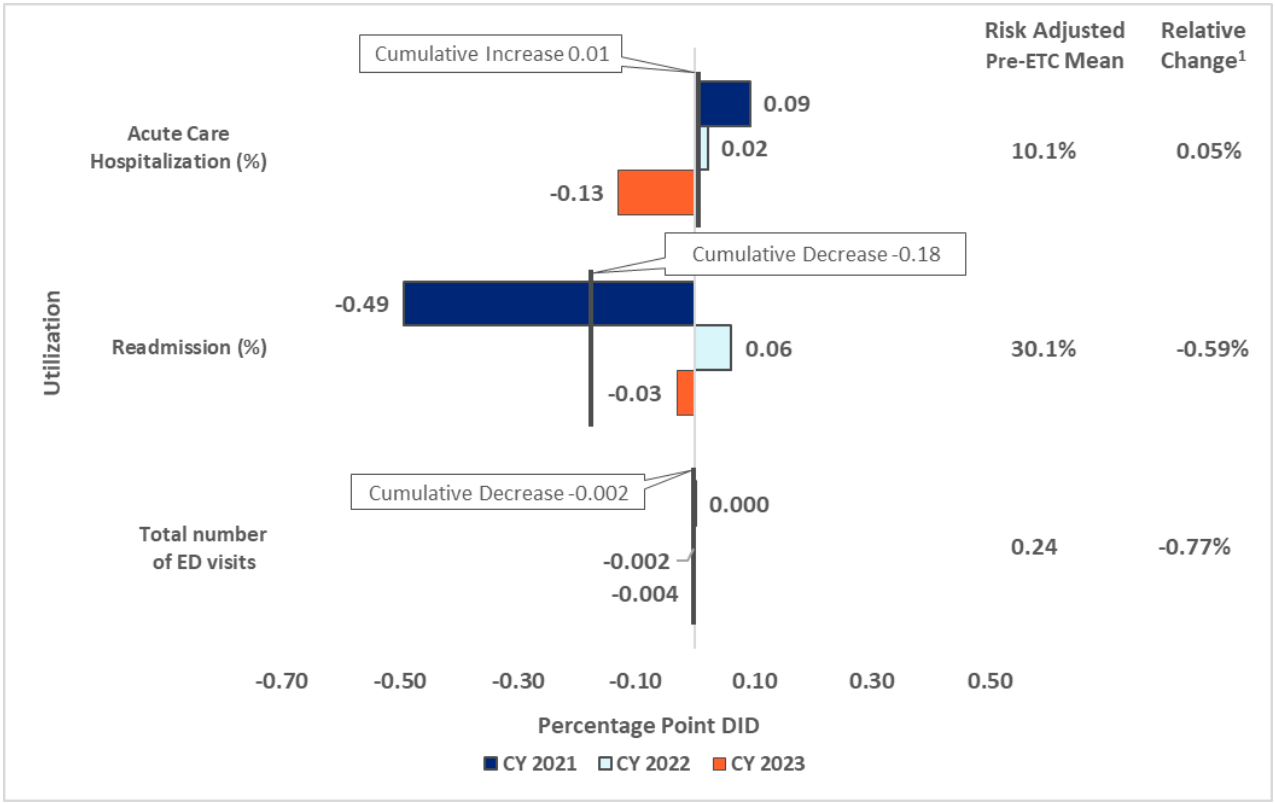
In this report, we examined acute care hospitalizations, hospital readmissions, and outpatient ED visits. New in the report, we also examined a measure of total ED use, which included all ED

visits, both those that resulted in inpatient hospitalization and those that did not. Given the relatively high ED use among patients with ESRD, we assessed whether changes in dialysis modality affected total ED visits. These utilization measures, potentially sensitive to modality choice, can provide insights into the mechanisms by which the model might affect the overall cost of care for dialysis patients. We used Medicare claims to define whether there was at least one event during each patient-month for all measures, except for total ED visits, which counts the number of visits in a month.[23]

Overall, we observed a declining trend in all four utilization measures between the pre-ETC period and the first 3 years of the model for both the ETC and comparison groups. The rate of decline was similar for both groups for all the measures, such that impact estimates indicate no change in utilization patterns during the first 3 years of the ETC Model (see **Exhibit 14, Appendix B, Exhibit B-22**).

Increased patient engagement in treatment choices under the model has the potential to reduce preventable ED visits. However, our findings show no evidence of ETC Model impact on acute care hospitalizations, hospital readmissions, or ED visits, which are all significant contributors to total Medicare expenditures for this population.

Exhibit 14. No Impact on Utilization Measures



[23] The total ED visits measure is defined as a count measure to ensure that all inpatient ED visits (with hospitalization) and outpatient ED visits are accounted for. If the outcome measure was defined as an in indicator instead of a count measure, an ED visit with hospitalization and an outpatient ED visit occurring in the same month will be underestimated and be counted only once.

.

Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021, CY 2022, and CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B, Section B.5**) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding).

CY = calendar year; DiD = difference-in-differences; ED = emergency department.

3.2.5. What Was the Impact of the ETC Model on Medicare Payments?

Medicare Payments

Potential Impacts | Changes in dialysis modality use and transplantation rates as well as associated improvements in quality of care could reduce Medicare payments, aligning with the model's explicit goal to reduce overall costs.

Findings | The ETC Model had no impact on Total Medicare Parts A & B payments (gross impact) or Part D payments.

When taking into account the ETC payment adjustments (HDPA and PPA), the model resulted in an estimated net increase of $99 million in total additional Medicare payments during CY 2021–2023.

Changes in dialysis modality use and associated improvements in QoC have the potential to influence health care utilization and Medicare payments. ETC participants are incentivized to promote home dialysis and transplantation, which may also enhance patient care through better education, shared decision-making, and long-term home dialysis use. These quality improvements, in addition to changes in the type, volume of services, and intensity of care, may affect Medicare payments, aligning with the model's goal of reducing Medicare payments.

We examined standardized Medicare Parts A & B payments per patient per month (PPPM),[24,25] along with major components of Part A and Part B payments to identify the source of any observed overall changes in payments. We defined separate payment categories for Medicare Parts A & B services, including payments for acute care hospitalizations, long-term care hospital (LTCH) and inpatient

Model Incentive Payments

- Home Dialysis Payment Adjustment (HDPA): upward adjustment only
- Performance Payment Adjustment (PPA): upward or downward adjustment, starting July 2022

Measures of Medicare payments per patient per month (PPPM) do not include model incentive payments and are used to assess gross savings.

[24] This measure reflects average Medicare payments across patients with FFS coverage in a given month for all Parts A & B services. Analyses are based on standardized Medicare payments so that differences in payments reflect differences in utilization and not ancillary parameters (that is, wage index, Disproportionate Share Hospital, Indirect Medical Education payments, quality incentive payments, and others that determine payments under Medicare Prospective Payment Systems).

[25] Measures of payments do not include model incentive payments in the form of either the HDPA (upward adjustment only) or the PPA (starting July 2022; upward or downward adjustment) and, as such, are used to assess gross savings and not net savings, which would incorporate costs of the model.

rehabilitation facility (IRF) stays under Part A and for outpatient dialysis-related services under Part B.

ESRD facilities receive a bundled payment for dialysis-related services, while nephrologists and related professionals receive a monthly capitation payment (MCP) for professional management services. Facility payments were designed to be similar for in-center and home dialysis, implying that in the absence of the ETC Model, one modality is not financially preferred over another. Increased use of home dialysis is incentivized by the ETC Model. Home dialysis is associated with lower total Medicare payments, largely due to lower rates of hospitalization.[26,27] In addition to total dialysis-related payments, this year we examined modality-specific Part B outpatient payments for in-center HD, home dialysis, PD, and home HD. The reported DiD estimates of Medicare payments do not include the adjustments for HDPA (applied during CY 2021–2023) and PPA (applied for CY 2022–2023).

Total Medicare Parts A & B payments. Total Medicare payments PPPM increased similarly in both groups, from $5,666 to $6,168 in the ETC group and from $5,722 to $6,211 in the comparison group (see **Appendix B, Exhibit B-21**), reflecting a 9% increase in total Medicare payments PPPM between the pre-ETC period and the first 3 years of the model. The yearly and cumulative impact estimates for total PPPM were relatively small and not statistically significant (see **Exhibit 15**), suggesting the ETC Model did not reduce Medicare payments in ETC areas relative to the comparison group over the 3-year period.

Part A payments. Part A payments, which accounted for 28% to 29% of Total Medicare Parts A & B payments during the pre-ETC period, increased similarly for both the ETC and comparison groups between the pre- and post-ETC periods (see **Appendix B, Exhibit B-21**). Additionally, none of the cumulative impact estimates for Medicare Part A components—of which acute care hospitalizations represent about 86%—were statistically significant (see **Appendix B, Exhibit B-22**). Medicare payments to LTCHs and IRFs had statistically significant yearly impact estimates for CY 2021 (–$7) and CY 2022 ($13) but not CY 2023. The impact estimate for "other Part A payments," which constitutes payments for home health services, was negative and statistically significant in CY 2023, implying slower growth in payments in the ETC group relative to the comparison group. The 3-year cumulative estimate was also negative (–$3 PPPM) and statistically significant (see **Appendix B, Exhibit B-22**). This payment category constitutes a small portion (<0.2%) of total payments PPPM of about $5,670 during the pre-ETC period, which likely helps explain why it is not a driver of any overall changes in payments (see **Appendix B, Exhibit B-21**).

Part B payments. Quality of care improvements or clinical practices adopted by ETC participants may lead to increased use of preventive services, outpatient office visits, and physician services. The model's incentives to increase home dialysis use and number of transplants could result in higher payments for outpatient institutional and professional services. Part B payments, which accounts for 71% to 72% of total Medicare Parts A & B payments, are categorized into total

[26] United States Renal Data System. 2024 (Figure 9.10). *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

[27] Is Home Dialysis the Way Forward for Medicare? Assessing Potential Cost Savings Associated with Peritoneal Dialysis, https://pmc.ncbi.nlm.nih.gov/articles/PMC9678038/

dialysis payments and "other Part B payments",[28] which include all non-dialysis-related services, such as evaluation and management services by physicians, outpatient institutional payments, imaging, and others.

The impact estimate for total Part B was positive and statistically significant for both CY 2022 and CY 2023, indicating faster growth in payments in ETC areas relative to the comparison group. The statistically significant increase of $40 PPPM in CY 2023 translates to a 1% increase over the pre-ETC mean of $4,124. This increase in Part B payments in the ETC group was primarily due to non-dialysis-related other Part B payments, which increased faster in the ETC group in both CY 2022 and CY 2023, resulting in positive impact estimates (see **Appendix B, Exhibit B-22**). The CY 2022 and CY 2023 impact estimates were statistically significant, indicating an emerging trend, even though the 3-year cumulative impact estimates for both total Part B and other Part B were not statistically significant.

The reason for faster ETC growth in non-dialysis Part B payments is not clear. One possibility may relate to the faster growth in kidney transplantation in the ETC group (see **Section 3.2.3**.). Part B outpatient payments to support pretransplant preparation may have contributed to the increase in other Part B payments in the ETC group relative to the comparison group.

Medicare payments for outpatient dialysis-related services (total dialysis payments), which represented about 70% of total Part B payments, increased similarly for both the groups over time. None of the 3-year cumulative impact estimates of the modality-specific Part B dialysis payments were significant, indicating that the ETC Model did not lead to any relative reductions in the dialysis-related costs (see **Appendix B, Exhibit B-22**).

Part D payments. Between the pre-ETC and the post-ETC periods, Part D payments PPPM declined in both the ETC and comparison areas (see **Appendix B, Exhibit B-21**). The DiD analysis indicates that the decline in Part D spending among patients enrolled in Part D was not statistically different between the two groups (see **Exhibit 15** and **Appendix B, Exhibit B-22**).[29]

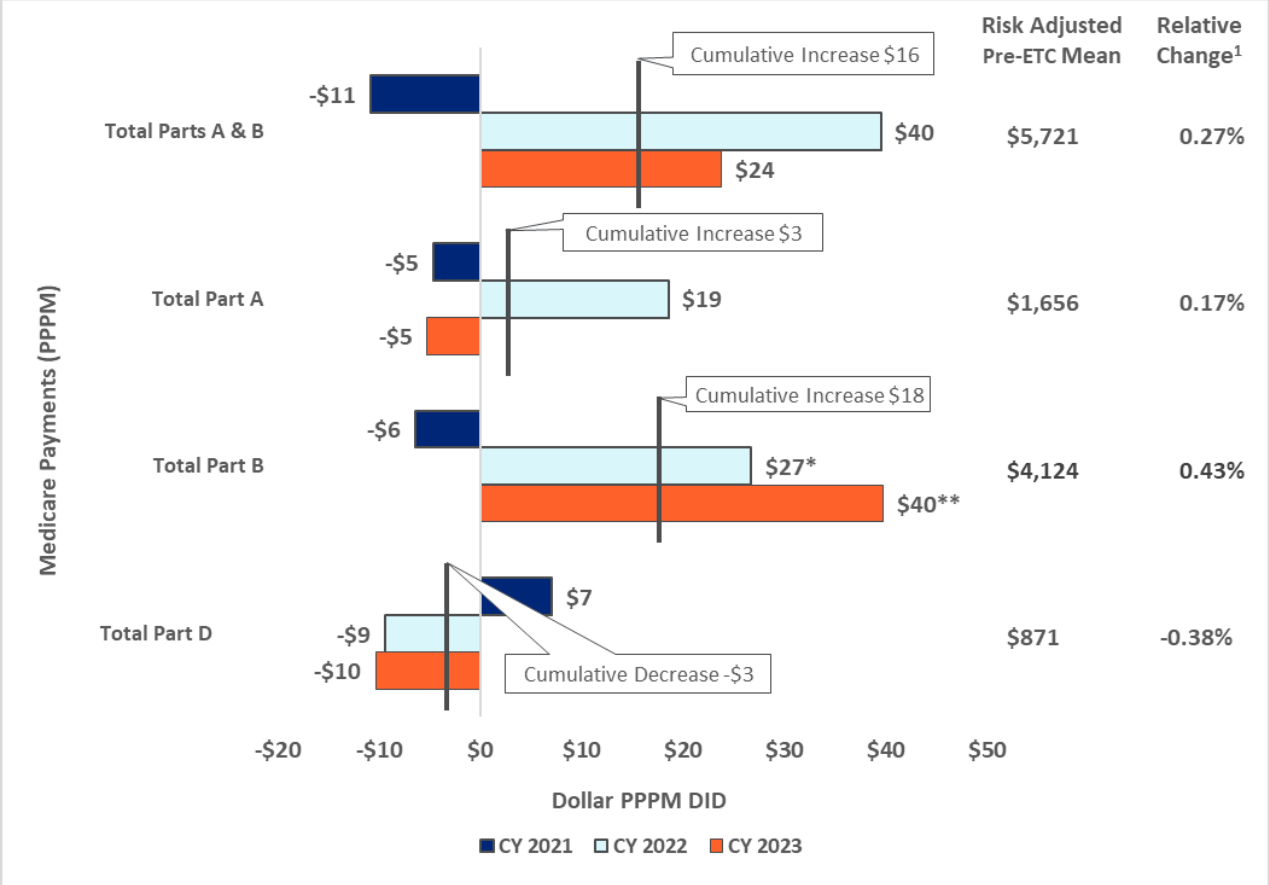
The model did not lead to a change in Total Medicare Parts A & B payments or in Part D payments, which is in alignment with our utilization findings. The increase in Part B payments in recent years may be linked with increases in transplants in the ETC areas. As noted in **Section 3.2.3.**, the ETC group experienced greater growth in total transplants, largely driven by deceased donor transplants. Medicare payments tend to rise immediately prior to transplantation, peaking in the month of transplant, and then steadily decline over time. However, our analysis of Medicare payments currently ends with the month of transplant, an approach that is intended to limit deviations from the approach used to measure the performance of participants under the ETC Model. This approach might not capture potential savings to Medicare over the longer term from increased transplantation and a decline in the use of chronic dialysis for ESRD. It is also important

[28] It is a derived payment category, total Part B minus total dialysis payments.

[29] We also analyzed the Part B drug frequency of ESRD facility claims for Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). TDAPA and TPNIES provide extra payments to ESRD facilities for newly developed drugs, supplies, and equipment that are temporarily paid outside the bundled prospective payment to ESRD facilities. We did not expect to see an impact of the ETC Model on these payments, and in fact, the frequency of claims for TDAPA and TPNIES items were balanced for facilities located in the ETC and comparison areas in both the pre-ETC and post-ETC periods (see **Appendix B, Section B.7**).

to note that the Medicare payment amounts used in these analyses do not include the application of the ETC payment adjustments. In the next section, we account for HDPA and PPA payments and explore the net impact of these adjustments on Medicare payments.

Exhibit 15. No Impact on Medicare Parts A & B and Part D Payments PPPM



Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021, CY 2022, and CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B, Section B.5**). Part A payment is estimated using two-part model. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding).

CY = calendar year; DiD = difference-in-differences; PPPM = per-patient per-month.

Net ETC payment adjustments. New in this report, we also examined the payment adjustments made to the participating ESRD facilities and Managing Clinicians during the first 3 years of model implementation. The HDPA represents positive payment adjustments only, while the PPA can be either positive or negative.[30] When accounting for both the HDPA and PPA, the net ETC

[30] In calculating the PPA, both the home dialysis rate and the transplant rate are aggregated to the ETC participant's aggregation group where relevant. For ESRD facilities, the aggregation group includes all ESRD facilities owned by the same legal entity that are in the same HRR. For Managing Clinicians, the aggregation group includes Managing Clinicians who are part of the same group practice. CMS calculates achievement scores for each participant based on their performance during the MY relative to historical benchmarks, which are determined

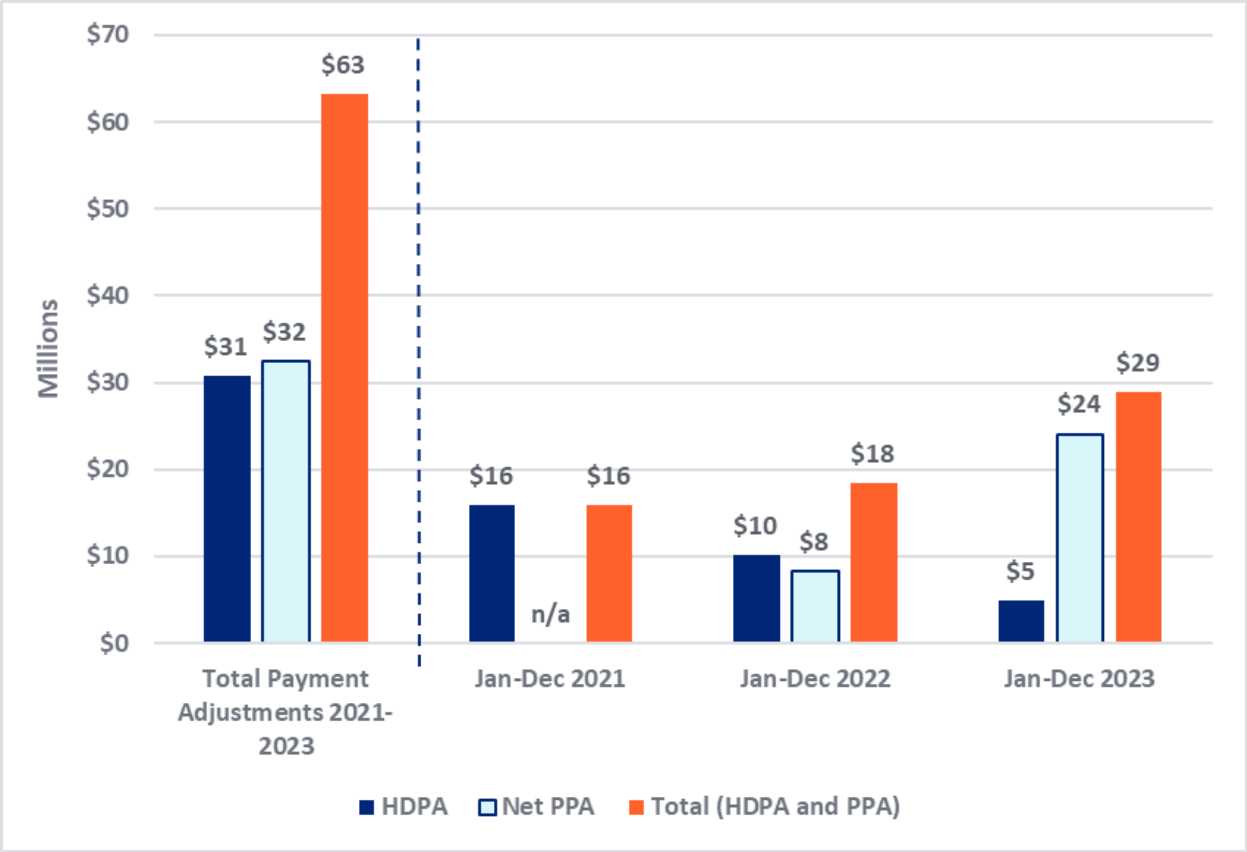
payment adjustments during CY 2021–2023 totaled $63 million. The total HDPA amounts accounted for almost half ($31 million) of the total ETC payment adjustments, while the total net PPA amounts accounted for the remaining $32 million (reflecting $51 million in positive PPA amounts and $19 million in negative PPA amounts) (see **Exhibit 15**).

The net ETC payment adjustments increased from $16 million in 2021, to $18 million in 2022, and to $29 million in 2023 (see **Exhibit 16**). As designed, the total HDPA amounts declined each year from CY 2021 to 2023 for both ESRD facilities and Managing Clinicians, with facilities receiving most additional payments made for services provided to home dialysis patients (see **Appendix B, Exhibit B-25**). Positive PPAs were more common and exceeded the negative PPA amounts for both types of ETC participants, resulting in an increase in net PPA amounts from $8 million for performance in 2021 paid in 2022 to $24 million for performance in 2022 paid in 2023 (see **Appendix B, Exhibit B-26**).

Starting in July 2023, the ETC Model provided additional support to health care providers who treat patients who are dually eligible for Medicare and Medicaid or who are enrolled in a Part D prescription drug plan and receive the Low Income Subsidy. These provisions which modified the calculation of the PPAs appear to have contributed to the increase in total net PPA amounts between January–June 2023 and July–December 2023 (see **Appendix B, Exhibit B-26**). For example, the total PPA amounts for participating ESRD facilities increased by $5.1 million over this period, from $8.3 million during January–June 2023 to $13.4 million during July–December 2023 (**Appendix B, Exhibit B-26**). Further analysis indicated that this increase in PPA amounts was driven by the subset of ESRD facilities that earned additional payments for achieving improvements in home dialysis and transplant rates among dually eligible patients and Part D LIS recipients during July–December 2023. For these facilities, total PPA amounts increased by $9.5 million between January–June 2023 and July–December 2023, while for those that did not earn this adjustment, total PPA amounts declined by $4.4 million—resulting in the overall net increase of $5.1 million.

based on rates in comparison geographic areas. CMS calculates improvement scores for each participant based on how their performance during the MY compares with their past performance during a benchmark year. The range for the PPA and the magnitude of the HDPA being applied to individual ETC participants is described in **Section 1.1**.

Exhibit 16. Total ETC Payment Adjustments (Millions) Increased over Time, CY 2021–2023



Note: HDPA and PPA payment adjustment figures reflect actual payments made to the ETC participants. The underlying data differ from the analytical sample used for impact analyses, as no eligibility or attribution criteria are applied here. CY = calendar year; HDPA = Home Dialysis Payment Adjustment; PPA = Performance Payment Adjustment.

We also examined average HDPA payment adjustment (always positive payment adjustment) per facility and separately per managing clinician. During 2021, 1,252 facilities and 2,281 managing clinicians received an HDPA. The average HDPA amount per facility was $11,825, whereas the average HDPA amount per managing clinician was $463 (see **Exhibit 17**).

Exhibit 17. Average HDPA Amounts for ESRD Facilities and Managing Clinicians, CY 2021–2023

HDPA Period	ESRD Facilities		Managing Clinicians	
	# of Facilities receiving HDPA	Mean	# of MCs receiving HDPA	Mean
Jan–Dec 2021	1,252	$11,825	2,281	$463
Jan–Dec 2022	1,347	$6,993	2,264	$290
Jan–Dec 2023	1,332	$3,405	2,295	$133

Since PPA amounts can be both positive and negative, we calculated average positive and negative PPA payment adjustment amounts separately for facilities and clinicians (see **Exhibit 18**). During July-December 2023, 1,167 facilities received positive a PPA with an average PPA of $18,732 per facility during this period, while 1,598 clinicians received a positive PPA with an average PPA of $1,273 per clinician during this period. Similarly, during July-December 2023, 510 facilities

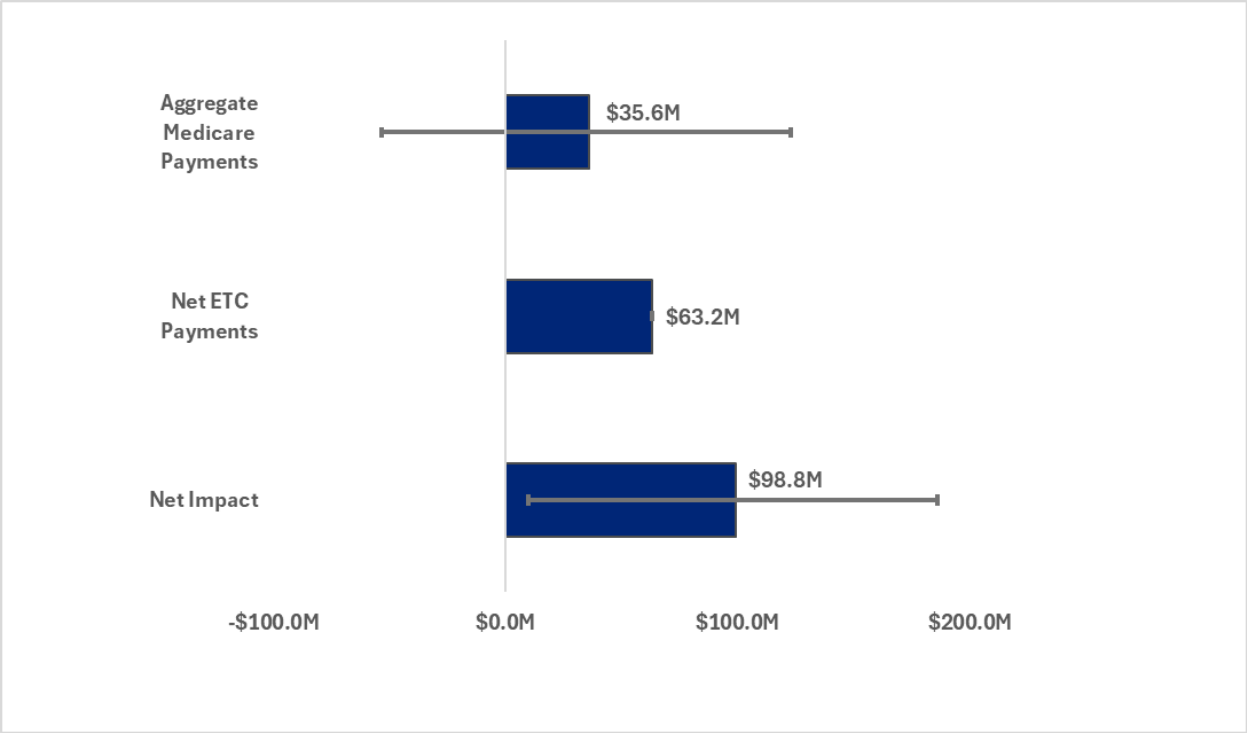
received a negative PPA with an average PPA of -$16,540, while there were 259 clinicians receiving a negative PPA with an average PPA of -$1,513 during this period (see **Exhibit 18**).

Exhibit 18. Average Positive PPA and Negative PPA Amounts for ESRD Facilities and Managing Clinicians, July 2022–Dec 2023

PPA Period	Positive PPA				Negative PPA			
	# of Facilities receiving positive PPA	Mean PPA	# of Managing Clinicians receiving positive PPA	Mean PPA	# of Facilities receiving negative PPA	Mean PPA	# of MC receiving negative PPA	Mean PPA
July–Dec 2022	950	$13,266	1,411	$917	405	-$12,950	263	-$1,363
Jan–June 2023	1,047	$12,091	1,350	$834	354	-$12,350	302	-$1,319
July–Dec 2023	1,167	$18,732	1,598	$1,273	510	-$16,540	259	-$1,513

Net Impact. As noted earlier, the ETC Model did not have a statistically significant impact on Total Medicare Parts A & B payments (gross impact). We estimated net impacts to Medicare by accounting for estimated changes in Total Medicare Parts A & B payments and the net effect of the ETC payment adjustments to model participants. For CY 2021-2023, the ETC Model had a non-statistically significant aggregate change in Total Medicare Parts A & B payments of $35.6 million (90% confidence interval: -$53.4 million to $122.4 million) (see **Exhibit 19**). As reported above (**Exhibit 16**), the total net payments to ETC participants during CY 2021–2023 totaled $63.2 million when combining the HDPA and PPA. Together, these components yield an estimated net increase in total Medicare payments of $98.8 million during CY 2021-2023 with a 90% confidence interval ranging from $9.7 million to $185.6 million (see **Exhibit 19** and **Appendix B, Exhibit B-27**).

Exhibit 19. Net Increase in Medicare Payments (Millions) due to the ETC Model, CY 2021–2023



Note: Pre-ETC period is CY 2017–2019. The cumulative impact estimate is a weighted average of the yearly DiD estimates, which reflect the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021- 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group (see Appendix B, Section B.5). Impact estimates are multiplied by patient-months (see **Appendix B, Exhibit B-28**). DiD = difference-in-differences; M = million

3.2.6. What Was the Impact of the ETC Model on Quality of Care?

Quality of Care

Potential Impacts | ETC may improve quality by incentivizing providers to carefully consider ESRD treatment options. ETC could also have a negative impact on quality if higher-risk patients are placed on home dialysis in response to model incentives.

Findings | The ETC Model had no measurable impact on quality of care, including peritonitis, vascular infections, hospitalizations with noninfectious vascular access complications, hospitalizations with ESRD-related complications, dialysis dose (Kt/V), and mortality.

This section addresses the impact of the ETC Model on several indicators that are potentially linked to quality of care. A large set of quality measures exists for dialysis and transplant care. For this evaluation, we focused on dialysis measures that could be affected by ETC, including rates of peritonitis, vascular infections, hospitalizations with noninfectious vascular access complications, hospitalizations with ESRD-related complications, dialysis dose (Kt/V) (see **Appendix B, Exhibit B-21**), and mortality (see **Appendix D**). Several motivations exist to monitor quality of care for the ETC Model. The model could incentivize providers to optimize dialysis modality selection in a way that might enhance quality measures. Alternatively, the model could have an

unintended negative impact on quality if the additional patients being placed on home dialysis have a higher risk of complications or if the additional patients placed on PD tend to be treated at facilities having relatively less experience with PD.[31,32] We included two quality measures for home dialysis to monitor this potential unintended consequence. The two quality measures (peritonitis, which is restricted to home PD patients, and vascular infections, which is restricted to HD patients) apply to all dialysis patients.

Peritonitis. Peritonitis is a major infectious complication of PD.[33] Peritonitis is a frequent contributing factor when patients decide to discontinue PD in favor of in-center HD. Peritonitis avoidance is a major goal in the management of PD patients, and providers can lower peritonitis risk in a variety of ways, including effective training and treatment protocols. The ETC Model emphasizes expansion of home dialysis, which is dominated by PD. It is possible that increased provider focus on PD could lead to improved QoC as revealed by lower rates of peritonitis and associated services. Alternatively, efforts to expand PD could result in changes to patient case mix with higher-risk patients using PD, which could adversely affect peritonitis risk.

We restricted the peritonitis evaluation to patient-months associated with PD treatment. Peritonitis risk was quantified as the percentage of patient-months with a submitted claim (inpatient, outpatient, carrier) containing a peritonitis diagnosis code. About 4.4% of patient-months were associated with a peritonitis claim. The rate was similar in the pre-ETC (CY 2017–2019) and ETC intervention (CY 2021–2023) periods for both the ETC and comparison groups (see **Appendix B**, **Exhibit B-22**). We found no statistically significant impact of the ETC Model on peritonitis rates (see **Exhibit 20**).

Vascular infections. Vascular infections in dialysis patients are usually related to HD vascular access devices. Among the available options, the infection risk is lowest for arteriovenous fistula, followed by arteriovenous grafts and vascular catheters. The DiD estimate was small and not statistically significant, indicating no difference between ETC and comparison areas in the frequency of vascular infections (see **Exhibit 20** and **Appendix B, Exhibit B-22**).

Hospitalizations with vascular complications. We also examined the frequency of hospitalizations related to noninfectious vascular complications, such as thrombosis. The rate of these complications is potentially influenced by ESRD facility procedures involved in connecting the patient to the dialysis machine. The DiD estimate was small and not statistically significant, indicating no impact due to the model (see **Exhibit 20**).

ESRD-related hospitalizations. ESRD-related hospitalizations arise from conditions that dialysis attempts to prevent, such as fluid overload and hyperkalemia (high serum potassium

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[31] Schaubel DE, Blake PG, Fenton SS. Effect of renal center characteristics on mortality and technique failure on peritoneal dialysis. *Kidney Int* 2001 Oct;60(4):1517–1524.

[32] Young EW, Kapke A, Ding Z, Baker R, Pearson J, Cogan C, Mukhopadhyay P, Turenne MN. Peritoneal dialysis patient outcomes under the Medicare expanded dialysis prospective payment system. *Clin J Am Soc Nephrol* 2019 Oct 7;14(10):1466-1474.

[33] Peritonitis is related to the presence within the peritoneal cavity of a foreign-body dialysis catheter and peritoneal fluid. Although PD patients are trained in sterile fluid exchange techniques, the catheter provides a portal of entry for pathogens, especially bacteria.

concentration). The DiD estimate was small and not statistically significant, indicating no difference between ETC and comparison areas (see **Exhibit 20**).

Dialysis dose (Kt/V). The goal of dialysis therapy is to remove toxins and fluid. Dialysis attempts to replace kidney function but cannot provide the degree of toxin removal achieved by normal kidneys. Kt/V provides a measure of the magnitude of toxin clearance. Dialysis providers are expected to monitor and manage dialysis to achieve recommended levels of Kt/V. The DiD estimate was small and not statistically significant, indicating no difference between ETC and comparison areas (see **Exhibit 20**).

Exhibit 20. No Impact on Quality of Care, CY 2021 - 2023

Outcomes	Cumulative DiD	Risk Adjusted Pre-ETC Mean	% Relative Change
Peritonitis[1]	-0.1	4.3%	-2.4%
Hospitalization with ESRD complications	-0.02	0.85%	-2.6%
Hospitalization with VA complications	-0.002	0.79%	-0.22%
Vascular Infection[2]	0.03	0.97%	2.8%
Kt/V	0.17	96.1%	0.18%

Note: Pre-ETC period is CY 2017–2019. Pre-ETC means were adjusted for patient, facility, and market characteristics. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see Appendix B, Section B.5). DiD = difference-in-differences; No DiD estimates are statistically significant at p-value <0.1

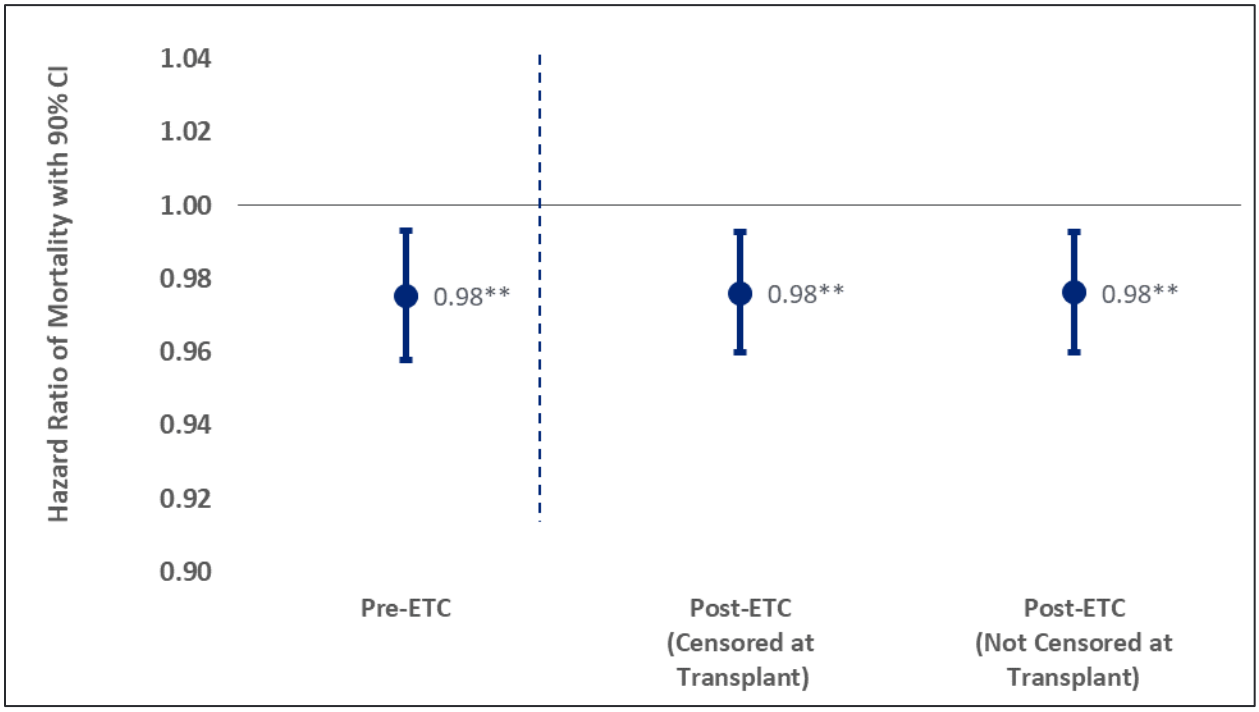
[1] Among PD patients.

[2] Among HD patients.

Mortality. Mortality is a relevant quality measure for all dialysis patients. About 20% of dialysis patients die each year, often due to cardiovascular or infectious complications. Mortality prevention has been a priority focus over the past few decades. The annual mortality rate has declined modestly as providers have identified and addressed a broad range of issues, such as vascular access, dialysis dose, fluid status, and blood pressure. Thus, mortality can be seen as an integrated measure that captures multiple aspects of care quality.

Based on a Cox proportional hazards model with adjustments for patient, facility, and market characteristics, there was no evidence of an impact of the ETC Model on patient survival during the first 3 years of the model. Patients in ETC areas had a small but statistically significant survival advantage (hazard ratio, HR=0.98) relative to the comparison group. However, this difference remained unchanged in the pre-ETC period and relative to the post-ETC period (see **Exhibit 21**). An analysis of trends in unadjusted death rates revealed increasing mortality for both groups, with rates remaining somewhat lower in the ETC group relative to the comparison group during CY 2017–2023 (see **Appendix D, Exhibit D-1**). The lack of a difference between the two approaches for censoring time at risk indicates that the ETC Model did not stimulate additional transplants sufficient to influence overall survival over the current 3-year intervention period (consistent with the ETC transplant findings described in **Section 3.2.3.**).

Exhibit 21. Risk of Mortality Slightly Lower in ETC Areas in Both Pre- and Post-ETC Periods



Note: Pre-ETC period is CY 2017–2019. Hazard ratios obtained from Cox proportional hazard models, adjusted for patient, facility, and market characteristics. * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level. We calculated hazard ratios using two approaches where the patient was followed for the outcome of death (1) until censored at transplant or end of the study period (censored at transplant) and (2) until censored at the end of study period (not censored at transplant). CI = confidence interval.

3.3. Conclusion

We evaluated the ETC Model for key outcomes directly incentivized by the model and other related outcomes of interest. As of 2023, the ETC Model showed no significant impact on the core outcomes of home dialysis use, kidney transplant waitlisting, and living donor kidney transplantation, but we did find that the model increased home dialysis training, deceased donor and total transplants, and loss of home dialysis patients to transplantation. The model had no impact on acute care hospitalizations, hospital readmissions, or ED visits, which are all significant contributors to total Medicare expenditures for this population. Consequently, there was no evidence of an impact on Total Medicare Parts A & B payments. However, when accounting for the combined net effects of the HDPA and the PPA, the model resulted in an estimated net increase in total Medicare payments of $99 million during CY 2021–2023. Quality of care measures were comparable in the ETC and comparison groups.

The potential of the model to influence outcomes increases over time due to provider adaptation and stronger financial incentives. It is important to note that the start of the ETC Model coincided with large-scale movement of beneficiaries from the Traditional (FFS) Medicare program to MA plans. The movement from FFS to MA reduced the number of patient-months in the ETC Model and diluted the financial incentives of the ETC Model. Thus, additional time may be needed to reliably measure the full impact of the ETC Model.

4. Did the ETC Model Have Different Impacts for Patient Subpopulations of Interest?

Key Findings: Patient Subpopulations of Interest	
Dialysis Modality 	Home dialysis use increased under the ETC Model for rural patients, who are likely to be among those patients who benefit the most from not having to make frequent trips to an ESRD facility. Home dialysis impacts did not differ based on dual eligibility or Part D LIS status. In our case studies, barriers to care were more frequently reported in rural areas, where patients referred to long travel times to a transplant center and to transportation challenges with periodic home dialysis patient appointments that do not occur on a consistent schedule (e.g., monthly). Many patients emphasized the importance of observing or trying home dialysis before choosing a modality type to help overcome fears and misconceptions.
Transplants 	There was no evidence of differential model impacts on waitlisting rates, overall transplant rates, or living donor transplant rates for patient subpopulations of interest. While some patients reported minimal barriers to transplant evaluation, others said the process was difficult and would have been easier if their providers had better prepared them for what to expect.
Utilization, Payments, and Quality 	We observed no overall pattern of differential impacts of the model on measures of utilization of acute care services, Total Medicare Parts A & B payments per patient per month, or quality of care for patient subpopulations of interest.
Modality Performance Scores 	In a context where the modified ETC payment adjustments provided additional support to ETC participants treating dually eligible beneficiaries and Part D LIS recipients, there was not a pattern of lower performance among ESRD facilities and Managing Clinicians who disproportionately treat these or other patient subpopulations of interest.
Patient Access to Home Dialysis and Transplants 	In interviews for the case studies, patients, ESRD facility staff, and Managing Clinicians in ETC areas reported the need for improved patient education on treatment options, transportation, mental health support services, and communication during the transplant process. Providers in case studies reported that lack of access to PD catheter placement surgery is a barrier to PD.
Participant Strategies 	Case study findings suggest that the modified payment adjustments are not a major driver of changes to reduce barriers to home dialysis and transplantation. ESRD facility staff viewed ETC Model goals as aligned with their focus on increasing home dialysis and transplantation for all patients and reported several strategies to address patient barriers to care. Managing Clinicians said the payment adjustment amounts were insufficient to implement the model.

Note: ESRD = end-stage renal disease; LIS = Low-Income Subsidy; PD = peritoneal dialysis.

In the context of the modified ETC payment adjustments that provide additional support to model participants treating dually eligible beneficiaries and Part D LIS recipients, which took effect in the second year of the model, we assessed the potential implications of the model for patients who may face greater barriers to home dialysis and transplantation. First, we examined whether the impacts of the ETC Model differ across for patient subpopulations of interest based on dual eligibility, Part D LIS status, and rural/urban location. Second, we examined whether the MPS of ETC participants differ for those who disproportionately treat patient subpopulations of interest such that the model may systematically decrease or increase future payments to these providers. In addition, we conducted case studies to improve our understanding of any efforts made by ETC participants to improve patient access to home dialysis and transplantation.

4.1. Methods

4.1.1. ETC Model Impacts on Patient Subpopulations of Interest

We specified DDD models to assess whether the impact of the ETC Model during CY 2021–2023 varied among patients with ESRD based on characteristics that relate directly to the modified ETC payment adjustments (including dual eligibility and Part D LIS status) as well as other factors. Additionally, new in this report, we tested for differences in impact estimates across patient subgroups based on rural versus urban residence. To conduct these tests, we extended our standard DiD models by formally testing whether there is a differential impact of the model for each patient subgroup relative to a reference subgroup.

We defined patient subgroups based on the following criteria:

- **Dual eligibility:** enrollment in both Medicare and Medicaid for patients with full Medicaid benefits[34]
- **Receipt of Part D LIS** (among Part D enrollees)
- **Rural/urban location:** rural, urban, and metropolitan subgroups based on the patient's mailing address[35]

For the patient subgroup analyses, we examined a subset of impact measures that are highly relevant to the design of the model or are potentially important indicators of patient well-being or resource use (**Exhibit 22**).

[34] Consistent with the definition of dual eligibility used in determining the ETC Model payment adjustments. Centers for Medicare & Medicaid Services. *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model.* 86 Fed. Reg. 213, November 8, 2021.

[35] Rural-urban indicators are based on the 2013 Rural-Urban Continuum Codes (RUCC): https://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx. RUCC = 1, 2, 3 classified as metro; 4, 5, 6, 7 as urban; and 8, 9 as rural.

Exhibit 22. Impact Measures for Patient Subgroup Analyses

Domain	Evaluation Measure
Dialysis Modality Point Prevalence (%)	▪ Percentage of patients receiving home dialysis (PD or home HD) in a given month
Modality Transition	▪ Monthly patient gains to home dialysis expressed as a percentage of patients receiving home dialysis in the corresponding month ▪ Monthly patient losses from home dialysis expressed as a percentage of patients receiving home dialysis in the corresponding month
Transplant Waitlisting	▪ Percentage of eligible patients on the transplant waitlist in a given month—overall
Transplant (per 1,000 patient-months)	▪ Percentage of patients receiving a living or deceased donor[1] kidney transplant in a given month ▪ Percentage of patients receiving a living donor[1] kidney transplant in a given month
Utilization	▪ Percentage of patients with at least one acute care hospitalization in a given month ▪ Percentage of patients with a hospital readmission in a given month ▪ Percentage of patients with at least one outpatient ED visit (without hospitalization) in a given month
Standardized Medicare Payments	▪ Total Parts A & B payments PPPM
QoC	▪ Percentage of PD patients with at least one diagnosis of peritonitis in a given month ▪ Percentage of HD patients with at least one vascular infection in a given month ▪ Percentage of patients with at least one hospitalization with a noninfectious vascular access complication in a given month ▪ Percentage of patients with at least one ESRD-related hospitalization in a given month ▪ Percentage of patients who have a Kt/V > 1.2 (for in-center HD patients) or Kt/V > 1.7 (for PD patients)

Note: All measures were analyzed at the patient-month level except for the hospital readmission measure, which was analyzed at the index discharge level. Transplant and waitlisting measures were restricted to patients less than 75 years old. Home dialysis: PD or home HD. [1]Among dialysis patients. Components of home dialysis gains (new patient gains, established patient gains, gains after failed transplant) and home dialysis losses (loss to in-center HD, loss to transplant, loss to death or withdrawal) were also examined (see **Appendix B, Section B.5.2**). ESRD = end-stage renal disease; HD = hemodialysis; PD = peritoneal dialysis; PPPM = per patient per month; QoC = quality of care.

We adjusted the primary analyses for the same set of patient, facility, and market characteristics as the overall impact analyses described in **Section 3**. However, using a fully adjusted model to assess impacts for patient subpopulations of interest can mask factors such as socioeconomic factors that contribute to differences in access to home dialysis or transplantation among subgroups that we aim to capture. To assess the sensitivity of our findings to the risk-adjustment approach, we also conducted DDD analyses that controlled for a smaller number of factors measured at the onset of ESRD. These factors included age, sex, primary cause of ESRD, comorbidities at onset of ESRD, body mass index, and duration of ESRD—factors associated with patient outcomes but unlikely to reflect differences in access to ESRD care. These analyses did not adjust for other patient, facility, or market characteristics used in the overall impact analysis. For more details on our analytic approach for these patient subgroup analyses and tests of the parallel trends assumption for the subgroups of interest, see **Appendix B, Section B.8**.

4.1.2. Analysis of Modality Performance Scores of ETC Participants

In addition to the possibility that the model has different impacts for patient subpopulations of interest, there could be patterns in the performance of ETC participants and the corresponding

ETC payment adjustments that have future implications for patient access to home dialysis and transplantation. For example, higher overall performance among ETC participants that disproportionately treat dually eligible beneficiaries or other patient subpopulations of interest who may generally have lower levels of access to care may lead to larger future payments to these providers through future ETC payment adjustments that could support future initiatives to address barriers to care. Alternatively, lower overall performance among participants that disproportionately treat patient subpopulations of interest may lead to negative ETC payment adjustments that limit the resources they can devote to any future initiatives to address barriers to care.

Using the available ETC performance reports for MY1 through MY4 that were prepared by the ETC Model implementation contractor, we assessed whether the MPS of ETC participants (including both ESRD facilities and Managing Clinicians) differ based on their patient mix. For this analysis, we defined three categories of ESRD facilities and Managing Clinicians:

- Lower MPS, based on the lowest quartile of MPS values among facilities/Managing Clinicians in the MY
- Middle MPS, which includes facilities/Managing Clinicians in the middle two quartiles of MPS values in the MY
- Higher MPS, based on being in the highest quartile of MPS values among facilities/Managing Clinicians in the MY

We compared ETC participants in the three MPS categories based on the dual eligibility status, Part D LIS status, and rural/urban status of their attributed patients. More specifically, we conducted unadjusted univariate regression models for each of the patient characteristics to examine differences among the three MPS categories of ESRD facilities and Managing Clinicians, using the lower MPS category as the reference group.

4.1.3. Case Studies on Patient Access to Care

The evaluation team conducted case studies in ETC Model areas to improve our understanding of factors that may affect patient access to home dialysis and transplants, as well as how ETC participants work to improve patient access to these treatments. Specifically, we examined nonmedical factors that can affect health. They include education access and quality, health care access and quality, neighborhood and built environment, social context, and economic stability.[36] We also explored the impact on the behavior of ETC Participants of the modified ETC payment adjustments that provide additional support to providers treating dually eligible beneficiaries and Part D LIS recipients.

We conducted 28 semi-structured interviews in total with three types of interview participants in both rural and urban locations: patients, Managing Clinicians, and ESRD facility staff (see **Exhibit 23**). Interview participants were located in 16 states across the United States (see

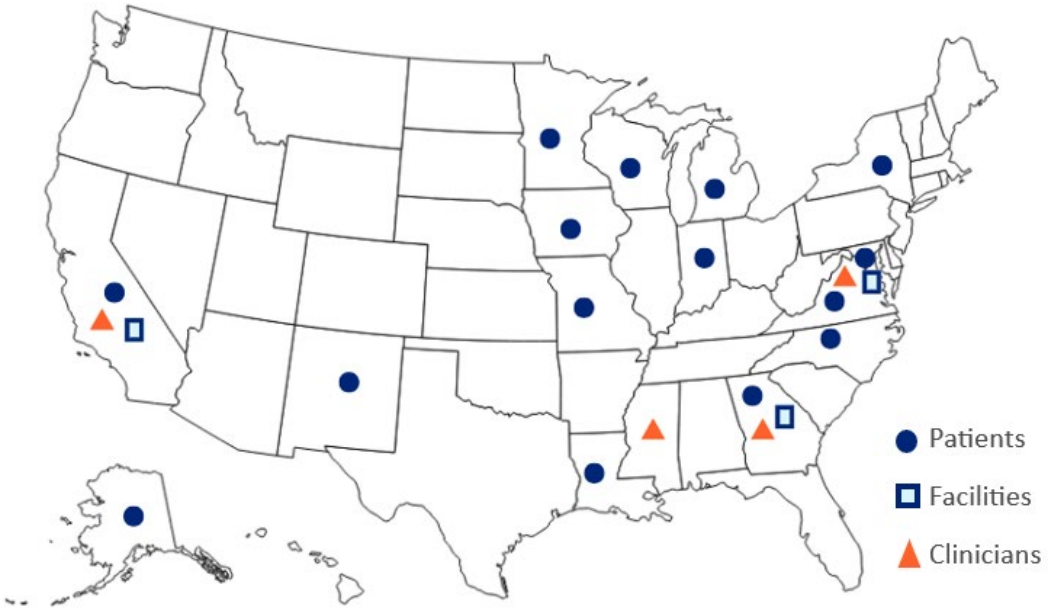
[36] Centers for Disease Control and Prevention. (2024, May 15). *Social Determinants of Health.* https://www.cdc.gov/public-health-gateway/php/about/social-determinants-of-health.html#:~:text=Overview-,Social%20determinants%20of%20health%20(SDOH)%20are%20non%2Dmedical%20factors,that%20shape%20everyday%20life%20conditions.

Exhibit 24). Providers were in four specific counties in these states, as well as some adjacent counties.

Exhibit 23. Case Study Participant Type by Urban or Rural Location

Participant Type	Urban	Rural	Total
Patients	7	9	**16**
Managing Clinicians	3	2	**5**
ESRD Facilities	3	4	**7**
Total	**13**	**15**	**28**

Exhibit 24. Geographic Location of Case Study Participants

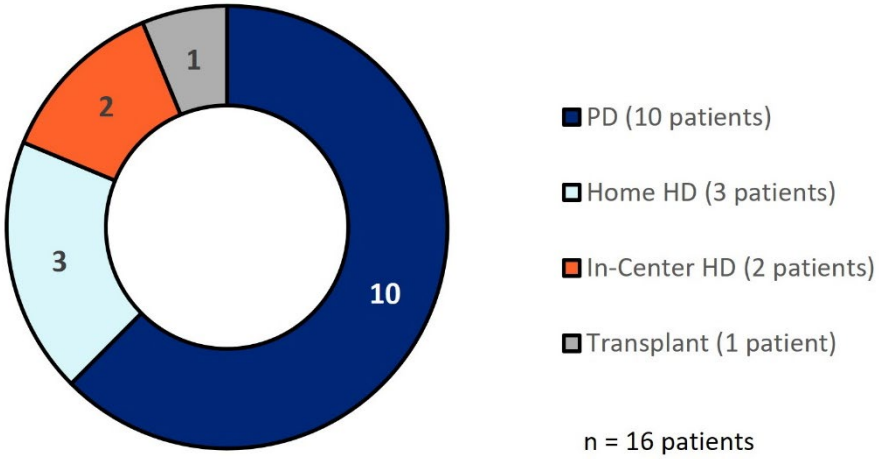


We selected the four provider case study areas because they include both urban and rural areas and have a disproportionately high percentage of dually eligible patients. See **Appendix A, Exhibit A-1** for more information on these and other provider case study area characteristics. We did not restrict patient interviews to the case study areas due to recruitment challenges. We compared findings across participant type and urban versus rural location. To contribute to our understanding of socioeconomic barriers to home dialysis and transplantation, all patients included in the sample were either dually eligible for Medicare and Medicaid or recipients of the Part D LIS. Additionally, all patients in the interview sample received care from providers who are in the ETC Model, had filled out an ETC or KCC Model survey about their experience with their care, and had expressed interest in being interviewed. Since most patients were recruited via the ETC home dialysis patient experience survey (discussed in **Section 5.**), findings may be more representative of the experiences of home dialysis patients rather than in-center dialysis patients.

Most patients were using PD at the time of their interview (see **Exhibit 25**). Six patients, one of whom had a failed transplant, had switched modalities at some point in their treatment. Notably, all

16 patients said they were using their preferred kidney failure treatment modality. See **Appendix H, Exhibit H-2** for additional details about patient sample characteristics.

Exhibit 25. Current Treatment Type among Patients Interviewed



Note: HD = hemodialysis; PD = peritoneal dialysis.

4.2. Results and Discussion

4.2.1. Did the Impacts of the ETC Model Differ by Patient Subgroup?

Home Dialysis

Potential Impacts | Based on the design of the ETC payment adjustments, the ETC Model could lead to larger gains in home dialysis use among dually eligible patients, Part D LIS recipients, and potentially other patient subpopulations. Alternatively, the ETC Model could lead to relatively smaller gains for some patients who face greater barriers to home dialysis, which could result in larger gaps in home dialysis or transplantation.

Findings | There was evidence that the ETC Model led to a relative increase in home dialysis use for rural patients.

The model did not have different impacts based on dual eligibility or Part D LIS status.

Dual eligibility and Part D LIS. Starting in CY 2022, the ETC Model payment adjustments provided additional support to ETC participants who treated patients who are dually eligible or recipients of the Part D LIS. In the pre-ETC period, about one-third of patients were dually eligible and two-thirds were enrolled in a Part D plan and received the Part D LIS (see **Appendix B, Exhibit B-11** for details). The level of overlap was high between dual eligibility and Part D LIS status; among dually eligible patients in ETC areas who were enrolled in a Part D plan, 99.6% were also recipients of the Part D LIS, while only 40.9% of non-dually eligible patients in ETC areas received the Part D LIS (see **Appendix B, Exhibit B-29**). Among Medicare beneficiaries

without ESRD, only 26.2% are recipients of the Part D LIS.[37] Through the first 3 years of the ETC Model, there was no evidence of differential effects on home dialysis use based on either dual eligibility or receipt of the Part D LIS (see **Exhibit 26**). Prior to the start of the ETC Model, use of home dialysis was lower among both dually eligible patients and Part D LIS recipients in ETC areas—4.4 and 5.3 percentage points lower than patients who were not dually eligible and not recipients of the Part D LIS, respectively (see **Exhibit 26**). However, these gaps appeared to remain relatively stable over time, as indicated by the non-statistically significant DDD estimates for these subgroups. For illustration, we provide plots of risk-adjusted trends in home dialysis use by dual eligibility for both the ETC and comparison groups in **Appendix B, Exhibit B-32**.

Exhibit 26. DDD Models Show Positive Impacts on Home Dialysis Use among Rural Patients in ETC Areas Relative to Comparison Group Areas, CY 2021–2023

Patient Subgroup		Cumulative DiD[1]	% Relative Change	DDD[1] (vs. ref group)	Pre-ETC Means in ETC Areas	Pre-ETC Gap in ETC Areas (vs. ref group)	% Change in Pre-ETC Gap
Dually Eligible[2]	Yes	0.10	1.1%	0.36	8.9%	–4.4%	–8.2%
	No (Ref)	–0.26	–1.9%	–	13.3%	–	–
Part D LIS Recipient	Yes	–0.02	–0.28%	0.03	9.0%	–5.3%	–0.58%
	No (Ref)	–0.06	–0.39%	–	14.3%	–	–
Rural and Urban	Rural	3.1**	19.0%	3.2**	16.1%	5.3%	61.3%
	Urban	0.64	4.0%	0.77	16.1%	5.2%	14.9%
	Metro (Ref)	–0.13	–1.2%	–	10.9%	–	–

Note: Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017–2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D.

[1] Corresponds to percentage point change.

[2] Includes dually eligible patients with full Medicaid benefits.

*Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

**Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

CY = calendar year; DDD = difference-in-difference-in-differences; DiD = difference-in-differences; LIS = Low-Income Subsidy.

Rural versus urban. New in this report, we explored whether impacts differed for patients in rural areas, who represented about 2% of patients in the ETC and comparison group.[38] We found no strong pattern between the rural/urban status of patients and their dual eligibility or Part D LIS status (see **Appendix B, Exhibit B-30 and B-31**).

We observed an effect on home dialysis use for patients in rural areas: There was a 3.2 percentage point gain in home dialysis among patients in rural areas relative to those in metropolitan areas ($p<0.05$; see **Exhibit 27**). This gain resulted in a level of home dialysis use among patients in rural

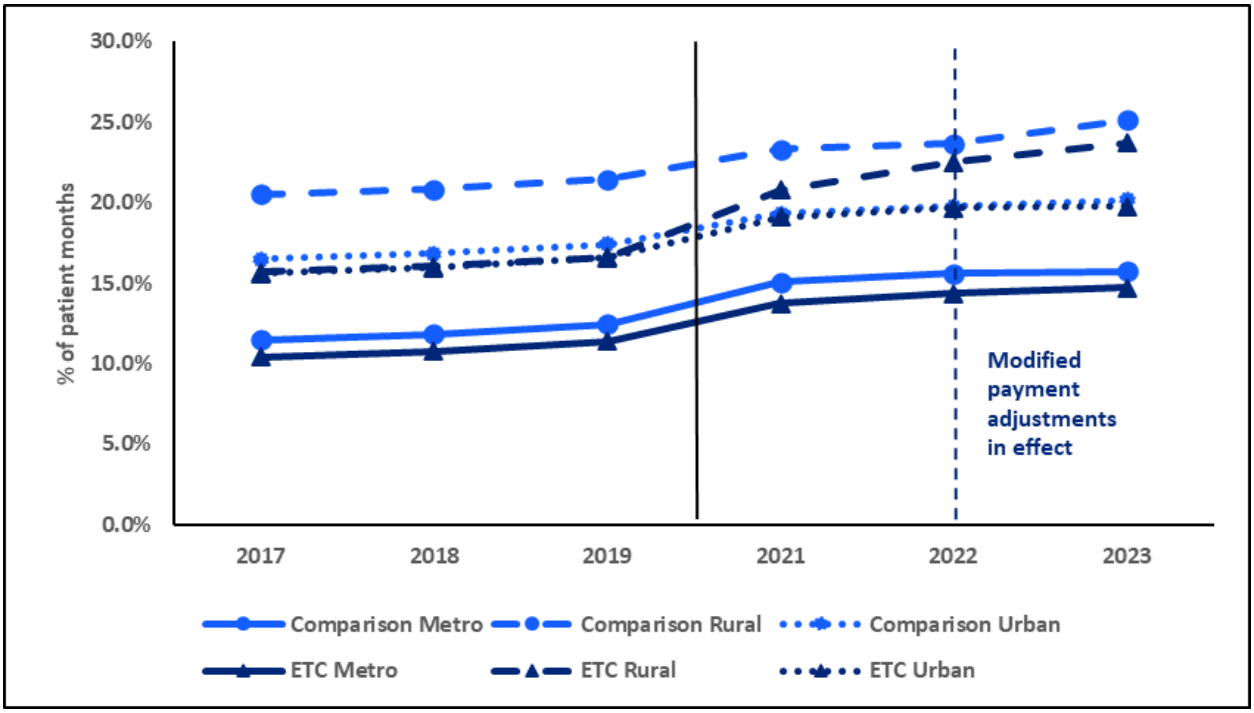
[37] United States Renal Data System. (2023). 2023 *USRDS Annual data report: Epidemiology of kidney disease in the United States.* https://usrds-adr.niddk.nih.gov/2023

[38] The rural/urban location of patients was based on their county of residence.

ETC areas in the post-ETC period that exceeded the level observed for both metropolitan and urban ETC areas (see **Exhibit 27**).

We found no evidence that the model led to different changes in home dialysis gains or home dialysis losses among rural patients (see **Appendix B, Exhibit B-35 and B-36** for details).

Exhibit 27. Adjusted Trends in Home Dialysis Use Show Faster Growth in Rural ETC Areas, CY 2017–2023



Note: CY = calendar year. Vertical dash line indicates modified ETC Model payment adjustments starting in CY 2022 which provided additional support to ETC participants who treated patients who are dually eligible or recipients of the Part D LIS.

With the ETC payment adjustments providing additional support to ETC participants for treating dually eligible patients and Part D LIS recipients in place for both the second and third years of the model, we continued to find no evidence of accelerated growth in home dialysis use in ETC areas among most patient subpopulations of interest. Instead, differences in home dialysis use among patient subgroups that predated the ETC Model have largely persisted. The exception was an observed gain in home dialysis for the relatively small rural patient subgroup. This increase could be a positive signal in that we might expect rural patients in particular to benefit from avoiding frequent trips to ESRD facilities for in-center HD treatments. Our qualitative case studies found that while dually eligible beneficiaries and Part D LIS recipients in both rural and urban areas face barriers to home dialysis, these barriers tend to be greater in rural areas (see **Section 4.2.3.** for further discussion of these findings). Thus, there may be more room for improvement in rural areas. The increased access to home dialysis among rural patients might suggest that some patients are successfully navigating the barriers they face and that ETC participants may be helping them with this process.

ETC participants may need more time to allocate additional staff, time, and resources toward home dialysis programs to begin to improve patient access to care. The qualitative data collected as part of this evaluation suggest important barriers to home dialysis likely remain for some patients. As

discussed in **Section 4.2.3.**, interviews with both patients and providers as part of our case studies point to a need for improvements in areas related to education about treatment options, mental health support for patients, and access to surgical placement of PD catheters, which could each help facilitate initiation or successful use of home dialysis. While there has been recent overall growth in home dialysis nationally, more time and resources may be needed to accelerate growth for patients who have traditionally been less likely to use home dialysis modalities and face greater barriers to care.

Waitlisting

Potential Impacts | The modified ETC payment adjustments could lead to gains in waitlisting among patients who are dually eligible or recipients of the Part D LIS and other patient subpopulations of interest. Alternatively, there could be relatively smaller gains for these patient subgroups under the ETC Model due to ongoing barriers to waitlisting.

Findings | We found no evidence of differential impacts of the ETC Model on waitlisting rates among the patient subgroups we examined.

The ETC Model did not have a different impact on waitlisting rates for patient subpopulations of interest (see **Exhibit 28**). As a result, the observed gaps in waitlisting that predated the ETC Model for certain patient subgroups largely persisted during the first 3 years of the model. For example, risk-adjusted waitlisting rates remained about 4 to 5 percentage points lower for dually eligible patients than non-dually eligible patients, in both ETC and comparison areas (see **Appendix B, Exhibit B-33**).

Exhibit 28. DDD Models Do Not Show Differential Impacts on Waitlisting for Patient Subpopulations of Interest, CY 2021–2023

Patient Subgroup		Cumulative DiD[1]	% Relative Change	DDD[1] (vs. Ref group)	Pre-ETC Means in ETC Areas	Pre-ETC Gap in ETC Areas (vs. Ref group)	% Change in Pre-ETC Gap
Dually Eligible[2]	Yes	0.73	4.4%	–0.11	16.8%	–4.1%	2.7%
	No (Ref)	0.84	4.0%	–	20.9%	–	–
Part D LIS Recipient	Yes	0.81	4.9%	0.23	16.3%	–6.2%	–3.8%
	No (Ref)	0.57	2.5%	–	22.5%	–	–
Rural and Urban	Rural	3.0*	14.8%	2.1	20.2%	1.0%	201.5%
	Urban	0.12	0.58%	–0.79	20.1%	0.90%	–87.6%
	Metro (Ref)	0.91	4.7%	–	19.2%	–	–

Note: Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017–2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D.

[1] Corresponds to percentage point change.

[2] Includes dually eligible beneficiaries with full Medicaid benefits.

*Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

**Indicates statistical significance of DiD or DDD estimate at p-value <0.05.
CY = calendar year; DDD = difference-in-difference-in-differences; DiD = difference-in-differences; LIS = Low-Income Subsidy.

Transplantation

Potential Impacts | The ETC Model could lead to relatively greater increases in living donor transplants and overall transplant rates among patients who are dually eligible or recipients of the Part D LIS and other patient subpopulations of interest. Alternatively, there could be relatively smaller gains for these patient subgroups under the ETC Model due to ongoing barriers to transplantation.

Findings | There was no evidence of differential impacts of the ETC Model on overall transplant rates or living donor transplant rates among the patient subgroups we examined.

Given the goal of the ETC Model to encourage greater use of kidney transplantation and the additional support provided to ETC participants treating dually eligible beneficiaries and Part D LIS recipients, we examined whether impacts of the model on overall rates of transplantation differ among patient subgroups when accounting for both deceased donor and living donor transplants. Based on DDD models, there were no statistically significant differential impacts on overall transplants based on dual eligibility, Part D LIS status, and rural/urban location (see **Exhibit 29**).

The overall increase in transplant rates in ETC areas relative to comparison areas (as described in **Section 3.2.3.**) appears to reflect increases among certain patient subgroups: not dually eligible, and in a metropolitan area (see **Exhibit 29**)**.** When considered together with the results presented above for waitlisting and below for living donor transplants, the increases in overall transplants for these subgroups do not appear to be driven by relative gains in waitlisting.

Exhibit 29. DDD Models Do Not Show Differential Impacts on Transplantation for Patient Subpopulations of Interest, CY 2021–2023

Patient Subgroup		Cumulative DiD[1]	% Relative Change	DDD[1] (vs. Ref group)	Pre-ETC Means in ETC Areas	Pre-ETC Gap in ETC Areas (vs. Ref group)	% Change in Pre-ETC Gap
Dually Eligible[2]	Yes	0.14	4.3%	–0.32	3.2	–1.0	30.7%
	No (Ref)	0.46**	10.7%	–	4.3	–	–
Part D LIS Recipient	Yes	0.17	5.6%	–0.09	3.1	–1.7	5.2%
	No (Ref)	0.26	5.4%	–	4.7	–	–
Rural and Urban	Rural	0.55	14.6%	0.17	3.8	–0.002	–9251.4%
	Urban	0.34	8.0%	–0.04	4.2	0.46	–9.1%
	Metro (Ref)	0.38*	10.0%	–	3.8	–	–

Note: Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017–2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D.

[1] Corresponds to transplants per 1,000 patient-months.

[2] Includes dually eligible beneficiaries with full Medicaid benefits.

*Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

**Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

CY = calendar year; DDD = difference-in-difference-in-differences; DiD = difference-in-differences; LIS = Low-Income Subsidy.

Since overall ETC Model incentives reflect a focus on living donor transplants, we separately tested whether there were differential impacts on living donor transplant rates among patient subgroups. DDD models did not show an impact of the model on living donor transplant rates for any of the patient subpopulations of interest when compared with their respective reference subgroups (see **Appendix B, Exhibit B-37**). As with the overall impact analyses, we also found no evidence that the ETC Model led to increases in living donor transplant rates when testing for impacts among individual subgroups (see **Appendix B, Exhibit B-37** for details).

Through the third year of the model, we found no evidence of relative gains in either waitlisting or transplantation for patient subpopulations of interest. Lower waitlisting and transplant rates among certain patient subgroups that predated the ETC Model—especially among dually eligible patients, Part D LIS recipients, and patients in—have largely persisted. These findings may reflect challenges in addressing what may be longstanding barriers in access to transplantation for some patients.

Certain barriers to transplantation are likely to be more common for some patients, particularly for patients with limited financial resources. Barriers can arise at various points throughout the transplant process. Whether a transplant is a viable option for patients will depend in part on whether they have the financial resources to cover the costs of being evaluated for a transplant, the transplant surgery, and post-transplant care. Once a patient expresses interest and is referred to a transplant center, there are then several steps involved in the process of being evaluated as a candidate for either a deceased donor or living transplant. The evaluation process involves a combination of tests, consultations, and procedures requested by the transplant center. In addition to out-of-pocket medical costs, there may be substantial time and expense involved for patients to travel to appointments depending on where patients live. For patients who are placed on an active waiting list for a deceased donor transplant, there are regular appointments to monitor their health and ensure that they are medically stable and remain a good candidate for a transplant.

Patients interviewed as part of the case studies identified a lack of transportation as well as a need for better communication and other support through the transplant evaluation process as important factors limiting transplantation (see **Section 4.2.3.** for details). Similarly, members of the Patient Advisory Group (PAG), which provided patient perspectives on the ETC and KCC Models to the evaluation team, identified a lack of sufficient education on dialysis and transplant modalities to support patient decision-making about their treatment as a common theme. In addition, PAG members raised concerns about the need for additional support for patients after referral for transplant evaluation, such as help understanding test results. Together, these patient perspectives point to a need for more information and support regarding transplantation and the transplant evaluation process, which could be more acute for the patient subgroups listed above and pose challenges in improving patient access to waitlisting and transplantation.

Other Outcomes

Potential Impacts | Differential impacts of the ETC Model on home dialysis use, waitlisting, and transplantation for patient subpopulations of interest could have either positive or negative implications for their relative levels of quality of care, utilization of acute care services, and Medicare spending.

Findings | There was no overall pattern of differential impacts of the ETC Model on measures of quality of care, utilization of acute care services, and Total Medicare Parts A & B payments PPPM among patient subgroups.

In determining whether the ETC Model has different impacts for across patient subgroups, it is important to consider other important outcomes among patients with ESRD beyond those aspects of ESRD care that relate directly to the model's incentives. For example, changes in the frequency of treatment complications involving the use of home dialysis could have implications for quality of care, utilization of services, and Medicare payments. Thus, we also examined changes in measures of acute care hospitalizations, hospital readmissions, outpatient ED use, hospitalizations with ESRD complications, hospitalizations with vascular access complications, peritonitis among PD patients, vascular infections, Kt/V, and Total Medicare Parts A & B payments PPPM. Broadly, there was not a pattern of the ETC Model leading to differential changes that either favored or disadvantaged patient subpopulations of interest, either overall[39] or for particular measures or patient subgroups. DDD estimates were generally not statistically significant (see **Appendix B, Exhibits B-40 to B-48**, for detailed results). Below we note the exceptions where DDD estimates were statistically significant:

- Acute care hospitalizations for Part D LIS recipients increased 0.3 percentage points (p=0.01);
- Hospitalizations due to ESRD complications declined for dually eligible patients by 0.08 percentage points (p=0.02); and
- Hospitalizations with ESRD complications increased for rural patients by 0.2 percentage points (p=0.05).

Other DDD estimates were not statistically significant for the 11 measures of quality of care, utilization, and Medicare spending that we compared across four types of patient subgroups (based on dual eligibility, Part D LIS status, and rural/urban location).

For the vast majority of measures and subgroups, we did not find evidence of a statistically significant effect of the model, and the exceptions noted above do not reflect a strong pattern of effects involving specific subgroups or specific measures. Thus, we conclude that there was not an important shift in quality of care, utilization of acute care services, or Medicare spending for patient subpopulations of interest relative to other patients due to the ETC Model. This finding also aligns with the limited evidence shown above of differential model impacts on use of home dialysis and transplantation involving these patient subgroups.

[39] Based on the 9 measures x 5 subgroup types = 45 total comparisons.

While the analyses presented in this section examined cumulative impacts of the model during its first 3 years, we also explored whether the observed impacts appeared to shift between the first year of the model and the second and third years of the model, when the modified payment adjustments providing additional support to ETC participants treating dually eligible beneficiaries and Part D LIS recipients took effect. However, the overall patterns for the relative impacts by patient subgroup were generally similar when examining impacts during each year. When testing whether results were sensitive to using a more limited set of risk-adjustment factors, we found that results were generally similar and do not suggest that our main findings are likely to be underestimating potential impacts of the model on differences in home dialysis and transplant between patient subgroups.

4.2.2. Does the Performance of ETC Participants Differ for Those Who Treat Patient Subpopulations of Interest?

ETC Performance and Patient Subpopulations of Interest

Potential Impacts | If MPS are lower among ETC participants that treat a larger proportion of dually eligible patients or other patient subpopulations of interest, the resulting ETC Model payment adjustments could result in lower payments to these providers and limit future resources for addressing barriers to care in these populations.

Findings | When the additional support was provided to ETC participants treating dually eligible beneficiaries and Part D LIS recipients during MY3 and MY4, there was not a pattern of lower performance among ESRD facilities and Managing Clinicians who disproportionately treat patient subpopulations of interest.

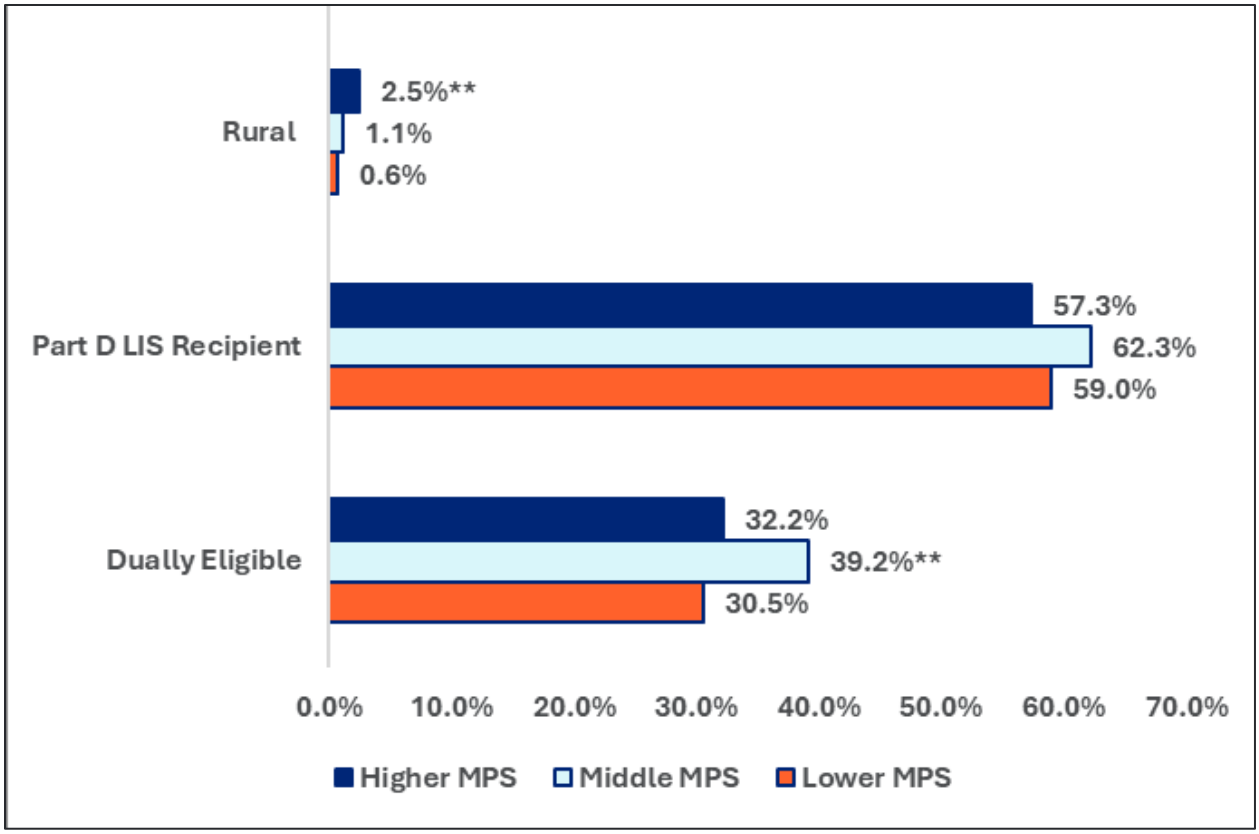
A potential unintended consequence of the ETC Model is that participants that disproportionately treat patient subpopulations of interest who have lower levels of access to care may perform worse under the model if they cannot address preexisting patient barriers to home dialysis and transplantation. The result could be widening gaps in the use of home dialysis and transplantation for some patient subgroups. To explore this possibility, we compared MPS among ETC participants based on the dual eligibility status, Part D LIS status, and rural/urban status of their attributed beneficiaries.

In MY4, we did not find a pattern suggesting that the MPS of facilities or Managing Clinicians differed based on their patient mix (**Exhibit 30 and Exhibit 31**). For example, as shown in **Exhibit 30,** the facilities in the middle MPS category had a larger share of dually eligible patients (39.2%) than facilities with higher or lower MPS values (32.2% and 30.5% of patients, respectively). There was a similar pattern across facility MPS categories for the percentage of patients who are Part D LIS recipients. Facilities with a lower MPS actually had the smallest share of patients from areas (**Exhibit 30**).

Before the payment adjustments were modified to provide additional support to ETC participants treating dually eligible patients and Part D LIS recipients (MY1–2), facilities with a lower MPS had a higher percentage of Part D LIS recipients than facilities in the middle MPS category ($p<0.1$; see **Appendix B, Exhibit B-52**). In MY1, facilities with a lower MPS also had a higher percentage of dually eligible patients than facilities in the middle MPS category ($p<0.1$; see **Appendix B,**

Exhibit B-52). In contrast, we did not observe either of these patterns in MYs when the modified payment adjustments were in effect.

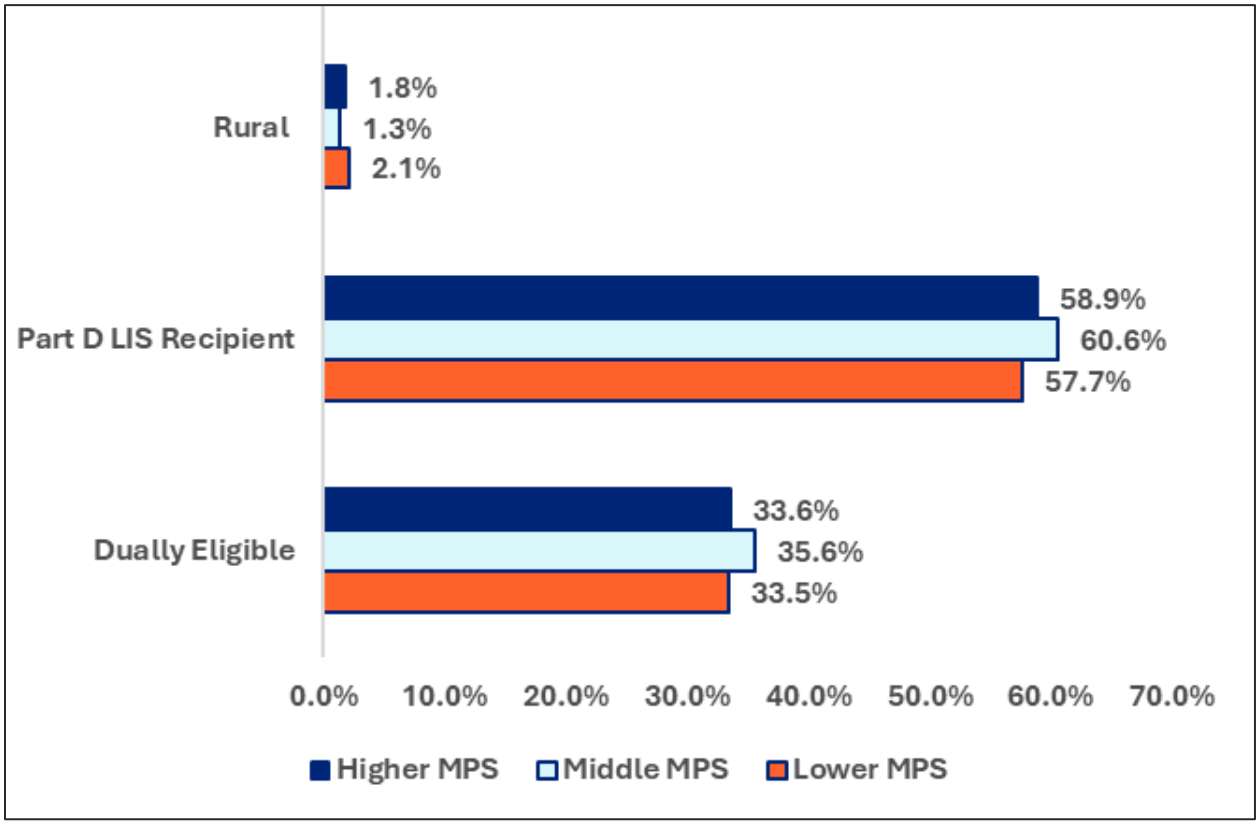
Exhibit 30. Characteristics of Patients Treated by ETC Facilities in MY4, by Facility MPS



Note: Analyses of Part D LIS recipients are limited to patients enrolled in Part D. Dually eligible is defined as Medicare patients with full Medicaid benefits. Figure presents the average percentage of patient-months with each characteristic among ETC facilities in each MPS group. Statistical significance is based on unadjusted univariate regression model for each patient characteristic to examine differences among the three MPS categories of ETC facilities, using the lower MPS category as the reference group. *Indicates statistical significance of estimated difference at p-value <0.1. **Indicates statistical significance of estimated difference at p-value <0.05. LIS = Low-Income Subsidy; MPS = Modality Performance Score.

Findings for MY4 were similar for the participating Managing Clinicians. When comparing Managing Clinician MPS groups based on their patient mix, we found no pattern of Managing Clinicians with lower performance disproportionately treating patient subpopulations of interest (**Exhibit 31**). As we found for facilities, data for MY3 also did not show a pattern of the MPS of Managing Clinicians differing based on their patient mix (see **Appendix B, Exhibit B-53**). As with the facilities, there were differences across Managing Clinician MPS categories in patient Part D LIS and dual eligible status in MY1 and MY2 that were no longer observed in MY3 and MY4. For example, in MY1, Managing Clinicians in the lower MPS category had higher percentages of Part D LIS recipients and dually eligible patients than those in the higher MPS category (see **Appendix B, Exhibit B-53**).

Exhibit 31. Characteristics of Patients Treated by ETC Managing Clinicians in MY4, by Managing Clinician MPS



Note: Analyses of Part D LIS recipients are limited to patients enrolled in Part D. Dually eligible is defined as Medicare patients with full Medicaid benefits. Figure presents the average percentage of patient-months with each characteristic among ETC Managing Clinicians in each MPS group. Statistical significance is based on unadjusted univariate regression model for each patient characteristic to examine differences among the three MPS categories of ETC Managing Clinicians, using the lower MPS category as the reference group. *Indicates statistical significance of estimated difference at p-value <0.1. **Indicates statistical significance of estimated difference at p-value <0.05. LIS = Low-Income Subsidy; MPS = Modality Performance Score.

Results for the two most recent MYs with available data on the performance of ETC participants do not suggest that the model is systematically applying less favorable payment adjustments to ESRD facilities and Managing Clinicians who disproportionately treat dually eligible beneficiaries, Part D LIS recipients, or patients in rural areas. The model therefore does not appear to be having an unintended effect of shifting resources away from these providers.

4.2.3. What Factors Impact Model Implementation among Patient Subpopulations of Interest, How Are Providers Working to Address these Factors, and What Is the Impact of the Modified Payment Adjustments on Provider Behavior?

Major barriers reported across all interview participant types include challenges related to transportation, modality education, mental health support, and communication to facilitate the transplant process. Additionally, some providers reported barriers related to patients' vascular access surgery. These barriers may help to explain why the impact analyses have not shown more gains in home dialysis and transplantation among patient subpopulations of interest, since they are often more likely to be affected by them.

4.2.3.1. Lack of Reliable Transportation

> *"If you don't have this transportation, it's hard...and it puts the patient in a very dangerous situation where their next transportation is in an ambulance to the hospital."*
>
> *– Rural ESRD facility social worker*

Lack of reliable transportation was the most commonly reported barrier to starting and maintaining home dialysis and to seeking a transplant. Patients and providers across both urban and rural locations reported this barrier. To the extent that lack of reliable transportation is a more common barrier for patients with lower incomes, it may be one of the factors limiting progress in reducing the preexisting gaps in home dialysis, waitlisting, and transplant rates involving dually eligible patients and Part D LIS recipients (as shown above in **Section 4.2.1.**).

In both urban and rural locations, transportation companies often missed scheduled pick-up times and made patients late for appointments, or they did not arrive at all. Participants reported that unreliable transportation affects home dialysis patients more than in-center patients because home dialysis patients visit dialysis clinics less consistently (for example, once per month as opposed to three times per week). Missing an appointment can lead to a long wait time to get a new transplant evaluation appointment, and some patients are never able to reschedule. Most patients reported that they do use telehealth for some home dialysis visits, when needed. However, many patients reported that either they or their provider prefer in-person visits. In-person appointments are also required for certain types of visits, such as when bloodwork is needed.

Additionally, transportation services are typically only available to some patients (such as those with Medicaid coverage within a specific county), leaving many other patients without transportation access. Although this limitation affects both urban and rural patients, it can more profoundly affect patients in rural areas, who are more likely to live farther from facilities and transplant centers. Most patients reported traveling 2 or more hours from their homes to reach a transplant center, with rural patients traveling 3 or more hours. These distances reportedly exceed what certain transportation services and insurance providers will cover; thus, transplants may not be an option for patients without reliable transportation. Despite this challenge facing rural patients in particular, we did not observe that waitlisting rates were lower for rural patients prior to the ETC Model or that rural patients were adversely affected by the model relative to patients in urban or metropolitan areas (as shown in **Section 4.2.1.**). Many patients also reported that lodging and food costs were not covered trip expenses for trips to transplant centers and were financial hardships. Although some patients can drive roundtrip in a day, making lodging unnecessary, some patients, especially older adults and those with disabilities, said that they cannot do so due to physical limitations.

When we asked providers about governmental policies that could help patients overcome treatment obstacles, they made several recommendations to address transportation issues. First, they indicated the need for government agencies to hold transportation companies accountable to improve their services. Second, providers also recommended that the government expand insurance coverage for transportation services, including mandating transportation coverage for all patients with ESRD and mandating Medicaid or Medicare transportation coverage between counties. Finally, one provider suggested implementing policies or incentives to encourage transplant center staff to conduct initial evaluations of patients while they are receiving in-center dialysis treatment. Although this approach may not be feasible due to legal and regulatory hurdles,

some transplant centers set up satellite evaluation clinics in rural areas to improve access for patients with limited transportation.

4.2.3.2. Patient and Provider Modality Education

Patients and providers frequently reported that both patients and providers must be well equipped with information and resources to enable patients to make the best treatment choices for themselves. Consistent with PAG findings, patients reported the need for earlier and more individualized education about ESRD treatment options. This included the ability to observe and even try home dialysis before choosing a modality and speaking with other patients with firsthand experience to help overcome common fears and misconceptions.

> *"I think everyone just needs to try to see how it [home dialysis] benefits them because a lot of them are scared. They won't get on a machine. They won't even try it [home dialysis] because they're so scared."*
>
> *– Rural home dialysis patient*

Several Managing Clinicians and ESRD facility staff said that they already provide education tailored to the needs of different patient populations, such as those with low health literacy. They create accessible educational materials, facilitate peer support and education, and allocate more time to patients in need of additional support to increase success with home modalities. Several providers described efforts taken within their practices and facilities to hold discussions about accurately assessing patients' abilities and shared decision-making. Similarly, many providers advocated for increased emphasis on home modality education for both patients and health care professionals to spread awareness of the benefits of home modalities and the importance of considering them for all patients.

4.2.3.3. Mental Health Support

Patients, Managing Clinicians, and ESRD facility staff described mental health support as a necessity to improve patients' ability to manage their dialysis treatment and seek transplantation. Several patients with experience on in-center or home dialysis described being exhausted, foggy, ill, and isolated while undergoing ESRD treatment. Additionally, patients with experience with in-center dialysis, home dialysis, or transplantation reported being overwhelmed and anxious. Patients stressed the importance of having access to mental health care for support coping with health and lifestyle changes during these times. One patient on home HD described the toll that managing dialysis without a care partner takes on her mental and physical health. She believes having the option to transition to in-center dialysis for 1–2 weeks per year would grant her the mental and emotional "breaks" she needs. Interview participants also reported that mental health services are often inaccessible in both low-income urban and rural locations where services may be overwhelmed or may not exist. A lack of adequate mental health services may be a concern for some patients who are considering home dialysis as a treatment option and may be a reason that some patients discontinue home dialysis.

> *"It's [home dialysis] very overwhelming…You are your own nurse, you are your own technician, you are your own social worker, you are your own electrician…you lost a certain part of your life."*
>
> *– Urban home dialysis patient*

4.2.3.4. Transplantation

Patients reported mixed experiences with transplant evaluations and waitlisting. While some patients experienced minimal barriers to being placed on a waitlist, others described challenges that prevented them from completing the evaluation. These include transportation barriers and costs, as described above, as well as issues with education and communication between patients, providers, and transplant centers. Several patients described feeling confused and overwhelmed while attempting to undergo transplant evaluation. They felt their providers had not adequately prepared them for what to expect during the evaluation, the number of appointments required, and the length of time that most patients spend on waitlists.

Of the 16 patients in our sample, three found the evaluation process so challenging that they decided not to pursue transplantation. These patients said that they would have had a better experience if they had received more education about steps in the transplant evaluation process, clearer communication from transplant center staff about appointments and evaluation requirements, and greater coordination of appointments to limit travel. Providers cited inconsistent communication between transplant centers and dialysis providers as a significant barrier to care coordination for patients seeking a transplant. Providers recommended that all ESRD facilities and nephrology offices employ transplant navigators or staff dedicated to helping patients navigate the transplant evaluation process.

4.2.3.5. Surgery Access

Many providers reported that lack of access to surgical placement of a PD catheter is a barrier to starting home dialysis and, therefore, negatively affects providers' ability to achieve ETC Model objectives. Several providers reported a lack of surgeons or long wait times for getting a PD catheter placed. Some providers, particularly Managing Clinicians, perceive that hospitals and surgeons are not motivated to perform these procedures due to low reimbursement rates, resulting in a scarcity of surgeons and long wait times to access surgical procedures. Several providers recommended implementing incentives or increasing reimbursement rates for these procedures to motivate hospitals and surgeons to perform them.

4.2.3.6. ETC Model Participant Strategies

Participant staff from ESRD facilities tended to speak more favorably than Managing Clinicians of the modified payment adjustments providing additional support for the treatment of dually eligible beneficiaries and Part D LIS recipients, which took effect in the second year of the model. They also tended to report that their facilities have prioritized increasing home modalities and transplants for years, especially over the past 3–4 years. Consistent with this finding, most patients in our sample (all of whom enabled providers to qualify for the additional support) reported receiving their first education about home dialysis and transplants from ESRD facility staff rather than from Managing Clinicians.

ESRD facility administrators reported many strategies to increase home dialysis and transplantation for patients who have historically had difficulty accessing this care. Strategies to increase home dialysis included providing internal payments to doctors to incentivize home dialysis (e.g., a payment if their patient starts on home dialysis or stays on dialysis for 6 months), connecting patients to external resources, doing motivational interviewing, providing peer support, using team-based care, and giving all interested patients a chance (for example, not making it mandatory to have a care partner).

> *"I provide community resources, if patients express that there's a need for them, helping educate patients about modalities at the clinic, also handling any patient concerns, if they did have concerns at home or in the clinic. And…if patients are having trouble paying their insurance premiums, there are different assistance programs out there, and I have to kind of facilitate that."*
>
> – Rural ESRD facility administrator

ESRD facility strategies to increase transplantation included giving providers an incentive payment when their patient gets a living donor transplant, connecting patients to resources, offering peer support, providing early referral, referring all interested patients (for example, regardless of perceived barriers), improving tracking of where patients are in the referral and evaluation process, and discussing progress toward goals.

In line with our qualitative findings in the second evaluation report, nearly all Managing Clinicians reported that the modified payment adjustments had little or no impact on how they provide care. Their responses are also in line with findings from the impact analyses in this report, which showed limited improvements in home dialysis and waitlisting rates either overall or for patient subpopulations of interest. Most providers, particularly Managing Clinicians, felt that they do not have the resources necessary to address the barriers to care described above and that current payment adjustments under the model are not significant enough to motivate change. However, many Managing Clinicians felt that increasing payment adjustments under the model could help fund additional resources necessary to improve patient care and access to home dialysis and transplant by better addressing socioeconomic, behavioral, and logistical barriers. These resources include additional staff (such as social workers, dietitians, and patient navigators), accessible mental health providers, and improved transportation services.

> *"There's more tracking done now. So, I will say one thing that's gotten a little better, at least for some practices, is even knowing who's been referred."*
>
> – Urban Managing Clinician

4.3. Conclusion

After 2 years with the model providing additional support to providers treating patients who are dually eligible or recipients of the Part D LIS, we found no emerging pattern of gains in home dialysis and transplantation for dually eligible patients and Part D LIS recipients, who are the focus of the model incentives. An exception is for patients in rural ETC areas, who showed gains in home dialysis use that warrant continued assessment. More commonly, the quantitative data indicate a pattern of existing gaps in home dialysis and transplantation for some patient subgroups that have largely persisted in the post-ETC period. These findings are reinforced by qualitative data collected as part of our case studies of patient access to care, in which a sample of ETC participants

did not identify concrete changes that they made directly in response to the model incentives targeting those who treat patients who are dually eligible or recipients of the Part D LIS. As one factor that may have limited their response to the model, some providers in our case study sample noted that they did not view the current payment adjustments under the model as being sufficient to provide the resources they would need to address patient barriers to home dialysis and transplant. We interviewed 13 patients who were dually eligible or recipients of the Part D LIS and who were successfully dialyzing at home. However, some of those patients, as well as ESRD facility staff and Managing Clinicians, suggested that there are challenges associated with home dialysis and transplant options for some patients with more limited resources that are not straightforward to address, the most common being reliable transportation. At the same time, when establishing financial incentives to improve care in areas where patients face greater barriers to care, there is a risk that they may benefit less and fall further behind other patients with respect to their access to care. However, we did not find evidence of this unintended impact of the model.

5. Did the ETC Model Impact Patient Experience of Care or Quality of Life?

Key Findings: Model Impacts

Patient Experience of Care

The ETC Model was not associated with differences in three measures of home dialysis patients' experience of care derived from the Home-DCE survey. There were also no differences in the eight measures of QoL derived from the PROMIS-29 QoL survey.

Similar to previous years' findings, in-center dialysis patients' experience of care did not change from the pre-ETC to the post-ETC period for all six measures derived from the ICH CAHPS survey.

Note: DCE= Dialysis Care Experience; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers; PROMIS = Patient-Reported Outcomes Measurement Information System; QoL = Quality of Life.

Patient-reported outcomes provide unique perspectives on aspects of patient care and health. Comparing patient-reported outcomes for patients in the ETC Model with those who are not in the model allows us to assess whether the model has a positive impact on patient experience with care and health-related QoL. The ETC Model could have benefits for patient-reported outcomes by improving how providers discuss treatment options with patients and how they manage the treatment of home dialysis patients. There may also be potential, however, for the model to have an unintended negative impact if the model incentives shift attention and resources away from the care of in-center hemodialysis patients.

We analyzed patient experience of care for both patients who dialyze in-center using the ICH CAHPS survey and for patients dialyzing at home by fielding the Home Dialysis Care Experience (Home-DCE) survey. Patient experience of care measures examined included ratings of kidney doctors, dialysis center staff, and dialysis center; nephrologists' communication and caring; quality of dialysis center care and operations; and providing information to patients. We also analyzed eight measures of QoL from patients using the PROMIS-29 survey: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social activities, pain interference, and pain intensity. All patient surveys were fielded for both the treatment and comparison groups.

5.1. Methods

Home Dialysis Care Experience Survey. To further evaluate the impact of the ETC Model on experience of care, we expanded our analyses this year by fielding the Home Dialysis Care Experience (Home-DCE) survey[40] to Medicare FFS beneficiaries who were attributed to the ETC Model (treatment group or comparison group) and who dialyzed at home. We randomly selected 8,385 patients with a Medicare FFS claim for home dialysis attributed to the ETC Model in 2022 and supplemented this with an additional 758 KCC patients[41] who were also attributed to the ETC Model in 2023, increasing the efficiency in our data collection efforts (total sample size of 9,143). The survey (available both in English and Spanish) was fielded from January through May 2024. We used a multi-mode approach (mail and phone), with phone follow-up initiated for non-respondents by interviewers trained in computer-assisted telephone interviews (CATI). We used

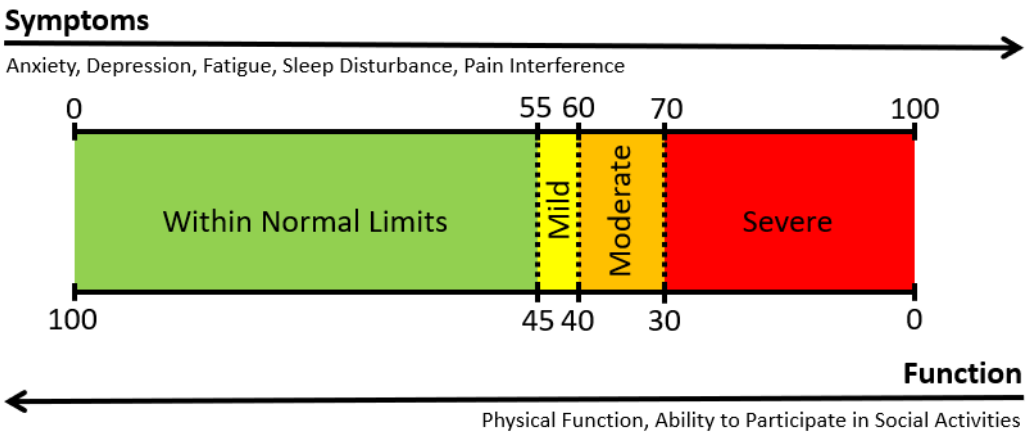
[40] Rivara MB, Edwards T, Patrick D, Anderson L, Himmelfarb J, Mehrotra R. Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis. Clin J Am Soc Nephrol 2021;16(4):588-598.

[41] We are also evaluators of the KCC model and its impact on patient experience with home dialysis.

linear regression, adjusting for select patient, facility characteristics, and survey mode, to assess the impact of the ETC Model on two global measures and one composite measure[42] (**Appendix F, Exhibit F-6**). Each observation was weighted by the inverse of the probability of selection by treatment group (ETC vs. comparison) into the survey sample as well as non-response. The regression methodology, including details about the Home-DCE survey, and measure definitions are described in **Appendix F.**

Quality of Life PROMIS-29 Survey. To further our understanding of the potential effects of the ETC Model on patients, we utilized the PROMIS-29 survey instrument, which has been validated in several chronic disease patient populations.[43] The survey captures eight outcomes of patient QoL: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, and pain intensity. Pain intensity is a one-question measure on a scale from 0 to 10, while all other outcomes are converted into a T-score, which is created to center around a reference population average of 50 with a standard deviation of 10 (**Exhibit 32**). The reference population includes respondents with chronic diseases, including kidney disease.

Exhibit 32. PROMIS-29 Domain Level T-Score Mapping



Note: PROMIS = Patient-Reported Outcomes Measurement Information System.
Source: Adapted from Sturgill D, Bal N, Nagavally S, and Wolfgram D. The Relationship between Dialysis Metrics and Patient-Reported Cognition, Fatigue, and Physical Function. Kidney Dis 2020;6:364–370.

For the measures of symptoms, anxiety, depression, fatigue, sleep disturbance, and pain interference measures, a T-score below 55 is considered within normal limits, 55-60 is considered "mildly" higher than the reference population, and 60-70 is considered "moderately" higher. For the measures of physical function and ability to participate in social roles and activities, a T-score higher than 45 is considered within normal limits, 40-45 is considered to be "mildly" lower than the reference population, and within 30-40 points is considered "moderately" lower.

[42] Measures were constructed by the Home-DCE survey developers (Rivara MB, Prince D, Leuther K, Hussein W, Mehrotra R, Edwards T, Schiller B, Patrick D. Evaluation and Measurement Properties of a Patient-Reported Experience Measure for Home Dialysis. Clin J Am Soc Nephrol 2024;19(5):602-609).

[43] The PROMIS-29 instrument can be found at http://www.healthmeasures.net/administrator/components/com_instruments/uploads/15-09-02_02-16-11_PROMIS-29Profilev2.0InvestigatorVersion.pdf

Survey participants were selected from a pool of home dialysis, in-center HD, and transplant patients for both ETC and comparison groups. The survey was fielded from March through June 2024. We used a multi-mode approach (mail and phone), with phone follow-up initiated for non-respondents by interviewers trained on computer-assisted telephone interview (CATI). Materials were available in English and Spanish. Among the 3,471 survey respondents (26.4% response rate), there was a similar number of respondents for each modality (**Appendix G, Exhibit G-4**).

Descriptive analyses showed similarity between patients in the survey sample and respondents in most characteristics (**Appendix G, Exhibit G-5**), as well as between the ETC and comparison groups among survey respondents (**Appendix G, Exhibit G-6**). We used linear regressions to evaluate the impact of the ETC Model on the eight PROMIS-29 outcomes, adjusting for several patient-mix factors and survey mode and a subset of the patient, facility, and market characteristics (**Appendix G, Exhibit G-6**). Further details about the methodology, including the PROMIS-29 data source, measure definitions, and results from the linear regressions are described in **Appendix G.**

ICH-CAHPS survey. We utilized data from the ICH-CAHPS surveys that are routinely administered to in-center HD patients nationally and provide information on experience of care before and after the start of the ETC Model. Consistent with evaluation of other measures discussed in **Section 3.**, we used a DiD framework to compare changes in three global ratings and three composite measures derived from ICH CAHPS data for patients over time in the ETC areas to patients in a comparison group consisting of HRRs that were not selected for inclusion in the ETC Model. Our facility survey wave-level analyses included ESRD facilities with ICH CAHPS survey data during the pre-ETC (spring 2017-fall 2019 survey waves) and post-ETC (spring 2021-fall 2023 survey waves) periods. All patients at a facility who responded to the ICH CAHPS survey were included in the analyses, regardless of whether the patients were attributed to the ETC Model. Descriptive analyses of facility characteristics showed similarities in the characteristics of facilities with ICH CAHPS data between the ETC and comparison areas (see **Appendix E, Exhibits E-5,** and **E-6**). The six ICH CAHPS-derived measures were adjusted for several patient-mix factors, survey mode, and for a subset of patient, facility, and market characteristics (see **Appendix E, Section E.4**). Further details about the DiD methodology, including the ICH CAHPS data source, measure definitions, and results from the dynamic trends test to assess parallel trends are described in **Appendix E**.

5.2. Results and Discussion

Patient Experience and Quality of Life

Potential Impacts | The ETC Model could have a positive impact on patient experience of care or their QoL by improving how providers discuss treatment options with patients in ways that lead to a better modality choice for each patient. The model could also impact QoL for in-center and home dialysis patients by affecting how providers manage their treatment. There is also potential for an unintended negative impact on experience of care and QoL for in-center HD patients in the event that the model incentives divert attention and resources away from the delivery of in-center HD.

Findings | There were no positive or negative impacts of the ETC Model on experience of care for home dialysis patients or in-center HD patients, including ratings of the dialysis center, the dialysis center staff, or the quality of center care and operations, which were examined for both patient groups. Similarly, the model was not associated with differences in eight aspects of QoL for home dialysis patients, in-center HD patients, or transplant patients.

5.2.1. Was the ETC Model Associated with Differences in Patient Experience of Care for Home Dialysis?

A central research question for the evaluation of the ETC Model involves its potential effects on patient experience of care, particularly for patients who dialyze at home since the model creates incentives for increased access to home dialysis. As such, experience of care may be better for patients who home dialyze in ETC areas as ESRD facility staff spend more time and resources in response to the model's incentives. Alternatively, since home dialysis is still relatively rare compared to in-center HD, providers may continue to focus on the more prominent modality, with no effect or an unintended adverse effect on home dialysis patients' experience of care.

Since data on patient experience for patients with ESRD dialyzing at home have not been routinely collected, we fielded the 26-item Home-DCE survey instrument[44] to ETC and non-ETC Medicare FFS beneficiaries who dialyze at home (see **Section 3.2.**). The two global measures – rating of dialysis center staff and rating of dialysis center – created by the Home-DCE survey developers,[45] closely align with two of the ICH-CAHPS global measures. Similarly, the composite measure – quality of home dialysis center care and operations – is similar to the ICH CAHPS-derived measure of quality of dialysis center care and operations (**Appendix F, Exhibit F-4**). Like the ICH CAHPS measures, the three Home-DCE-derived measure outcomes reported reflect "top-box" scores, reflecting the highest level of satisfaction. As such, analyses of the Home-DCE data complement analyses of the existing ICH CAHPS data (discussed below) that capture patient experience for patients with ESRD dialyzing in-center.

[44] Rivara MB, Edwards T, Patrick D, Anderson L, Himmelfarb J, Mehrotra R. Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis. *Clin J Am Soc Nephrol* 2021;16(4):588-598.

[45] Rivara MB, Prince D, Leuther K, Hussein W, Mehrotra R, Edwards T, Schiller B, Patrick D. Evaluation and Measurement Properties of a Patient-Reported Experience Measure for Home Dialysis. *Clin J Am Soc Nephrol* 2024;19(5):602-609.

We had 3,654 survey respondents (40.0% response rate) out of which 3,126 (85.6%) indicated on the survey that they had dialyzed at home for at least 3 months.[46] The final sample of 3,126 patients (1,299 in the ETC group; 1,827 in the comparison group) were similar to the overall ETC home dialysis population on most patient characteristics[47] (**Appendix F, Exhibit F-5**) and also showed a high degree of balance between the ETC and comparison groups (**Appendix F, Exhibit F-6**).

The unadjusted measure values are similar between the ETC and comparison groups with 86.6% to 90% of home dialysis patients rating their dialysis center and its staff nine or ten on a scale of one (worst) to 10 (best) (**Exhibit 33**). Values for the composite measure that assessed patients' perception of the quality of care were also high (78%-78.5%).

After adjusting for patient and facility characteristics, there continued to be no difference between ETC and the comparison group for the three home dialysis patient experience of care measures (**Exhibit 33 and Appendix F, Exhibit F-7**).

Exhibit 33. No Difference in Home Dialysis Patient Experience of Care Measures between ETC and Comparison Groups: All Patients

Measures	Unadjusted Means		Model Estimate	p-value	Lower 90% CI	Upper 90% CI
	ETC	Comparison				
Rating of Dialysis Center Staff	90.0%	88.2%	1.8%	0.20	-0.51%	4.1%
Rating of Dialysis Center	88.6%	86.6%	2.4%	0.12	-0.14%	5.0%
Quality of Home Dialysis Center Care and Operations	78.5%	78.0%	0.50%	0.59	-1.0%	2.0%

Note: Results are weighted. Means are unadjusted. Model estimates were adjusted for patient, facility, and market characteristics. Analyses were performed at the patient level. The regression analysis for the two global rating measures models most favorable response (rating of 9 or 10 for global rating question) vs. other responses. The composite measure calculation reflects the most favorable response on 12 individual questions. CI = Confidence interval.

5.2.2. Was the ETC Model Associated with Differences in Patient Quality of Life?

By encouraging greater consideration and use of home dialysis and transplantation as treatment options for ESRD – particularly living donor transplants – there is potential for patients in the ETC Model to realize higher QoL than patients outside the model. More effective communication between providers and patients about treatment options could facilitate greater access to alternatives to in-center HD and a more tailored approach to modality selection that better aligns with patient treatment and life goals. This represents a potential benefit for all patients, whether they are undergoing home dialysis or in-center HD or receive a transplant.

[46] All patients were identified as dialyzing at home from FFS Medicare claims. However, during the fielding period that began 12 months later (January 2024), 524 respondents indicated on the survey they did not dialyze at home for at least three months, and the survey skip patterns excluded them from subsequent questions that were used to construct the measures; these patients were therefore excluded from the analysis. A small number of these patients (156) ignored the survey skip patterns and provided at least 1 response to the core survey questions. However, we excluded their responses since they did not self-identify as a home dialysis patient.

[47] Except age and number of months on home dialysis for both ETC and comparison groups and the Midwest region for the comparison group.

We analyzed eight QoL measures from patients using the PROMIS-29 survey: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social activities, pain interference, and pain intensity. All surveys were fielded to both patients in the treatment group and patients in the comparison group. Our analysis is based on data for 3,471 patients (1,566 in the ETC group; 1,905 in the comparison group) across the three modalities who responded to the survey (see **Appendix G, Exhibit G-4**). Descriptive analyses showed similarity in the majority of characteristics between the overall ETC population and respondents (**Appendix G, Exhibit G-5**) as well as between the ETC and comparison groups within the analytic sample of respondents (**Appendix G, Exhibit G-6**).

The unadjusted QoL measure values are similar between the ETC and comparison groups across the eight outcomes (**Exhibit 34**). Based on a comparison of patient QoL for all respondents between the ETC and comparison groups, we found no clinically meaningful differences in QoL for all eight outcomes (**Exhibit 34**). For the first seven outcomes in **Exhibit 34**, which use T-scores, a value of 50 represents the average for the reference population and 10 represents one standard deviation. Lower scores are interpreted as being better for all measures except physical function and ability to participate in social activities. Both the ETC and comparison groups are within five points of 50 for all seven T-score outcomes except physical function and pain interference, suggesting the other five outcomes are within normal limits.[48]

Although the physical function scale was lower for the ETC group by an average of 1.0 point (90% CI of [-1.8,-0.28]), it is not considered clinically meaningful since the magnitude of the difference does not exceed 3 points.[49] When examining QoL separately for home dialysis patients, in-center HD patients, and transplant recipients, no estimates were clinically meaningful (**Appendix G, Exhibits G-7–G-9**).[50]

Exhibit 34. No Clinically Meaningful Differences in Patient QoL between ETC and Comparison Groups: All Patients

Outcome	Unadjusted Mean		Model Estimate	p-value	Lower 90% CI	Upper 90% CI
	ETC	Comparison				
Physical function	37.4	37.5	-1.0	0.02	-1.8	-0.28
Anxiety	52.6	53.0	0.21	0.72	-0.74	1.2
Depression	51.4	51.5	0.42	0.47	-0.53	1.4
Fatigue	54.6	54.8	0.58	0.29	-0.32	1.5
Sleep Disturbance	52.0	52.8	-0.27	0.66	-1.3	0.76
Ability to Participate in Social Activities	45.5	45.4	-0.38	0.48	-1.2	0.49
Pain Interference	57.3	58.0	-0.43	0.48	-1.4	0.57
Pain Intensity	4	5	-0.28	0.14	-0.59	0.03

[48] Physical function is between 10-20 points lower than 50 for both groups, suggesting a moderately lower amount of physical function compared to the reference population and pain interference is between 5-10 points higher than 50 for both groups, suggesting a mildly higher amount of pain interference compared to the reference population.

[49] *Meaningful Change for PROMIS.* (n.d.). https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/meaningful-change

[50] One estimate was statistically significant, but the magnitude was well below the threshold to suggest meaningful results.

Note: Results are weighted. Model estimates were adjusted for patient, facility, and market characteristics. Analyses were performed at the patient level. Lower scores are interpreted as being better for all measures except physical function and ability to participate in social activities. All rows except pain intensity are T-scores scaled to have a mean of 50 and a standard deviation of 10 for the reference population. Pain intensity was rated on a scale from 0 to 10, with 10 being the worst. CI = Confidence interval; QoL = Quality of Life.

5.2.3. What Was the Impact of the ETC Model on Patient Experience of Care for In-Center Dialysis?

Changing patterns in modality use – a key focus of the ETC Model – could potentially have important implications for patient experience of care. Although encouraging more home dialysis is a key focus of the ETC Model, there is also potential for the model to influence patient experience of care for those undergoing in-center HD, which continues to be the predominant treatment modality for ESRD. For patients dialyzing in facilities in the ETC areas, their experience of care may be enhanced through greater communication about treatment options and shared decision making with staff. Alternatively, if staff and resources are diverted away from in-center dialysis care in response to the model's emphasis on increasing access to home dialysis and transplantation, there could be an unintended adverse impact on in-center HD patients' experience of care.

To examine experience of care among in-center HD patients, we used "top-box" scores, reflecting the highest level of satisfaction (for example, the percent who gave a rating of nine or 10 on a zero to 10 scale) for six measures derived from the ICH CAHPS survey: rating of kidney doctors (global); rating of dialysis center staff (global); rating of dialysis center (global); nephrologists' communication and caring (composite); quality of dialysis center care and operations (composite); and providing information to patients (composite) (see **Appendix E**).

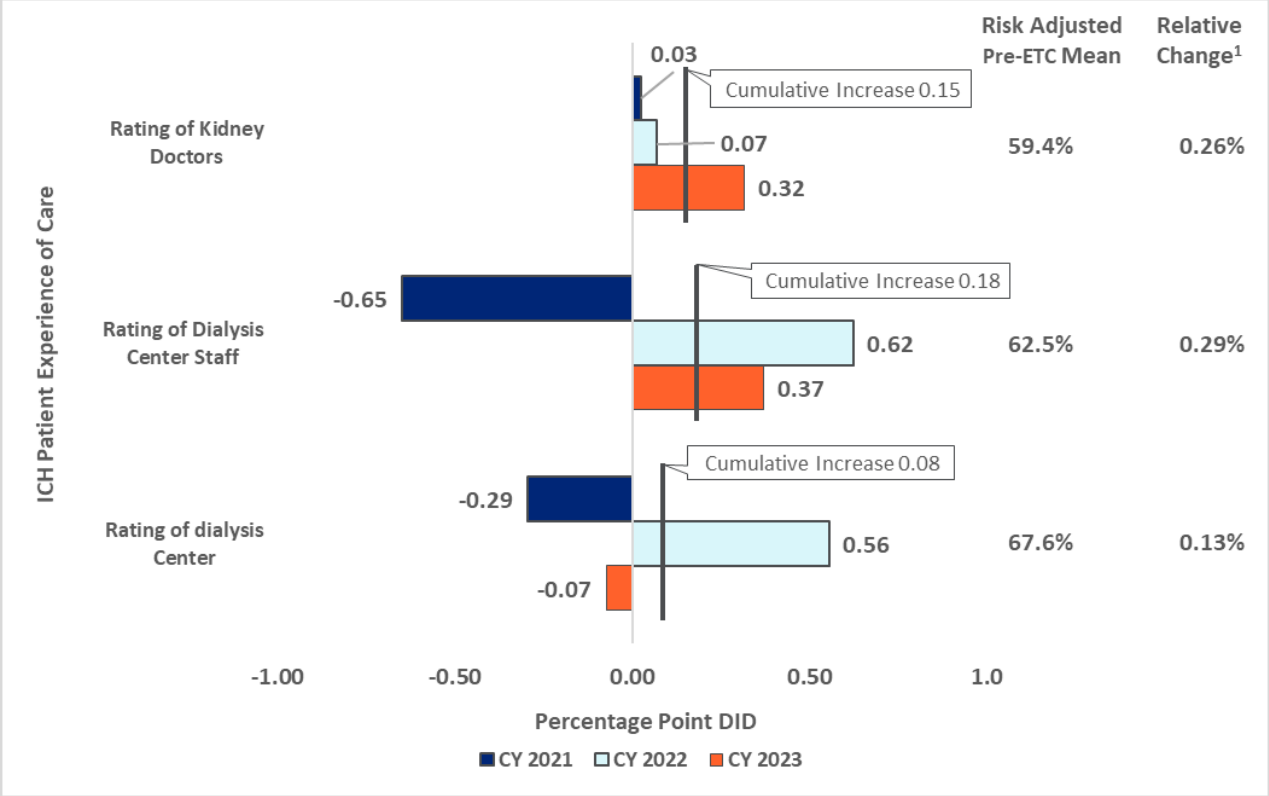
Our analysis is based on data for patients who responded to the ICH CAHPS survey and dialyzed at ESRD facilities that are located in the ETC and comparison areas and had at least 30 completed ICH CAHPS surveys from the two most recent survey waves. Approximately 60% of ESRD facilities included in the overall impact analysis were included in the ICH CAHPS analysis in the pre-ETC period, with similar shares between the ETC and comparison groups (see **Appendix E.3**). Following implementation of the ETC Model, the share of ESRD facilities with ICH CAHPS data ranged from 47% and 49% of in the ETC group and comparison group, respectively, in the first year of the model 62% and 63%, respectively, in the third year of the model. The decline in the number of ESRD facilities with ICH CAHPS data in the initial years of the model was driven by declines in survey response rates, which were highest in the fall 2017 survey wave (33% for both ETC and comparison groups), lowest in the fall 2021 survey wave (20% in both groups), and were higher in the 2022 and 2023 waves (ranging from 24% to 26% in both groups; see **Appendix E** for details).

Similar to our previously reported findings,[51] relative to the comparison group, we found no statistically significant impact of the ETC Model on any of the six in-center HD patient experience measures in the post-ETC period, cumulatively or for the three individual CYs (**Exhibit 32** and

[51] The Lewin Group (July 2023). *ETC Model 1st Annual Evaluation Report and Appendices*. The Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation. https://innovation.cms.gov/data-and-reports/2023/etc-1st-eval-report-app and The Lewin Group (January 2024). *ETC Model 2nd Annual Evaluation Report and Appendices*. The Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation. https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt.

Exhibit 36).[52] A limitation of the analysis was that the sample was based on all patients with ESRD receiving in-center HD at the facility (including patients not covered by the Medicare FFS program) rather than restricting solely to patients attributed to the ETC Model.

Exhibit 35. No Impact on Global Measures of ICH Patient Experience of Care



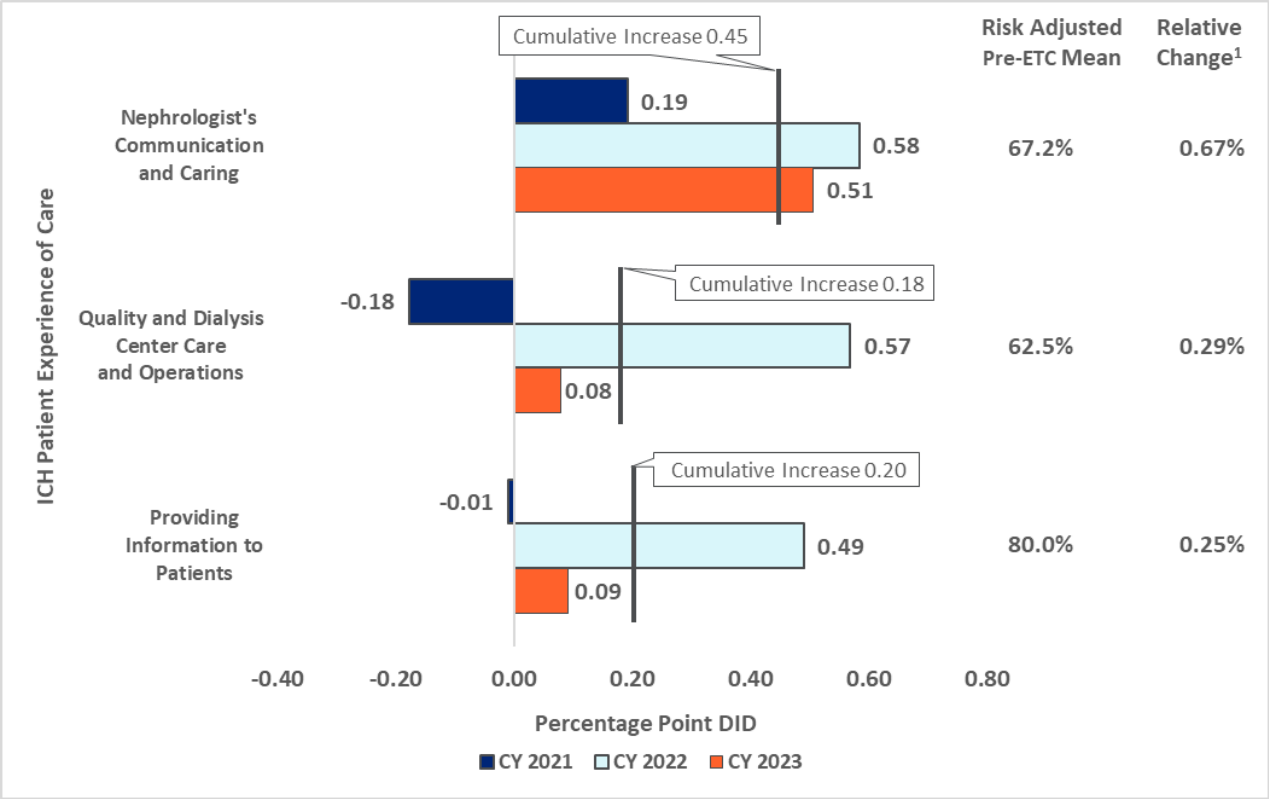
Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021 - CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B.5**) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding).

CY = calendar year; DiD = difference-in-differences; ICH = In-Center Hemodialysis.

[52] Findings were similar based on DiD analyses that were limited to a subset of facilities with available ICH CAHPS data in both the pre-ETC and post-ETC periods (see **Appendix E, Exhibit E-9**).

Exhibit 36. No Impact on Composite Measures of ICH Patient Experience of Care



Note: Pre-ETC period is CY 2017–2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021 - CY 2023 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B.5**) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

[1] Relative change based on cumulative (CY 2021 + CY 2022 + CY 2023) DiD estimate (before rounding).

CY = calendar year; DiD = difference-in-differences; ICH = In-Center Hemodialysis.

5.3. Conclusion

To examine the ETC Model's impact on patient experience, we surveyed patients who dialyze at home and who were therefore more directly impacted by the ETC Model incentives. We also fielded a separate survey to home dialysis, in-center HD patients and transplant recipients to assess differences in patient QoL associated with the model. Our cross-sectional analyses found no difference in experience of care for home dialysis patients for three measures that mapped closely to similar ICH CAHPS measures, nor on ESRD patient QoL with respect to physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social activities, and pain interference or intensity. There was no change in experience of care for in-center HD patients, based on ICH CAHPS survey data, in six patient-reported outcomes. These results reinforce our claims-based findings that suggest the model did not improve or adversely affect the quality of patient care.

6. Discussion

The ETC Model design features a randomized selection process and mandatory participation of both ESRD facilities and Managing Clinicians, which provides a strong foundation for evaluating the effects of the model. The selection process yielded a geographically broad and diverse sample for the intervention. There was a high overall level of balance between ETC areas and the areas not selected for the model (that is, comparison geographic areas) on a wide range of factors. The DiD framework exhibited balance across ETC and comparison group characteristics, parallel trends in the pre-ETC period for the vast majority of outcomes and impact estimates were robust to alternative risk-adjustment covariates.

AR3 summarizes ETC Model results through the first 3 years of its implementation period. The ETC Model establishes financial incentives for participating ESRD facilities and Managing Clinicians to expand home dialysis, transplant waitlisting and living donor kidney transplantation. The incentive periods and two types of payment adjustments under the model were both in effect as of July 2022, when the initial PPAs were applied and certain payments to participating ESRD facilities and Managing Clinicians were adjusted either upward or downward based on their performance on home dialysis and transplant measures. We used a mixed methods research design that included both quantitative and qualitative data. This report presents analyses of home dialysis use, transplantation, and other outcomes, integrated with results from recently administered home dialysis patient experience of care and QoL surveys. Additionally, we conducted case study interviews with patients, ESRD facility staff, and Managing Clinicians in ETC areas to better understand factors that affect patient access to home dialysis and transplantation, how ETC participants work to improve access, and the impact on provider behavior of the additional support provided for the treatment of patients who are dually eligible for Medicare and Medicaid or recipients of the Part D LIS. The qualitative data provide context for interpreting results of the quantitative analyses.

Growth in home dialysis in the ETC and comparison groups was similar through the first 3 years of the model. This includes recent growth for both PD and HHD. We did find that home dialysis training grew at a faster rate in ETC vs. comparison areas in all three model years, a potential signal of model impact. We also found higher home dialysis gains in some model years and a consistent pattern of higher losses from home dialysis to transplantation in ETC areas. These small but emerging trends suggest additional home dialysis gains were offset by higher transplantation, which would be considered a positive patient outcome. We expect clarification of these early signals as the model continues. As in AR2, there was no evidence of accelerated growth in home dialysis use in ETC areas among patients and facilities for whom early gains may have occurred more readily, including younger dialysis patients or patients treated at facilities with larger, established home dialysis programs.

Our ETC Model findings cover the calendar years from 2017 through 2023. In fact, home dialysis has been growing at a slow but steady rate since 2010, following a long period of decline. The start of the current growth phase coincides with the introduction of the current Medicare ESRD prospective payment system, which eliminated some of the financial incentives that favored in-center hemodialysis. Home dialysis rates have been growing steadily from 12% in the pre-ETC period to 16% in the post-ETC period for both the groups. The overall growth rate over 2017–2023 of approximately 0.6 percentage points/year reflects patient availability and provider capacity.

Further, the expansion of home dialysis capacity requires time to grow infrastructure, especially nursing and medical staff with the training and level of interest needed for a successful program. Given the clinical complexity of the patient population and the need for development of home dialysis infrastructure, it is still early to form conclusions about the long-term effects of the ETC Model incentives in driving further home dialysis expansion.

With respect to transplantation, there was also no evidence through the first 3 years of the model of an impact on either waitlisting rates or living donor transplant rates, which are both a specific focus of the ETC Model incentive structure. There was evidence of faster growth in overall transplant rates in ETC areas relative to comparison areas in all model years, significantly for 2021 and 2023. The growth in overall transplants was entirely attributable to growth in deceased donor transplants. The transplant findings are consistent with higher losses from home dialysis to transplantation. The losses from home dialysis to transplantation may have diluted the ETC Model impact on home dialysis prevalence (see above). The growth in transplantation in ETC areas may not be attributable to the ETC Model incentives given the lack of impact on transplant waitlisting and the absence of direct incentives for deceased donor transplantation. In response to long transplant wait times and federal oversight attention, the regional organ procurement organizations and transplant centers have expanded organ procurement and placement efforts, resulting in substantial growth in deceased organ transplants since 2015.[53] There are fewer OPOs and transplant centers than ESRD facilities in the US. Natural variation exists in the magnitude of transplant growth by organ procurement organization and transplant center.

Together, the quantitative and qualitative data suggest home dialysis and transplant options that predated the ETC Model. Furthermore, the growth in home dialysis and transplant rates was comparable in both ETC and comparison areas through the first 3 years of the model. In interviews that we conducted with staff from ESRD facilities and Managing Clinicians in 2023 (described in **AR2**), ETC participants described robust patient engagement efforts to inform patients of dialysis modality and transplant options, with most patient engagement and education strategies predating model implementation. If participants perceive the ETC Model as part of a broader movement to place greater emphasis on facilitating home dialysis and transplantation for patients, we may not expect changes in practice to be confined to ETC areas.

In the context of these findings related to home dialysis and transplantation, there was also no pattern of changes in key utilization and payment outcomes. There were no model impacts on either acute care hospitalizations or hospital readmissions, which are both relatively common among patients with ESRD. As in prior annual reports, DiD analyses continue to indicate no statistically significant change in overall Medicare payments among dialysis patients due to the ETC Model aside from the effects of the HDPA and the PPA. As a new addition to this report, our analysis of the net impact of the model on Medicare spending when taking into account the ETC payment adjustments showed a net increase in total Medicare payments to the participating ESRD facilities and Managing Clinicians through the first 3 years of the model combined. Some of this increase was driven by the positive adjustments made through the HDPA. It is likely that the modified payment adjustments providing additional support for the treatment of dually eligible

[53] Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Accessed 10/15/2024. http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx

patients and Part D LIS recipients contributed to the net positive PPA amounts starting in July 2023. While the HDPA was no longer in effect starting in CY 2024, the net impact on Medicare payments in the remaining years of the model will continue to depend on the relative magnitude of the positive and negative adjustments made through the PPA.

Given that the ETC Model aims to achieve increased use of home dialysis and transplantation while preserving or enhancing quality of care for Medicare beneficiaries, we explored whether changes in dialysis modality use had impacts on patient QoC. We examined several indicators of quality of care that involved a range of clinical complications and other important patient outcomes and found no measurable impact of the model. More generally, there was no early evidence of adverse unintended impacts of the model, which will continue to be an important area of focus for the evaluation.

With the modified payment adjustments providing additional support for the treatment of dually eligible patients and Part D LIS recipients in place for two years, the model did not lead to a pattern of either relatively larger or relatively smaller gains among patient subpopulations of interest who were previously less likely to use home dialysis or to be transplanted. Lower rates of home dialysis use, waitlisting, and transplantation among certain patient groups that predated the ETC Model – especially among dually eligible patients and Part D LIS recipients – have largely persisted. There was a positive impact of the model on home dialysis use among rural patients, which led to home dialysis use that further exceeded that of patients in other areas. When examining the MPS of ETC participants, there was also no indication that the current payment adjustments lead to systematically lower payments to providers who may face greater challenges in improving access to home dialysis and transplant among their patient populations.

In alignment with the quantitative findings, the case study findings do not suggest that the modified payment adjustments used for the most recent two years of the model have been a major driver of change among ESRD facilities and Managing Clinicians to address patient barriers to home dialysis and transplantation. While ESRD facility staff reported a greater focus on increasing home dialysis and transplant for years, particularly the last 3-4 years, they did not know if this was driven by the model. This may be because facility-level staff in our sample did not have access to this type of information.

Findings from the case studies provide insights into barriers that can hinder access to home dialysis and transplantation as well as success with home dialysis. Patients and participant reported barriers included the need for improved patient education on ESRD treatment options, poor access to reliable transportation, lack of mental health support services, the need for improved education about the transplant process and coordination with transplant centers, and limited access to PD placement surgery. One factor that was noted by some ETC participants, particular Managing Clinicians, as a constraint under the model was that even with the additional support provided for treating patients who are dually eligible or recipients of the Part D LIS, they did not find the magnitude of the payment adjustments to be sufficient to provide the resources that they would need to better address socioeconomic, behavioral, and logistical barriers to home dialysis and transplantation.

While the evaluation findings in this report are based on 3 years of experience with the model, we note that longer-term impacts of the model are still possible. ETC participants may continue to adapt their practices and learn from ongoing efforts to encourage use of home dialysis and transplantation as successful options for patients. Responses to the model may continue to evolve

as these incentives and payment adjustments are in effect for a longer period of time and as the magnitude of PPA penalties and bonuses increases.

The ETC Model continues to be affected by growing enrollment of beneficiaries with ESRD in MA plans. We have observed similar changes in the size and composition of the ETC eligible FFS population in both the ETC and comparison groups through the model's first 3 years but as noted in **Section 2.**, FFS and MA beneficiaries differ in demographic and socioeconomic characteristics. This change in the demographic profile of Medicare FFS population, making FFS not fully representative of all ESRD dialysis patients, may have implications in fully comprehending the impact of the model. Furthermore, efforts by dialysis providers to promote home dialysis, transplant waitlisting, and transplantation may be applied to all dialysis patients, regardless of their insurance status.

There is also a need to consider the influence of the related Kidney Care Choices (KCC) Model, which began on January 1, 2022. Based on areas of overlap between the ETC and KCC Models with regard to both certain model goals (for example, involving both transplantation and home dialysis) and participation (that is, for providers participating in both models), effects of the two models could be mutually reinforcing and also introduce potential confounders when examining model impacts. The KCC Model establishes multiple incentives that are either directly or indirectly related to transplantation and home dialysis. The KCC Model includes both bonus payments for beneficiaries with a functioning kidney transplant as well as the potential for shared savings under the CKCC option (for example, to share in any cost savings that may result from transplantation). There is potential for the KCC Model to promote greater use of home dialysis by including beneficiaries with advanced CKD and establishing incentives for ESRD starts. In addition, under the Kidney Care First option of the KCC Model, the MCP amount is increased to standardize Medicare payments for nephrology services for home dialysis and in-center dialysis patients. In the analyses for this report, we accounted for the participation of Managing Clinicians in the KCC Model with the goal of estimating ETC Model impacts that are independent of the KCC Model.